

AMENDMENT NO. _____ Calendar No. _____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—117th Cong., 2d Sess.

S. 4348

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by Mrs. MURRAY (for herself and Mr. BURR)

Viz:

1 Strike all after the enacting clause and insert the fol-
2 lowing:

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) **SHORT TITLE.**—This Act may be cited as the
5 “Food and Drug Administration Safety and Landmark
6 Advancements Act of 2022” or the “FDASLA Act of
7 2022”.

8 (b) **TABLE OF CONTENTS.**—The table of contents for
9 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—FEES RELATING TO DRUGS

2

- Sec. 101. Short title; finding.
- Sec. 102. Definitions.
- Sec. 103. Authority to assess and use drug fees.
- Sec. 104. Reauthorization; reporting requirement.
- Sec. 105. Sunset dates.
- Sec. 106. Effective date.
- Sec. 107. Savings clause.

TITLE II—FEES RELATING TO DEVICES

- Sec. 201. Short title; finding.
- Sec. 202. Definitions.
- Sec. 203. Authority to assess and use device fees.
- Sec. 204. Reauthorization; reporting requirement.
- Sec. 205. Accreditation programs.
- Sec. 206. Sunset dates.
- Sec. 207. Effective date.
- Sec. 208. Savings clause.

TITLE III—FEES RELATING TO GENERIC DRUGS

- Sec. 301. Short title; finding.
- Sec. 302. Authority to assess and use human generic drug fees.
- Sec. 303. Reauthorization; reporting requirements.
- Sec. 304. Sunset dates.
- Sec. 305. Effective date.
- Sec. 306. Savings clause.

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

- Sec. 401. Short title; finding.
- Sec. 402. Definitions.
- Sec. 403. Authority to assess and use biosimilar biological product fees.
- Sec. 404. Reauthorization; reporting requirements.
- Sec. 405. Sunset dates.
- Sec. 406. Effective date.
- Sec. 407. Savings clause.

TITLE V—IMPROVING REGULATION OF DRUGS AND BIOLOGICAL PRODUCTS

- Sec. 501. Alternatives to animal testing.
- Sec. 502. Safer disposal of opioids.
- Sec. 503. Clarifications to exclusivity provisions for first interchangeable biosimilar biological products.
- Sec. 504. Improvements to the Purple Book.
- Sec. 505. Therapeutic equivalence evaluations.
- Sec. 506. Modernizing accelerated approval.
- Sec. 507. Rare disease pilot program.
- Sec. 508. Supporting review and development of drugs to treat rare diseases.
- Sec. 509. Generic drug labeling changes.

TITLE VI—OTHER REAUTHORIZATIONS

- Sec. 601. Reauthorization of the critical path public-private partnership.
- Sec. 602. Reauthorization of the best pharmaceuticals for children program.

3

- Sec. 603. Reauthorization of the humanitarian device exemption incentive.
- Sec. 604. Reauthorization of the pediatric device consortia program.
- Sec. 605. Reauthorization of provision pertaining to drugs containing single enantiomers.
- Sec. 606. Reauthorization of orphan drug grants.
- Sec. 607. Reauthorization of certain device inspections.

TITLE VII—ENHANCING FDA HIRING AUTHORITIES

- Sec. 701. Enhancing FDA hiring authority for scientific, technical, and professional personnel.
- Sec. 702. Strategic workforce plan and report.

TITLE VIII—ADVANCING REGULATION OF COSMETICS, DIETARY SUPPLEMENTS, AND IN VITRO CLINICAL TESTS

Subtitle A—Cosmetics

- Sec. 801. Short title.
- Sec. 802. Amendments to cosmetic requirements.
- Sec. 803. Enforcement and conforming amendments.
- Sec. 804. Records inspection.
- Sec. 805. Talc-containing cosmetics.
- Sec. 806. PFAS in cosmetics.
- Sec. 807. Sense of the Senate on animal testing.
- Sec. 808. Funding.

Subtitle B—Dietary Supplements

- Sec. 811. Regulation of dietary supplements.

Subtitle C—In Vitro Clinical Tests

- Sec. 821. Short title.
- Sec. 822. Definitions.
- Sec. 823. Regulation of in vitro clinical tests.
- Sec. 824. Enforcement and other provisions.
- Sec. 825. Transition.
- Sec. 826. Emergency use authorization.
- Sec. 827. Antimicrobial susceptibility tests.
- Sec. 828. Combination products.
- Sec. 829. Resources.
- Sec. 830. Authorization of appropriations.
- Sec. 831. Guidance on Diagnostic Innovation.

TITLE IX—OTHER PROVISIONS

- Sec. 901. Facilities management.
- Sec. 902. User fee program transparency and accountability.
- Sec. 903. OTC hearing aids final rule.
- Sec. 904. Enhancing coordination and transparency on inspections.
- Sec. 905. Certificates to foreign governments.
- Sec. 906. Importation of drugs.
- Sec. 907. Improving information technology systems of the Food and Drug Administration.
- Sec. 908. Regulation of certain products as drugs.

Sec. 909. Reporting on mailroom and Office of the Executive Secretariat of the Food and Drug Administration.

Sec. 910. Protecting infants and improving formula supply.

1 **TITLE I—FEES RELATING TO**
2 **DRUGS**

3 **SEC. 101. SHORT TITLE; FINDING.**

4 (a) **SHORT TITLE.**—This title may be cited as the
5 “Prescription Drug User Fee Amendments of 2022”.

6 (b) **FINDING.**—Congress finds that the fees author-
7 ized by the amendments made in this title will be dedi-
8 cated toward expediting the drug development process and
9 the process for the review of human drug applications, in-
10 cluding postmarket drug safety activities, as set forth in
11 the goals identified for purposes of part 2 of subchapter
12 C of chapter VII of the Federal Food, Drug, and Cosmetic
13 Act (21 U.S.C. 379g et seq.), in the letters from the Sec-
14 retary of Health and Human Services to the Chairman
15 of the Committee on Health, Education, Labor, and Pen-
16 sions of the Senate and the Chairman of the Committee
17 on Energy and Commerce of the House of Representa-
18 tives, as set forth in the Congressional Record.

19 **SEC. 102. DEFINITIONS.**

20 Section 735 of the Federal Food, Drug, and Cosmetic
21 Act (21 U.S.C. 379g) is amended—

22 (1) in paragraph (1), in the matter following
23 subparagraph (B), by striking “an allergenic extract
24 product, or” and inserting “does not include an ap-

1 plication with respect to an allergenic extract prod-
2 uct licensed before October 1, 2022, does not include
3 an application with respect to a standardized aller-
4 genic extract product submitted pursuant to a notifi-
5 cation to the applicant from the Secretary regarding
6 the existence of a potency test that measures the al-
7 lergenic activity of an allergenic extract product li-
8 censed by the applicant before October 1, 2022, does
9 not include an application with respect to”;

10 (2) in paragraph (3), in the matter following
11 subparagraph (C)—

12 (A) by inserting “licensed before October
13 1, 2022, a standardized allergenic extract prod-
14 uct submitted pursuant to a notification to the
15 applicant from the Secretary regarding the ex-
16 istence of a potency test that measures the al-
17 lergenic activity of an allergenic extract product
18 licensed by the applicant before October 1,
19 2022,” after “an allergenic extract product”;
20 and

21 (B) by adding at the end the following: “If
22 a written request to place a product in the dis-
23 continued section of either of the lists described
24 in subparagraph (C) is submitted to the Sec-
25 retary on behalf of an applicant, and the re-

1 quest identifies the date the product is, or will
2 be, withdrawn from sale, then, for purposes of
3 assessing the prescription drug program fee
4 under section 736(a)(2), the Secretary shall
5 consider such product to have been included in
6 the discontinued section on the later of (i) the
7 date such request was received, or (ii) if the
8 product will be withdrawn from sale on a future
9 date, such future date when the product is
10 withdrawn from sale. For purposes of subpara-
11 graph (C), a product shall be considered with-
12 drawn from sale once the applicant has ceased
13 its own distribution of the product, whether or
14 not the applicant has ordered recall of all pre-
15 viously distributed lots of the product, except
16 that a routine, temporary interruption in supply
17 shall not render a product withdrawn from
18 sale.”; and

19 (3) by adding at the end the following:

20 “(12) The term ‘skin-test diagnostic product’—

21 “(A) means a product—

22 “(i) for prick, scratch, intradermal, or
23 subcutaneous administration;

1 “(ii) expected to produce a limited,
2 local reaction at the site of administration
3 (if positive), rather than a systemic effect;

4 “(iii) not intended to be a preventive
5 or therapeutic intervention; and

6 “(iv) intended to detect an immediate
7 or delayed-type skin hypersensitivity reac-
8 tion to aid in the diagnosis of—

9 “(I) an allergy to an anti-
10 microbial agent;

11 “(II) an allergy that is not to an
12 antimicrobial agent, if the diagnostic
13 product was authorized for marketing
14 prior to October 1, 2022; or

15 “(III) infection with fungal or
16 mycobacterial pathogens; and

17 “(B) includes positive and negative con-
18 trols required to interpret the results of a prod-
19 uct described in subparagraph (A).”.

20 **SEC. 103. AUTHORITY TO ASSESS AND USE DRUG FEES.**

21 (a) TYPES OF FEES.—Section 736(a) of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C. 379h(a)) is
23 amended—

24 (1) in the matter preceding paragraph (1), by
25 striking “2018” and inserting “2023”;

1 (2) in paragraph (1)—

2 (A) in subparagraph (A), by striking “sub-
3 section (c)(5)” each place it appears and insert-
4 ing “subsection (c)(6)”;

5 (B) in subparagraph (C), by inserting
6 “prior to approval” after “or was withdrawn”;
7 and

8 (C) by adding at the end the following:

9 “(H) EXCEPTION FOR SKIN-TEST DIAG-
10 NOSTIC PRODUCTS.—A human drug application
11 for a skin-test diagnostic product shall not be
12 subject to a fee under subparagraph (A).”;

13 (3) in paragraph (2)—

14 (A) in subparagraph (A)—

15 (i) by striking “subsection (c)(5)” and
16 inserting “subsection (c)(6)”;

17 (ii) by striking “Except as provided”
18 and inserting the following:

19 “(i) PAYMENT OF FEES.—Except as
20 provided”; and

21 (iii) by adding at the end the fol-
22 lowing:

23 “(ii) PREVIOUSLY DISCONTINUED
24 DRUG PRODUCTS.—If a drug product that
25 is identified in a human drug application

1 approved as of October 1 of a fiscal year
2 is not a prescription drug product as of
3 that date because the drug product is in
4 the discontinued section of a list identified
5 in section 735(3), and on any subsequent
6 day during such fiscal year the drug prod-
7 uct is a prescription drug product, then ex-
8 cept as provided in subparagraphs (B) and
9 (C), each person who is named as the ap-
10 plicant in a human drug application with
11 respect to such product, and who, after
12 September 1, 1992, had pending before the
13 Secretary a human drug application or
14 supplement, shall pay the annual prescrip-
15 tion drug program fee established for a fis-
16 cal year under subsection (c)(6) for such
17 prescription drug product. Such fee shall
18 be due on the last business day of such fis-
19 cal year and shall be paid only once for
20 each product for a fiscal year in which the
21 fee is payable.”; and

22 (B) by amending subparagraph (B) to read
23 as follows:

24 “(B) EXCEPTION FOR CERTAIN PRESCRIP-
25 TION DRUG PRODUCTS.—A prescription drug

1 program fee shall not be assessed for a pre-
2 scription drug product under subparagraph (A)
3 if such product is—

4 “(i) a large volume parenteral product
5 (a sterile aqueous drug product packaged
6 in a single-dose container with a volume
7 greater than or equal to 100 mL, not in-
8 cluding powders for reconstitution or phar-
9 macy bulk packages) identified on the list
10 compiled under section 505(j)(7);

11 “(ii) pharmaceutically equivalent (as
12 defined in section 314.3 of title 21, Code
13 of Federal Regulations (or any successor
14 regulations)), to another product on the
15 list of products compiled under section
16 505(j)(7) (not including the discontinued
17 section of such list); or

18 “(iii) a skin-test diagnostic product.”.

19 (b) FEE REVENUE AMOUNTS.—Section 736(b) of the
20 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
21 379h(b)) is amended—

22 (1) in paragraph (1)—

23 (A) in the matter preceding subparagraph
24 (A), by striking “2018 through 2022” and in-
25 serting “2023 through 2027”;

1 (B) by redesignating subparagraphs (C)
2 through (F) as subparagraphs (D) through (G),
3 respectively;

4 (C) by inserting after subparagraph (B)
5 the following:

6 “(C) The dollar amount equal to the stra-
7 tegic hiring and retention adjustment for the
8 fiscal year (as determined under subsection
9 (c)(2));”;

10 (D) in subparagraph (D), as so redesi-
11 gated, by striking “(c)(2)” and inserting
12 “(c)(3)”;

13 (E) in subparagraph (E), as so redesi-
14 gated, by striking “(c)(3)” and inserting
15 “(c)(4)”;

16 (F) in subparagraph (F), as so redesi-
17 gated, by striking “(c)(4)” and inserting
18 “(c)(5)”;

19 (G) in subparagraph (G), as so redesi-
20 gated, by striking clauses (i) through (v) and
21 inserting the following:

22 “(i) \$65,773,693 for fiscal year 2023.

23 “(ii) \$25,097,671 for fiscal year 2024.

24 “(iii) \$14,154,169 for fiscal year
25 2025.

1 “(iv) \$4,864,860 for fiscal year 2026.

2 “(v) \$1,314,620 for fiscal year

3 2027.”; and

4 (2) in paragraph (3)—

5 (A) in subparagraph (A), by striking

6 “2018, \$878,590,000” and inserting “2023,

7 \$1,151,522,958”; and

8 (B) in subparagraph (B)—

9 (i) by striking “2019 through 2022”

10 and inserting “2024 through 2027”; and

11 (ii) by striking “subsection (c)(3) or

12 (c)(4)” and inserting “subsection (c)(4) or

13 (c)(5)”.

14 (c) ADJUSTMENTS; ANNUAL FEE SETTING.—Section

15 736(c) of the Federal Food, Drug, and Cosmetic Act (21

16 U.S.C. 379h(c)) is amended—

17 (1) in paragraph (1)(B)(ii), by striking “Wash-

18 ington-Baltimore, DC–MD–VA–WV” and inserting

19 “Washington–Arlington–Alexandria, DC–VA–MD–

20 WV”;

21 (2) by redesignating paragraphs (2) through

22 (6) as paragraphs (3) through (7), respectively;

23 (3) by inserting after paragraph (1) the fol-

24 lowing:

1 “(2) STRATEGIC HIRING AND RETENTION AD-
2 JUSTMENT.—For each fiscal year, after the annual
3 base revenue established in subsection (b)(1)(A) is
4 adjusted for inflation in accordance with paragraph
5 (1), the Secretary shall further increase the fee rev-
6 enue and fees—

7 “(A) for fiscal year 2023, by \$9,000,000;
8 and

9 “(B) for fiscal year 2024 and each subse-
10 quent fiscal year, by \$4,000,000.”;

11 (4) in paragraph (3), as so redesignated—

12 (A) in subparagraph (A)—

13 (i) by striking “for inflation”; and

14 (ii) by striking “paragraph (1)” and
15 inserting “paragraphs (1) and (2)”;

16 (B) by amending subparagraph (B) to read
17 as follows:

18 “(B) METHODOLOGY.—For purposes of
19 this paragraph, the Secretary shall employ the
20 capacity planning methodology utilized by the
21 Secretary in setting fees for fiscal year 2021, as
22 described in the notice titled ‘Prescription Drug
23 User Fee Rates for Fiscal Year 2021’ (85 Fed.
24 Reg. 46651; August 3, 2020). The workload
25 categories used in forecasting shall include only

1 the activities described in such notice and, as
2 feasible, additional activities that are directly
3 related to the direct review of applications and
4 supplements, including additional formal meet-
5 ing types, the direct review of postmarketing
6 commitments and requirements, the direct re-
7 view of risk evaluation and mitigation strate-
8 gies, and the direct review of annual reports for
9 approved prescription drug products. Subject to
10 the exceptions in the preceding sentence, the
11 Secretary shall not include as workload cat-
12 egories in forecasting any non-core review ac-
13 tivities, including any activities that the Sec-
14 retary referenced for potential future use in
15 such notice but did not utilize in the setting
16 fees for fiscal year 2021.”;

17 (C) by striking subparagraph (C);

18 (D) by redesignating subparagraphs (D)
19 and (E) as subparagraphs (C) and (D), respec-
20 tively;

21 (E) in subparagraph (C), as so redesign-
22 ated—

23 (i) by striking “year) and” and insert-
24 ing “year),”; and

1 (ii) by striking the period and insert-
2 ing “, and subsection (b)(1)(C) (the dollar
3 amount of the strategic hiring and reten-
4 tion adjustment).”; and

5 (F) in subparagraph (D), as so redesign-
6 dated, by striking “paragraph (5)” and insert-
7 ing “paragraph (6)”;

8 (5) in paragraph (4), as so redesignated—

9 (A) by amending subparagraph (A) to read
10 as follows:

11 “(A) INCREASE.—For fiscal year 2023 and
12 subsequent fiscal years, the Secretary shall, in
13 addition to adjustments under paragraphs (1),
14 (2), and (3), further increase the fee revenue
15 and fees if such an adjustment is necessary to
16 provide for at least the following amounts of op-
17 erating reserves of carryover user fees for the
18 process for the review of human drug applica-
19 tions for each fiscal year, as follows:

20 “(i) For fiscal year 2023, at least 8
21 weeks of operating reserves.

22 “(ii) For fiscal year 2024, at least 9
23 weeks of operating reserves.

1 “(iii) For fiscal year 2025 and subse-
2 quent fiscal years, at least 10 weeks of op-
3 erating reserves.”; and

4 (B) in subparagraph (C), by striking
5 “paragraph (5)” and inserting “paragraph
6 (6)”;

7 (6) by amending paragraph (5), as so redesign-
8 nated, to read as follows:

9 “(5) ADDITIONAL DIRECT COST ADJUST-
10 MENT.—The Secretary shall, in addition to adjust-
11 ments under paragraphs (1), (2), (3), and (4), fur-
12 ther increase the fee revenue and fees—

13 “(A) for fiscal year 2023, by \$44,386,150;
14 and

15 “(B) for fiscal years 2024 through 2027,
16 by the amount set forth in clauses (i) through
17 (iv), as applicable, multiplied by the Consumer
18 Price Index for urban consumers (Washington-
19 Arlington-Alexandria, DC-VA-MD-WV; Not
20 Seasonally Adjusted; All Items; Annual Index)
21 for the most recent year of available data, di-
22 vided by such Index for 2021—

23 “(i) for fiscal year 2024, \$60,967,993;

24 “(ii) for fiscal year 2025,
25 \$35,799,314;

1 “(iii) for fiscal year 2026,
2 \$35,799,314; and

3 “(iv) for fiscal year 2027,
4 \$35,799,314.”; and

5 (7) in paragraph (6), as so redesignated, by
6 striking “2017” and inserting “2022”.

7 (d) CREDITING AND AVAILABILITY OF FEES.—Sec-
8 tion 736(g)(3) of the Federal Food, Drug, and Cosmetic
9 Act (21 U.S.C. 379h(g)(3)) is amended by striking “2018
10 through 2022” and inserting “2023 through 2027”.

11 (e) WRITTEN REQUESTS FOR WAIVERS, REDUC-
12 TIONS, AND REFUNDS.—Section 736(i) of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 379h(i)) is
14 amended to read as follows:

15 “(i) WRITTEN REQUESTS FOR WAIVERS, REDUC-
16 TIONS, EXEMPTIONS, AND RETURNS; DISPUTES CON-
17 CERNING FEES.—To qualify for consideration for a waiver
18 or reduction under subsection (d), an exemption under
19 subsection (k), or the return of any fee paid under this
20 section, including if the fee is claimed to have been paid
21 in error, a person shall submit to the Secretary a written
22 request justifying such waiver, reduction, exemption, or
23 return not later than 180 days after such fee is due. A
24 request submitted under this paragraph shall include any
25 legal authorities under which the request is made.”.

1 (f) ORPHAN DRUGS.—Section 736(k) of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C. 379h(k)) is
3 amended—

4 (1) in paragraph (1)(B), by striking “during
5 the previous year” and inserting “, as determined
6 under paragraph (2)”; and

7 (2) in paragraph (2), by striking “that its gross
8 annual revenues” and all that follows through the
9 period at the end and inserting “supported by tax
10 returns submitted to the Internal Revenue Service,
11 or, as necessary, by other appropriate financial in-
12 formation, that its gross annual revenues did not ex-
13 ceed \$50,000,000 for the last calendar year ending
14 prior to the fiscal year for which the exemption is
15 requested.”.

16 **SEC. 104. REAUTHORIZATION; REPORTING REQUIREMENT.**

17 Section 736B of the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 379h–2) is amended—

19 (1) by striking “2018” each place it appears
20 and inserting “2023”;

21 (2) by striking “Prescription Drug User Fee
22 Amendments of 2017” each place it appears and in-
23 serting “Prescription Drug User Fee Amendments
24 of 2022”;

1 (3) in subsection (a)(4), by striking “2020” and
2 inserting “2023”; and

3 (4) in subsection (f), by striking “2022” each
4 place it appears and inserting “2027”.

5 **SEC. 105. SUNSET DATES.**

6 (a) AUTHORIZATION.—Sections 735 and 736 of the
7 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g;
8 379h) shall cease to be effective October 1, 2027.

9 (b) REPORTING REQUIREMENTS.—Section 736B of
10 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 379h–2) shall cease to be effective January 31, 2028.

12 (c) PREVIOUS SUNSET PROVISION.—Effective Octo-
13 ber 1, 2022, subsections (a) and (b) of section 104 of the
14 FDA Reauthorization Act of 2017 (Public Law 115–52)
15 are repealed.

16 **SEC. 106. EFFECTIVE DATE.**

17 The amendments made by this title shall take effect
18 on October 1, 2022, or the date of the enactment of this
19 Act, whichever is later, except that fees under part 2 of
20 subchapter C of chapter VII of the Federal Food, Drug,
21 and Cosmetic Act (21 U.S.C. 379g et seq.) shall be as-
22 sessed for all human drug applications received on or after
23 October 1, 2022, regardless of the date of the enactment
24 of this Act.

1 **SEC. 107. SAVINGS CLAUSE.**

2 Notwithstanding the amendments made by this title,
3 part 2 of subchapter C of chapter VII of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), as in
5 effect on the day before the date of the enactment of this
6 title, shall continue to be in effect with respect to human
7 drug applications and supplements (as defined in such
8 part as of such day) that were accepted by the Food and
9 Drug Administration for filing on or after October 1,
10 2017, but before October 1, 2022, with respect to assess-
11 ing and collecting any fee required by such part for a fiscal
12 year prior to fiscal year 2023.

13 **TITLE II—FEES RELATING TO**
14 **DEVICES**

15 **SEC. 201. SHORT TITLE; FINDING.**

16 (a) **SHORT TITLE.**—This title may be cited as the
17 “Medical Device User Fee Amendments of 2022”.

18 (b) **FINDING.**—Congress finds that the fees author-
19 ized under the amendments made by this title will be dedi-
20 cated toward expediting the process for the review of de-
21 vice applications and for assuring the safety and effective-
22 ness of devices, as set forth in the goals identified for pur-
23 poses of part 3 of subchapter C of chapter VII of the Fed-
24 eral Food, Drug, and Cosmetic Act in the letters from the
25 Secretary of Health and Human Services to the Chairman
26 of the Committee on Health, Education, Labor, and Pen-

1 sions of the Senate and the Chairman of the Committee
2 on Energy and Commerce of the House of Representa-
3 tives, as set forth in the Congressional Record.

4 **SEC. 202. DEFINITIONS.**

5 Section 737 of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 379i) is amended—

7 (1) in paragraph (9)—

8 (A) in the matter preceding subparagraph
9 (A), by striking “and premarket notification
10 submissions” and inserting “premarket notifica-
11 tion submissions, and de novo classification re-
12 quests”;

13 (B) in subparagraph (D), by striking “and
14 submissions” and inserting “submissions, and
15 de novo classification requests”;

16 (C) in subparagraph (F), by striking “and
17 premarket notification submissions” and insert-
18 ing “premarket notification submissions, and de
19 novo classification requests”;

20 (D) in subparagraphs (G) and (H), by
21 striking “or submissions” each place it appears
22 and inserting “submissions, or requests”; and

23 (E) in subparagraph (K), by striking “or
24 premarket notification submissions” and insert-

1 ing “premarket notification submissions, or de
2 novo classification requests”; and
3 (2) in paragraph (11), by striking “2016” and
4 inserting “2021”.

5 **SEC. 203. AUTHORITY TO ASSESS AND USE DEVICE FEES.**

6 (a) TYPES OF FEES.—Section 738(a) of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 379j(a)) is
8 amended—

9 (1) in paragraph (1), by striking “2018” and
10 inserting “2023”; and

11 (2) in paragraph (2)—

12 (A) in subparagraph (A)—

13 (i) in the matter preceding clause (i),
14 by striking “2017” and inserting “2022”;

15 (ii) in clause (iii), by striking “75 per-
16 cent” and inserting “80 percent”; and

17 (iii) in clause (viii), by striking “3.4
18 percent” and inserting “4.5 percent”;

19 (B) in subparagraph (B)(iii), by striking
20 “or premarket notification submission” and in-
21 serting “premarket notification submission, or
22 de novo classification request”; and

23 (C) in subparagraph (C), by striking “or
24 periodic reporting concerning a class III device”
25 and inserting “periodic reporting concerning a

1 class III device, or de novo classification re-
 2 quest”.

3 (b) FEE AMOUNTS.—Section 738(b) of the Federal
 4 Food, Drug, and Cosmetic Act (21 U.S.C. 379j(b)) is
 5 amended—

6 (1) in paragraph (1), by striking “2018
 7 through 2022” and inserting “2023 through 2027”;

8 (2) by amending the table in paragraph (2) to
 9 read as follows:

| “Fee Type | Fiscal Year 2023 | Fiscal Year 2024 | Fiscal Year 2025 | Fiscal Year 2026 | Fiscal Year 2027 |
|----------------------------------|------------------------|------------------------|------------------------|------------------------|------------------------|
| Premarket Ap- plication | \$425,000 | \$435,000 | \$445,000 | \$455,000 | \$470,000 |
| Establishment Registration .. | \$6,250 | \$6,875 | \$7,100 | \$7,575 | \$8,465”; |

10 and

11 (3) in paragraph (3), by amending subpara-
 12 graphs (A) through (E) to read as follows:

13 “(A) \$312,606,000 for fiscal year 2023.

14 “(B) \$335,750,000 for fiscal year 2024.

15 “(C) \$350,746,400 for fiscal year 2025.

16 “(D) \$366,486,300 for fiscal year 2026.

17 “(E) \$418,343,000 for fiscal year 2027.”.

18 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section
 19 738(c) of the Federal Food, Drug, and Cosmetic Act (21
 20 U.S.C. 379j(c)) is amended—

1 (1) in paragraph (1), by striking “2017” and
2 inserting “2022”;

3 (2) in paragraph (2)—

4 (A) by striking “2018” each place it ap-
5 pears and inserting “2023”;

6 (B) in subparagraph (B)(ii), by striking
7 “2016” and inserting “2022”;

8 (C) in subparagraph (C)(i)(II), by striking
9 “Washington-Baltimore, DC-MD-VA-WV”
10 and inserting “Washington-Arlington-Alexan-
11 dria, DC-VA-MD-WV”; and

12 (D) in subparagraph (D), by striking
13 “2022” and inserting “2027”;

14 (3) in paragraph (3), by striking “2018
15 through 2022” and inserting “2023 through 2027”;

16 (4) by redesignating paragraphs (4) and (5) as
17 paragraphs (7) and (8), respectively; and

18 (5) by inserting after paragraph (3) the fol-
19 lowing:

20 “(4) PERFORMANCE IMPROVEMENT ADJUST-
21 MENT.—

22 “(A) IN GENERAL.—For each of fiscal
23 years 2025 through 2027, after the adjustment
24 under paragraph (3), the base establishment
25 registration fee amounts for such fiscal year

1 shall be increased to reflect changes in the re-
2 source needs of the Secretary due to improved
3 review performance goals for the process for the
4 review of device applications identified in the
5 letters described in section 201(b) of the Med-
6 ical Device User Fee Amendments of 2022, as
7 the Secretary determines necessary to achieve
8 an increase in total fee collections for such fis-
9 cal year, equal to the following amounts, as ap-
10 plicable:

11 “(i) For fiscal year 2025, the product
12 of—

13 “(I) the amount determined
14 under subparagraph (B)(i)(I); and

15 “(II) the applicable inflation ad-
16 justment under paragraph (2)(B) for
17 such fiscal year.

18 “(ii) For fiscal year 2026, the product
19 of—

20 “(I) the sum of the amounts de-
21 termined under subparagraphs
22 (B)(i)(II), (B)(ii)(I), and (B)(iii)(I);
23 and

1 “(II) the applicable inflation ad-
2 justment under paragraph (2)(B) for
3 such fiscal year.

4 “(iii) For fiscal year 2027, the prod-
5 uct of—

6 “(I) the sum of the amounts de-
7 termined under subparagraphs
8 (B)(i)(III), (B)(ii)(II), and
9 (B)(iii)(II); and

10 “(II) the applicable inflation ad-
11 justment under paragraph (2)(B) for
12 such fiscal year.

13 “(B) AMOUNTS.—

14 “(i) PRESUBMISSION AMOUNT.—For
15 purposes of subparagraph (A), with respect
16 to the presubmission written feedback goal,
17 the amounts determined under this sub-
18 paragraph are as follows:

19 “(I) For fiscal year 2025,
20 \$15,396,600 if the goal for fiscal year
21 2023 is met.

22 “(II) For fiscal year 2026—

23 “(aa) \$15,396,600 if the
24 goal for fiscal year 2023 is met

1 and the goal for fiscal year 2024
2 is missed; or

3 “(bb) \$36,792,200 if the
4 goal for fiscal year 2024 is met.

5 “(III) For fiscal year 2027—

6 “(aa) \$15,396,600 if the
7 goal for fiscal year 2023 is met
8 and the goal for each of fiscal
9 years 2024 and 2025 is missed;

10 “(bb) \$36,792,200 if the
11 goal for fiscal year 2024 is met
12 and the goal for fiscal year 2025
13 is missed; or

14 “(cc) \$40,572,600 if the
15 goal for fiscal year 2025 is met.

16 “(ii) DE NOVO CLASSIFICATION RE-
17 QUEST AMOUNT.—For purposes of sub-
18 paragraph (A), with respect to the de novo
19 decision goal, the amounts determined
20 under this subparagraph are as follows:

21 “(I) For fiscal year 2026,
22 \$6,323,500 if the goal for fiscal year
23 2023 is met.

24 “(II) For fiscal year 2027—

1 “(aa) \$6,323,500 if the goal
2 for fiscal year 2023 is met and
3 the goal for fiscal year 2024 is
4 missed; or

5 “(bb) \$11,765,400 if the
6 goal for fiscal year 2024 is met.

7 “(iii) PREMARKET NOTIFICATION AND
8 PREMARKET APPROVAL AMOUNT.—For
9 purposes of subparagraph (A), with respect
10 to the 510(k) decision goal, 510(k) shared
11 outcome total time to decision goal, PMA
12 decision goal, and PMA shared outcome
13 total time to decision goal, the amounts de-
14 termined under this subparagraph are as
15 follows:

16 “(I) For fiscal year 2026,
17 \$1,020,000 if the 4 goals for fiscal
18 year 2023 are met.

19 “(II) For fiscal year 2027—

20 “(aa) \$1,020,000 if the 4
21 goals for fiscal year 2023 are met
22 and one or more of the 4 goals
23 for fiscal year 2024 is missed; or

1 “(bb) \$3,906,000 if the 4
2 goals for fiscal year 2024 are
3 met.

4 “(C) PERFORMANCE CALCULATION.—For
5 purposes of this paragraph, performance of the
6 following goals shall be determined as specified
7 in the letters described in section 201(b) of the
8 Medical Device User Fee Amendments of 2022
9 and based on data available as of the applicable
10 dates as follows:

11 “(i) The performance of the pre-
12 submission written feedback goal—

13 “(I) for fiscal year 2023, shall be
14 based on data available as of March
15 31, 2024;

16 “(II) for fiscal year 2024, shall
17 be based on data available as of
18 March 31, 2025; and

19 “(III) for fiscal year 2025, shall
20 be based on data available as of
21 March 31, 2026.

22 “(ii) The performance of the de novo
23 decision goal, 510(k) decision goal, 510(k)
24 shared outcome total time to decision goal,

1 PMA decision goal, and PMA shared out-
2 come total time to decision goal—

3 “(I) for fiscal year 2023, shall be
4 based on data available as of March
5 31, 2025; and

6 “(II) for fiscal year 2024, shall
7 be based on data available as of
8 March 31, 2026.

9 “(D) DEFINITIONS.—For purposes of this
10 paragraph, the terms ‘presubmission written
11 feedback goal’, ‘de novo decision goal’, ‘510(k)
12 decision goal’, ‘510(k) shared outcome total
13 time to decision goal’, ‘PMA decision goal’, and
14 ‘PMA shared outcome total time to decision
15 goal’ have the meanings given such terms in the
16 goals identified in the letters described in sec-
17 tion 201(b) of the Medical Device User Fee
18 Amendments of 2022.

19 “(5) HIRING ADJUSTMENT.—

20 “(A) IN GENERAL.—For each of fiscal
21 years 2025 through 2027, after the adjust-
22 ments under paragraphs (3) and (4), if applica-
23 ble, the base establishment registration fee
24 amounts shall be decreased as the Secretary de-
25 termines necessary to achieve a reduction in

1 total fee collections equal to the hiring adjust-
2 ment amount under subparagraph (B), if the
3 number of hires to support the process for the
4 review of device applications falls below the fol-
5 lowing thresholds for the applicable fiscal years:

6 “(i) For fiscal year 2025, 85 percent
7 of the hiring goal specified in subpara-
8 graph (C) for fiscal year 2023.

9 “(ii) For fiscal year 2026, 90 percent
10 of the hiring goal specified in subpara-
11 graph (C) for fiscal year 2024.

12 “(iii) For fiscal year 2027, 90 percent
13 of the hiring goal specified in subpara-
14 graph (C) for fiscal year 2025.

15 “(B) HIRING ADJUSTMENT AMOUNT.—The
16 hiring adjustment amount for fiscal year 2025
17 and each subsequent fiscal year is the product
18 of—

19 “(i) the number of hires by which the
20 hiring goal specified in subparagraph (C)
21 for the fiscal year before the prior fiscal
22 year was missed;

23 “(ii) \$72,877; and

1 “(iii) the applicable inflation adjust-
2 ment under paragraph (2)(B) for the fiscal
3 year for which the hiring goal was missed.

4 “(C) HIRING GOALS.—

5 “(i) IN GENERAL.—For purposes of
6 subparagraph (B), the hiring goals for
7 each of fiscal years 2023 through 2025 are
8 as follows:

9 “(I) For fiscal year 2023, 144
10 hires.

11 “(II) For fiscal year 2024, 42
12 hires.

13 “(III) For fiscal year 2025—

14 “(aa) 24 hires if the base es-
15 tablishment registration fees are
16 not increased by the amount de-
17 termined under paragraph
18 (4)(A)(i); or

19 “(bb) 83 hires if the base
20 establishment registration fees
21 are increased by the amount de-
22 termined under paragraph
23 (4)(A)(i).

24 “(ii) NUMBER OF HIRES.—For pur-
25 poses of this paragraph, the number of

1 hires for a fiscal year shall be determined
2 by the Secretary, as set forth in the letters
3 described in section 201(b) of the Medical
4 Device User Fee Amendments of 2022.

5 “(6) OPERATING RESERVE ADJUSTMENT.—

6 “(A) IN GENERAL.—For each of fiscal
7 years 2023 through 2027, after the adjust-
8 ments under paragraphs (3), (4), and (5), if ap-
9 plicable, if the Secretary has operating reserves
10 of carryover user fees for the process for the re-
11 view of device applications in excess of the des-
12 ignated amount in subparagraph (B), the Sec-
13 retary shall decrease the base establishment
14 registration fee amounts to provide for not
15 more than such designated amount of operating
16 reserves.

17 “(B) DESIGNATED AMOUNT.—Subject to
18 subparagraph (C), for each fiscal year, the des-
19 ignated amount in this subparagraph is equal
20 to the sum of—

21 “(i) 13 weeks of operating reserves of
22 carryover user fees; and

23 “(ii) the 1 month of operating re-
24 serves described in paragraph (8).

1 “(C) EXCLUDED AMOUNT.—For the period
2 of fiscal years 2023 through 2026, a total
3 amount equal to \$118,000,000 shall not be con-
4 sidered part of the designated amount under
5 subparagraph (B) and shall not be subject to
6 the decrease under subparagraph (A).”.

7 (d) SMALL BUSINESSES.—Section 738 of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amend-
9 ed—

10 (1) in subsection (d)(2)(B)(iii), by inserting “,
11 if extant,” after “national taxing authority”; and

12 (2) in subsection (e)(2)(B)(iii), by inserting “,
13 if extant,” after “national taxing authority”.

14 (e) CONDITIONS.—Section 738(g) of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C. 379j(g)) is
16 amended—

17 (1) in paragraph (1)(A), by striking
18 “\$320,825,000” and inserting “\$398,566,000”; and

19 (2) in paragraph (2), by inserting “de novo
20 classification requests,” after “class III device,”.

21 (f) AUTHORIZATION OF APPROPRIATIONS.—Section
22 738(h)(3) of the Federal Food, Drug, and Cosmetic Act
23 (21 U.S.C. 379j(h)(3)) is amended to read as follows:

24 “(3) AUTHORIZATION OF APPROPRIATIONS.—

1 “(A) IN GENERAL.—For each of the fiscal
2 years 2023 through 2027, there is authorized to
3 be appropriated for fees under this section an
4 amount equal to the revenue amount deter-
5 mined in subparagraph (B), less the amount of
6 reductions determined in subparagraph (C).

7 “(B) REVENUE AMOUNT.—For purposes of
8 this paragraph, the revenue amount for each
9 fiscal year is the sum of—

10 “(i) the total revenue amount under
11 subsection (b)(3) for the fiscal year, as ad-
12 justed under subsection (c)(2); and

13 “(ii) the performance improvement
14 adjustment amount for the fiscal year
15 under subsection (c)(4)(A), if applicable.

16 “(C) AMOUNT OF REDUCTIONS.—For pur-
17 poses of this paragraph, the amount of reduc-
18 tions for each fiscal year is the sum of—

19 “(i) the hiring adjustment amount for
20 the fiscal year under subsection (c)(5), if
21 applicable; and

22 “(ii) the operating reserve adjustment
23 amount for the fiscal year under sub-
24 section (c)(6), if applicable.”.

1 **SEC. 204. REAUTHORIZATION; REPORTING REQUIREMENT.**

2 (a) PERFORMANCE REPORTS.—Section 738A(a) of
3 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 379j–1(a)) is amended—

5 (1) by striking “fiscal year 2018” each place it
6 appears and inserting “fiscal year 2023”; and

7 (2) by striking “Medical Device User Fee
8 Amendments of 2017” each place it appears and in-
9 sserting “Medical Device User Fee Amendments of
10 2022”;

11 (3) in paragraph (1)—

12 (A) in subparagraph (A), by redesignating
13 the second clause (iv) (relating to analysis) as
14 clause (v); and

15 (B) in subparagraph (A)(iv) (relating to
16 rationale for MDUFA program changes), by
17 striking “fiscal year 2020” and inserting “fiscal
18 year 2023”; and

19 (4) in paragraph (4), by striking “2018
20 through 2022” and inserting “2023 through 2027.”

21 (b) REAUTHORIZATION.—Section 738A(b) of the
22 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
23 1(b)) is amended—

24 (1) in paragraph (1), by striking “2022” and
25 inserting “2027”; and

1 (2) in paragraph (5), by striking “2022” and
2 inserting “2027”.

3 **SEC. 205. ACCREDITATION PROGRAMS.**

4 (a) ACCREDITATION SCHEME FOR CONFORMITY AS-
5 SESSMENT.—Section 514(d) of the Federal Food, Drug,
6 and Cosmetic Act (21 U.S.C. 360d(d)) is amended—

7 (1) in the subsection heading, by striking
8 “PILOT”;

9 (2) in paragraph (1)—

10 (A) in the matter preceding subparagraph

11 (A), by striking “pilot”;

12 (B) in subparagraph (A)—

13 (i) by inserting “meeting criteria spec-
14 ified by the Secretary in guidance” after
15 “testing laboratories”;

16 (ii) by inserting “in guidance” after
17 “by the Secretary”; and

18 (iii) by striking “assess the conform-
19 ance of a device with” and inserting “con-
20 duct testing to support the assessment of
21 the conformance of a device to”; and

22 (C) in subparagraph (B)—

23 (i) by striking “determinations” and
24 inserting “results”;

1 (ii) by inserting “to support” after
2 “so accredited”; and

3 (iii) by striking “a particular such de-
4 termination” and inserting “particular
5 such results”;

6 (3) in paragraph (2)—

7 (A) in the paragraph heading, by striking
8 “DETERMINATIONS” and inserting “RESULTS”;

9 (B) in subparagraph (A)—

10 (i) by striking “determinations by
11 testing laboratories” and all that follows
12 through “such determinations or” and in-
13 serting “results by testing laboratories ac-
14 credited pursuant to this subsection, in-
15 cluding by conducting periodic audits of
16 such results or of the”;

17 (ii) by inserting a comma after “or
18 testing laboratories”;

19 (iii) by inserting “or recognition of an
20 accreditation body” after “accreditation of
21 such testing laboratory”; and

22 (iv) by striking “such device” and in-
23 serting “a device”; and

24 (C) in subparagraph (B)—

1 (i) by striking “by a testing labora-
2 tory so accredited” and inserting “under
3 this subsection”; and

4 (ii) by inserting “or recognition of an
5 accreditation body” before “under para-
6 graph (1)(A)”;

7 (4) in paragraph (3)(C)—

8 (A) in the subparagraph heading, by in-
9 serting “AND TRANSITION” after “INITIATION”;
10 and

11 (B) by adding at the end the following:
12 “After September 30, 2023, such pilot program
13 will be considered to be completed, and the Sec-
14 retary shall have the authority to continue oper-
15 ating a program consistent with this sub-
16 section.”; and

17 (5) by striking paragraph (4).

18 (b) ACCREDITED PERSONS.—Section 523(c) of the
19 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 360m(c)) is amended by striking “2022” and inserting
21 “2027”.

22 **SEC. 206. SUNSET DATES.**

23 (a) AUTHORIZATION.—Sections 737 and 738 of the
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i;
25 379fj) shall cease to be effective October 1, 2027.

1 (b) REPORTING REQUIREMENTS.—Section 738A of
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 379j–1) shall cease to be effective January 31, 2028.

4 (c) PREVIOUS SUNSET PROVISION.—Effective Octo-
5 ber 1, 2022, subsections (a) and (b) of section 210 of the
6 FDA Reauthorization Act of 2017 (Public Law 115–52)
7 are repealed.

8 **SEC. 207. EFFECTIVE DATE.**

9 The amendments made by this title shall take effect
10 on October 1, 2022, or the date of the enactment of this
11 Act, whichever is later, except that fees under part 3 of
12 subchapter C of chapter VII of the Federal Food, Drug,
13 and Cosmetic Act (21 U.S.C. 379i et seq.) shall be as-
14 sessed for all submissions listed in section 738(a)(2)(A)
15 of such Act received on or after October 1, 2022, regard-
16 less of the date of the enactment of this Act.

17 **SEC. 208. SAVINGS CLAUSE.**

18 Notwithstanding the amendments made by this title,
19 part 3 of subchapter C of chapter VII of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in
21 effect on the day before the date of the enactment of this
22 title, shall continue to be in effect with respect to the sub-
23 missions listed in section 738(a)(2)(A) of such Act (as de-
24 fined in such part as of such day) that on or after October
25 1, 2017, but before October 1, 2022, were received by the

1 Food and Drug Administration with respect to assessing
2 and collecting any fee required by such part for a fiscal
3 year prior to fiscal year 2023.

4 **TITLE III—FEES RELATING TO**
5 **GENERIC DRUGS**

6 **SEC. 301. SHORT TITLE; FINDING.**

7 (a) **SHORT TITLE.**—This title may be cited as the
8 “Generic Drug User Fee Amendments of 2022”.

9 (b) **FINDING.**—The Congress finds that the fees au-
10 thorized by the amendments made in this title will be dedi-
11 cated to human generic drug activities, as set forth in the
12 goals identified for purposes of part 7 of subchapter C
13 of chapter VII of the Federal Food, Drug, and Cosmetic
14 Act, in the letters from the Secretary of Health and
15 Human Services to the Chairman of the Committee on
16 Health, Education, Labor, and Pensions of the Senate and
17 the Chairman of the Committee on Energy and Commerce
18 of the House of Representatives, as set forth in the Con-
19 gressional Record.

20 **SEC. 302. AUTHORITY TO ASSESS AND USE HUMAN GE-**
21 **NERIC DRUG FEES.**

22 (a) **TYPES OF FEES.**—Section 744B(a) of the Fed-
23 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j-
24 42(a)) is amended—

1 (1) in the matter preceding paragraph (1), by
2 striking “2018” and inserting “2023”;

3 (2) in paragraph (2)(C), by striking “fiscal
4 years 2018 through 2022” and inserting “fiscal
5 years 2023 through 2027”;

6 (3) in paragraph (3)(B), by striking “fiscal
7 years 2018 through 2022” and inserting “fiscal
8 years 2023 through 2027”;

9 (4) in paragraph (4)(D), by striking “fiscal
10 years 2018 through 2022” and inserting “fiscal
11 years 2023 through 2027”; and

12 (5) in paragraph (5)(D), by striking “fiscal
13 years 2018 through 2022” and inserting “fiscal
14 years 2023 through 2027”.

15 (b) FEE REVENUE AMOUNTS.—Section 744B(b) of
16 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 379j–42(b)) is amended—

18 (1) in paragraph (1)—

19 (A) in subparagraph (A)—

20 (i) in the heading, by striking “2018”
21 and inserting “2023”;

22 (ii) by striking “2018” and inserting
23 “2023”; and

24 (iii) by striking “\$493,600,000” and
25 inserting “\$582,500,000”; and

1 (B) in subparagraph (B)—

2 (i) in the heading, by striking “2019
3 THROUGH 2022” and inserting “2024
4 THROUGH 2027”;

5 (ii) by striking “For each” and insert-
6 ing the following:

7 “(i) IN GENERAL.—For each”;

8 (iii) by striking “2019 through 2022”
9 and inserting “2024 through 2027”;

10 (iv) by striking “\$493,600,000” and
11 inserting “the base revenue amount under
12 clause (ii)”;

13 (v) by adding at the end the following:

14 “(ii) BASE REVENUE AMOUNT.—The
15 base revenue amount for a fiscal year is
16 the total revenue amount established under
17 this paragraph for the previous fiscal year,
18 not including any adjustments made for
19 such previous fiscal year under subsection
20 (c)(3).”; and

21 (2) in paragraph (2)—

22 (A) in subparagraph (C), by striking “one-
23 third the amount” and inserting “24 percent”;

24 (B) in subparagraph (D), by striking
25 “Seven” and inserting “Six”; and

1 (C) in subparagraph (E)(i), by striking
2 “Thirty-five” and inserting “Thirty-six”.

3 (c) ADJUSTMENTS.—Section 744B(c) of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(c)) is
5 amended—

6 (1) in paragraph (1)—

7 (A) in the matter preceding subparagraph
8 (A)—

9 (i) by striking “2019” and inserting
10 “2024”; and

11 (ii) by striking “the product of the
12 total revenues established in such notice
13 for the prior fiscal year” and inserting
14 “the base revenue amount for the fiscal
15 year determined under subsection
16 (b)(1)(B)(ii)”; and

17 (B) in subparagraph (C), by striking
18 “Washington-Baltimore, DC–MD–VA–WV”
19 and inserting “Washington-Arlington-Alexan-
20 dria, DC–VA–MD–WV”; and

21 (2) by striking paragraph (2) and inserting the
22 following:

23 “(2) CAPACITY PLANNING ADJUSTMENT.—

24 “(A) IN GENERAL.—Beginning with fiscal
25 year 2024, the Secretary shall, in addition to

1 the adjustment under paragraph (1), further in-
2 crease the fee revenue and fees under this sec-
3 tion for a fiscal year, in accordance with this
4 paragraph, to reflect changes in the resource
5 capacity needs of the Secretary for human ge-
6 neric drug activities.

7 “(B) CAPACITY PLANNING METHOD-
8 OLOGY.—The Secretary shall establish a capac-
9 ity planning methodology for purposes of this
10 paragraph, which shall—

11 “(i) be derived from the methodology
12 and recommendations made in the report
13 titled ‘Independent Evaluation of the
14 GDUFA Resource Capacity Planning Ad-
15 justment Methodology: Evaluation and
16 Recommendations’ as announced in the
17 Federal Register on August 3, 2020 (85
18 Fed. Reg. 46658); and

19 “(ii) incorporate approaches and at-
20 tributes determined appropriate by the
21 Secretary, including those made in such re-
22 port recommendations, except the workload
23 categories used in forecasting resources
24 shall only be those specified in section
25 VIII.B.2.e. of the letters described in sec-

1 tion 301(b) of the Generic Drug User Fee
2 Amendments of 2022.

3 “(C) LIMITATIONS.—

4 “ (i) IN GENERAL.—Under no cir-
5 cumstances shall an adjustment under this
6 paragraph result in fee revenue for a fiscal
7 year that is less than the sum of the
8 amounts under subsection (b)(1)(B)(ii)
9 (the base revenue amount for the fiscal
10 year) and paragraph (1) (the dollar
11 amount of the inflation adjustment for the
12 fiscal year).

13 “(ii) ADDITIONAL LIMITATION.—An
14 adjustment under this paragraph shall not
15 exceed 3 percent of the sum described in
16 clause (i) for the fiscal year, except that
17 such limitation shall be 4 percent if—

18 “(I) for purposes of an adjust-
19 ment for fiscal year 2024, the Sec-
20 retary determines that, during the pe-
21 riod from April 1, 2021, through
22 March 31, 2023—

23 “(aa) the total number of
24 abbreviated new drug applica-

1 tions submitted was greater than
2 or equal to 2,000; or

3 “(bb) thirty-five percent or
4 more of abbreviated new drug ap-
5 plications submitted related to
6 complex products (as that term is
7 defined in section XI of the let-
8 ters described in section 301(b)
9 of the Generic Drug User Fee
10 Amendments of 2022);

11 “(II) for purposes of an adjust-
12 ment for fiscal year 2025, the Sec-
13 retary determines that, during the pe-
14 riod from April 1, 2022, through
15 March 31, 2024—

16 “(aa) the total number of
17 abbreviated new drug applica-
18 tions submitted was greater than
19 or equal to 2,300; or

20 “(bb) thirty-five percent or
21 more of abbreviated new drug ap-
22 plications submitted related to
23 complex products (as so defined);

24 “(III) for purposes of an adjust-
25 ment for fiscal year 2026, the Sec-

1 retary determines that, during the pe-
2 riod from April 1, 2023, through
3 March 31, 2025—

4 “(aa) the total number of
5 abbreviated new drug applica-
6 tions submitted was greater than
7 or equal to 2,300; or

8 “(bb) thirty-five percent or
9 more of abbreviated new drug ap-
10 plications submitted related to
11 complex products (as so defined);
12 and

13 “(IV) for purposes of an adjust-
14 ment for fiscal year 2027, the Sec-
15 retary determines that, during the pe-
16 riod from April 1, 2024, through
17 March 31, 2026—

18 “(aa) the total number of
19 abbreviated new drug applica-
20 tions submitted was greater than
21 or equal to 2,300; or

22 “(bb) thirty-five percent or
23 more of abbreviated new drug ap-
24 plications submitted related to
25 complex products (as so defined).

1 “(D) PUBLICATION IN FEDERAL REG-
2 ISTER.—The Secretary shall publish in the Fed-
3 eral Register notice under subsection (a), the
4 fee revenue and fees resulting from the adjust-
5 ment and the methodology under this para-
6 graph.

7 “(3) OPERATING RESERVE ADJUSTMENT.—

8 “(A) IN GENERAL.—For fiscal year 2024
9 and subsequent fiscal years, the Secretary may,
10 in addition to adjustments under paragraphs
11 (1) and (2), further increase the fee revenue
12 and fees under this section if such an adjust-
13 ment is necessary to provide operating reserves
14 of carryover user fees for human generic drug
15 activities for not more than the number of
16 weeks specified in subparagraph (B).

17 “(B) NUMBER OF WEEKS.—The number of
18 weeks specified in this subparagraph is—

19 “(i) 8 weeks for fiscal year 2024;

20 “(ii) 9 weeks for fiscal year 2025; and

21 “(iii) 10 weeks for each of fiscal year
22 2026 and 2027.

23 “(C) DECREASE.—If the Secretary has
24 carryover balances for human generic drug ac-
25 tivities in excess of 12 weeks of the operating

1 reserves referred to in subparagraph (A), the
2 Secretary shall decrease the fee revenue and
3 fees referred to in such subparagraph to provide
4 for not more than 12 weeks of such operating
5 reserves.

6 “(D) RATIONALE FOR ADJUSTMENT.—If
7 an adjustment under this paragraph is made,
8 the rationale for the amount of the increase or
9 decrease (as applicable) in fee revenue and fees
10 shall be contained in the annual Federal Reg-
11 ister notice under subsection (a) publishing the
12 fee revenue and fees for the fiscal year in-
13 volved.”.

14 (d) ANNUAL FEE SETTING.—Section 744B(d)(1) of
15 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 379j–42(d)(1)) is amended—

17 (1) in the heading, by striking “2018 THROUGH
18 2022” and inserting “2023 THROUGH 2027”;

19 (2) by striking “more” and inserting “later”;
20 and

21 (3) by striking “2018 through 2022” and in-
22 serting “2023 through 2027”.

23 (e) EFFECT OF FAILURE TO PAY FEES.—The head-
24 ing of paragraph (3) of section 744B(g) of the Federal
25 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(g)) is

1 amended by striking “AND PRIOR APPROVAL SUPPLEMENT
2 FEE”.

3 (f) CREDITING AND AVAILABILITY OF FEES.—Sec-
4 tion 744B(i)(3) of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 379j–42(i)(3)) is amended by striking
6 “2018 through 2022” and inserting “2023 through
7 2027”.

8 **SEC. 303. REAUTHORIZATION; REPORTING REQUIREMENTS.**

9 Section 744C of the Federal Food, Drug, and Cos-
10 metic Act (21 U.S.C. 379j–43) is amended—

11 (1) in subsection (a)—

12 (A) by striking “2018” each place it ap-
13 pears and inserting “2023”; and

14 (B) by striking “Generic Drug User Fee
15 Amendments of 2017” each place it appears
16 and inserting “Generic Drug User Fee Amend-
17 ments of 2022”;

18 (2) in subsection (b), by striking “2018” and
19 inserting “2023”;

20 (3) in subsection (c)—

21 (A) by striking “2018” and inserting
22 “2023”; and

23 (B) by striking “Generic Drug User Fee
24 Amendments of 2017” each place it appears

1 and inserting “Generic Drug User Fee Amend-
2 ments of 2022”; and

3 (4) in subsection (f)—

4 (A) in paragraph (1), by striking “2022”
5 and inserting “2027”; and

6 (B) in paragraph (5), by striking “January
7 15, 2022” and inserting “January 15, 2027”.

8 **SEC. 304. SUNSET DATES.**

9 (a) AUTHORIZATION.—Sections 744A and 744B of
10 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 379j–41; 379j–42) shall cease to be effective October 1,
12 2027.

13 (b) REPORTING REQUIREMENTS.—Section 744C of
14 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
15 379j–43) shall cease to be effective January 31, 2028.

16 (c) PREVIOUS SUNSET PROVISION.—Effective Octo-
17 ber 1, 2022, subsections (a) and (b) of section 305 of the
18 FDA Reauthorization Act of 2017 (Public Law 115–52)
19 are repealed.

20 **SEC. 305. EFFECTIVE DATE.**

21 The amendments made by this title shall take effect
22 on October 1, 2022, or the date of the enactment of this
23 Act, whichever is later, except that fees under part 7 of
24 subchapter C of chapter VII of the Federal Food, Drug,
25 and Cosmetic Act (21 U.S.C. 379j–41 et seq.) shall be

1 assessed for all abbreviated new drug applications received
2 on or after October 1, 2022, regardless of the date of the
3 enactment of this Act.

4 **SEC. 306. SAVINGS CLAUSE.**

5 Notwithstanding the amendments made by this title,
6 part 7 of subchapter C of chapter VII of the Federal Food,
7 Drug, and Cosmetic Act, as in effect on the day before
8 the date of the enactment of this title, shall continue to
9 be in effect with respect to abbreviated new drug applica-
10 tions (as defined in such part as of such day) that were
11 received by the Food and Drug Administration within the
12 meaning of section 505(j)(5)(A) of such Act (21 U.S.C.
13 355(j)(5)(A)), prior approval supplements that were sub-
14 mitted, and drug master files for Type II active pharma-
15 ceutical ingredients that were first referenced on or after
16 October 1, 2017, but before October 1, 2022, with respect
17 to assessing and collecting any fee required by such part
18 for a fiscal year prior to fiscal year 2023.

19 **TITLE IV—FEES RELATING TO**
20 **BIOSIMILAR BIOLOGICAL**
21 **PRODUCTS**

22 **SEC. 401. SHORT TITLE; FINDING.**

23 (a) **SHORT TITLE.**—This title may be cited as the
24 “Biosimilar User Fee Amendments of 2022”.

1 (b) FINDING.—Congress finds that the fees author-
2 ized by the amendments made in this title will be dedi-
3 cated to expediting the process for the review of biosimilar
4 biological product applications, including postmarket safe-
5 ty activities, as set forth in the goals identified for pur-
6 poses of part 8 of subchapter C of chapter VII of the Fed-
7 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51
8 et seq.), in the letters from the Secretary of Health and
9 Human Services to the Chairman of the Committee on
10 Health, Education, Labor, and Pensions of the Senate and
11 the Chairman of the Committee on Energy and Commerce
12 of the House of Representatives, as set forth in the Con-
13 gressional Record.

14 **SEC. 402. DEFINITIONS.**

15 Section 744G of the Federal Food, Drug, and Cos-
16 metic Act (21 U.S.C. 379j–51) is amended—

17 (1) in paragraph (1)—

18 (A) by striking “Washington-Baltimore,
19 DC–MD–VA–WV” and inserting “Washington–
20 Arlington–Alexandria, DC–VA–MD–WV”;

21 (B) by striking “October of” and inserting
22 “September of”; and

23 (C) by striking “October 2011” and insert-
24 ing “September 2011”; and

25 (2) in paragraph (4)(B)(iii)—

- 1 (A) by striking subclause (II); and
2 (B) by redesignating subclauses (III) and
3 (IV) as subclauses (II) and (III), respectively.

4 **SEC. 403. AUTHORITY TO ASSESS AND USE BIOSIMILAR BIO-**
5 **LOGICAL PRODUCT FEES.**

6 (a) TYPES OF FEES.—Section 744H(a) of the Fed-
7 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j-
8 52(a)) is amended—

9 (1) in the matter preceding paragraph (1), by
10 striking “2018” and inserting “2023”;

11 (2) in paragraph (1)—

12 (A) in subparagraph (A)—

13 (i) in clause (iv)(I), by striking “5
14 days” and inserting “7 days”; and

15 (ii) in clause (v)(II), by striking “5
16 days” and inserting “7 days”;

17 (B) in subparagraph (B)—

18 (i) in clause (i), by inserting “, except
19 that, in the case that such product (includ-
20 ing, where applicable, ownership of the rel-
21 evant investigational new drug application)
22 is transferred to a licensee, assignee, or
23 successor of such person, and written no-
24 tice of such transfer is provided to the Sec-
25 retary, such licensee, assignee or successor

1 shall pay the annual biosimilar biological
2 product development fee” before the pe-
3 riod;

4 (ii) in clause (iii)—

5 (I) in subclause (I), by striking
6 “; or” and inserting a semicolon;

7 (II) in subclause (II), by striking
8 the period and inserting “; or”; and

9 (III) by adding at the end the
10 following:

11 “(III) been administratively re-
12 moved from the biosimilar biological
13 product development program for the
14 product under subparagraph (E)(v).”;
15 and

16 (iii) in clause (iv), by striking “accept-
17 ed for filing on or after October 1 of such
18 fiscal year” and inserting “subsequently
19 accepted for filing”;

20 (C) in subparagraph (D)—

21 (i) in clause (i)—

22 (I) in the matter preceding sub-
23 clause (I), by striking “shall, if the
24 person seeks to resume participation
25 in such program, pay” and inserting

1 “or who has been administratively re-
2 moved from such program for a prod-
3 uct under subparagraph (E)(v) shall,
4 if the person seeks to resume partici-
5 pation in such program, pay all an-
6 nual biosimilar biological product de-
7 velopment fees previously assessed for
8 such product and still owed and”;

9 (II) in subclause (I)—

10 (aa) by striking “5 days”
11 and inserting “7 days”; and

12 (bb) by inserting “or the
13 date of administrative removal,
14 as applicable” after “discon-
15 tinued”; and

16 (III) in subclause (II), by insert-
17 ing “or the date of administrative re-
18 moval, as applicable” after “discon-
19 tinued”; and

20 (ii) in clause (ii), by inserting “, ex-
21 cept that, in the case that such product
22 (including, where applicable, ownership of
23 the relevant investigational new drug appli-
24 cation) is transferred to a licensee, as-
25 signee, or successor of such person, and

1 written notice of such transfer is provided
2 to the Secretary, such licensee, assignee or
3 successor shall pay the annual biosimilar
4 biological product development fee” before
5 the period at the end; and

6 (D) in subparagraph (E), by adding at the
7 end the following:

8 “(v) ADMINISTRATIVE REMOVAL FROM
9 THE BIOSIMILAR BIOLOGICAL PRODUCT
10 DEVELOPMENT PROGRAM.—If a person has
11 failed to pay an annual biosimilar biological
12 product development fee for a product
13 as required under subparagraph (B) for a
14 period of 2 consecutive fiscal years, the
15 Secretary may administratively remove
16 such person from the biosimilar biological
17 product development program for the prod-
18 uct. At least 30 days prior to administra-
19 tively removing a person from the bio-
20 similar biological product development pro-
21 gram for a product under this clause, the
22 Secretary shall provide written notice to
23 such person of the intended administrative
24 removal.”;

1 (3) in paragraph (2)(D), by inserting “prior to
2 approval” after “withdrawn”;

3 (4) in paragraph (3)—

4 (A) in subparagraph (A)—

5 (i) in clause (i), by striking “; and”
6 and inserting a semicolon;

7 (ii) by redesignating clause (ii) as
8 clause (iii); and

9 (iii) by inserting the following after
10 clause (i):

11 “(ii) may be dispensed only under pre-
12 scription pursuant to section 503(b); and”;
13 and

14 (B) by adding at the end the following:

15 “(E) MOVEMENT TO DISCONTINUED
16 LIST.—

17 “(i) WRITTEN REQUEST TO PLACE ON
18 DISCONTINUED LIST.—

19 “(I) IN GENERAL.—If a written
20 request to place a product on the list
21 of discontinued biosimilar biological
22 products referred to in subparagraph
23 (A)(iii) is submitted to the Secretary
24 on behalf of an applicant, and the re-
25 quest identifies the date the product

1 is, or will be, withdrawn from sale,
2 then for purposes of assessing the bio-
3 similar biological product program fee,
4 the Secretary shall consider such
5 product to have been included on such
6 list on the later of—

7 “(aa) the date such request
8 was received; or

9 “(bb) if the product will be
10 withdrawn from sale on a future
11 date, such future date when the
12 product is withdrawn from sale.

13 “(II) WITHDRAWN FROM SALE
14 DEFINED.—For purposes of this
15 clause, a product shall be considered
16 withdrawn from sale once the appli-
17 cant has ceased its own distribution of
18 the product, whether or not the appli-
19 cant has ordered recall of all pre-
20 viously distributed lots of the product,
21 except that a routine, temporary
22 interruption in supply shall not render
23 a product withdrawn from sale.

24 “(ii) PRODUCTS REMOVED FROM DIS-
25 CONTINUED LIST.—If a biosimilar biologi-

1 cal product that is identified in a bio-
2 similar biological product application ap-
3 proved as of October 1 of a fiscal year ap-
4 pears, as of October 1 of such fiscal year,
5 on the list of discontinued biosimilar bio-
6 logical products referred to in subpara-
7 graph (A)(iii), and on any subsequent day
8 during such fiscal year the biosimilar bio-
9 logical product does not appear on such
10 list, except as provided in subparagraph
11 (D), each person who is named as the ap-
12 plicant in the biosimilar biological product
13 application shall pay the annual biosimilar
14 biological product program fee established
15 for a fiscal year under subsection (c)(5) for
16 such biosimilar biological product. Not-
17 withstanding subparagraph (B), such fee
18 shall be due on the last business day of
19 such fiscal year and shall be paid only once
20 for each product for each fiscal year.”; and

21 (5) by striking paragraph (4).

22 (b) FEE REVENUE AMOUNTS.—Section 744H(b) of
23 the Federal Food, Drug, and Cosmetic Act ((21 U.S.C.
24 379j–52(b)) is amended—

25 (1) by striking paragraph (1);

1 (2) by redesignating paragraphs (2) through
2 (4) as paragraphs (1) through (3), respectively;

3 (3) in paragraph (1), as so redesignated—

4 (A) in the paragraph heading, by striking
5 “SUBSEQUENT FISCAL YEARS” and inserting
6 “IN GENERAL”;

7 (B) in the matter preceding subparagraph
8 (A), by striking “2019 through 2022” and in-
9 serting “2023 through 2027”;

10 (C) in subparagraph (A), by striking
11 “paragraph (4)” and inserting “paragraph
12 (3)”;

13 (D) by redesignating subparagraphs (C)
14 and (D) as subparagraphs (D) and (E), respec-
15 tively;

16 (E) by inserting after subparagraph (B)
17 the following:

18 “(C) the dollar amount equal to the stra-
19 tegic hiring and retention adjustment (as deter-
20 mined under subsection (c)(2));”;

21 (F) in subparagraph (D), as so redesign-
22 ated, by striking “subsection (c)(2)); and” and
23 inserting “subsection (c)(3));”;

1 (G) in subparagraph (E), as so redesignig-
2 nated, by striking “subsection (c)(3).” and in-
3 serting “subsection (c)(4); and”; and

4 (H) by adding at the end the following:

5 “(F) for fiscal years 2023 and 2024, addi-
6 tional dollar amounts equal to—

7 “(i) \$4,428, 886 for fiscal year 2023;

8 and

9 “(ii) \$320,569 for fiscal year 2024.”;

10 (4) in paragraph (2), as so redesignated—

11 (A) in the paragraph heading, by striking
12 “; LIMITATIONS ON FEE AMOUNTS”;

13 (B) by striking subparagraph (B); and

14 (C) by redesignating subparagraphs (C)
15 and (D) as subparagraphs (B) and (C), respec-
16 tively; and

17 (5) by amending paragraph (3), as so redesignig-
18 nated, to read as follows:

19 “(3) ANNUAL BASE REVENUE.—For purposes
20 of paragraph (1), the dollar amount of the annual
21 base revenue for a fiscal year shall be—

22 “(A) for fiscal year 2023, \$43,376,922;

23 and

24 “(B) for fiscal years 2024 through 2027,
25 the dollar amount of the total revenue amount

1 established under paragraph (1) for the pre-
2 vious fiscal year, excluding any adjustments to
3 such revenue amount under subsection (c)(4).”.

4 (c) ADJUSTMENTS; ANNUAL FEE SETTING.—Section
5 744H(e) of the Federal Food, Drug, and Cosmetic Act
6 ((21 U.S.C. 379j–52(c)) is amended—

7 (1) in paragraph (1)—

8 (A) in subparagraph (A)—

9 (i) in the matter preceding clause (i),
10 by striking “subsection (b)(2)(B)” and in-
11 serting “subsection (b)(1)(B)”; and

12 (ii) in clause (i), by striking “sub-
13 section (b)” and inserting “subsection
14 (b)(1)(A)”; and

15 (B) in subparagraph (B)(ii), by striking
16 “Washington-Baltimore, DC–MD–VA–WV”
17 and inserting “Washington–Arlington–Alexan-
18 dria, DC–VA–MD–WV”;

19 (2) by striking paragraph (4);

20 (3) by redesignating paragraphs (2) and (3) as
21 paragraphs (3) and (4), respectively;

22 (4) by inserting after paragraph (1) the fol-
23 lowing:

24 “(2) STRATEGIC HIRING AND RETENTION AD-
25 JUSTMENT.—For each fiscal year beginning in fiscal

1 year 2023, after the annual base revenue under sub-
2 section (b)(1)(A) is adjusted for inflation in accord-
3 ance with paragraph (1), the Secretary shall further
4 increase the fee revenue and fees by \$150,000.”;

5 (5) in paragraph (3), as so redesignated—

6 (A) in subparagraph (A)—

7 (i) by striking “Beginning with the
8 fiscal year described in subparagraph
9 (B)(ii)(II)” and inserting “For each fiscal
10 year”; and

11 (ii) by striking “adjustment under
12 paragraph (1), further increase” and in-
13 sserting “adjustments under paragraphs (1)
14 and (2), further adjust”; and

15 (B) by amending subparagraph (B) to read
16 as follows:

17 “(B) METHODOLOGY.—For purposes of
18 this paragraph, the Secretary shall employ the
19 capacity planning methodology utilized by the
20 Secretary in setting fees for fiscal year 2021, as
21 described in the notice titled ‘Biosimilar User
22 Fee Rates for Fiscal Year 2021’ (85 Fed. Reg.
23 47220; August 4, 2020). The workload cat-
24 egories used in forecasting shall include only
25 the activities described in such notice and, as

1 feasible, additional activities that are also di-
2 rectly related to the direct review of biosimilar
3 biological product applications and supplements,
4 including additional formal meeting types and
5 the direct review of postmarketing commitments
6 and requirements, the direct review of risk eval-
7 uation and mitigation strategies, and the direct
8 review of annual reports for approved biosimilar
9 biological products. Subject to the exceptions in
10 the preceding sentence, the Secretary shall not
11 include as workload categories in forecasting
12 any non-core review activities, including any ac-
13 tivities that the Secretary referenced for poten-
14 tial future use in such notice but did not utilize
15 in setting fees for fiscal year 2021.”; and

16 (C) in subparagraph (C)—

17 (i) by striking “subsections (b)(2)(A)”
18 and inserting “subsections (b)(1)(A)”;

19 (ii) by striking “and (b)(2)(B)” and
20 inserting “, (b)(1)(B)”;

21 (iii) by inserting “, and (b)(1)(C) (the
22 dollar amount of the strategic hiring and
23 retention adjustment)” before the period at
24 the end;

1 (6) by amending paragraph (4), as so redesignig-
2 nated, to read as follows:

3 “(4) OPERATING RESERVE ADJUSTMENT.—

4 “(A) INCREASE.—For fiscal year 2023 and
5 subsequent fiscal years, the Secretary shall, in
6 addition to adjustments under paragraphs (1),
7 (2), and (3), further increase the fee revenue
8 and fees if such an adjustment is necessary to
9 provide for at least 10 weeks of operating re-
10 serves of carryover user fees for the process for
11 the review of biosimilar biological product appli-
12 cations.

13 “(B) DECREASE.—

14 “(i) FISCAL YEAR 2023.—For fiscal
15 year 2023, if the Secretary has carryover
16 balances for the process for the review of
17 biosimilar biological product applications in
18 excess of 33 weeks of such operating re-
19 serves, the Secretary shall decrease such
20 fee revenue and fees to provide for not
21 more than 33 weeks of such operating re-
22 serves.

23 “(ii) FISCAL YEAR 2024.—For fiscal
24 year 2024, if the Secretary has carryover
25 balances for the process for the review of

1 biosimilar biological product applications in
2 excess of 27 weeks of such operating re-
3 serves, the Secretary shall decrease such
4 fee revenue and fees to provide for not
5 more than 27 weeks of such operating re-
6 serves.

7 “(iii) FISCAL YEAR 2025 AND SUBSE-
8 QUENT FISCAL YEARS.—For fiscal year
9 2025 and subsequent fiscal years, if the
10 Secretary has carryover balances for the
11 process for the review of biosimilar biologi-
12 cal product applications in excess of 21
13 weeks of such operating reserves, the Sec-
14 retary shall decrease such fee revenue and
15 fees to provide for not more than 21 weeks
16 of such operating reserves.

17 “(C) FEDERAL REGISTER NOTICE.—If an
18 adjustment under subparagraph (A) or (B) is
19 made, the rationale for the amount of the in-
20 crease or decrease (as applicable) in fee revenue
21 and fees shall be contained in the annual Fed-
22 eral Register notice under paragraph (5)(B) es-
23 tablishing fee revenue and fees for the fiscal
24 year involved.”; and

1 (7) in paragraph (5), in the matter preceding
2 subparagraph (A), by striking “2018” and inserting
3 “2023”.

4 (d) CREDITING AND AVAILABILITY OF FEES.—Sec-
5 tion 744H(f)(3) of the Federal Food, Drug, and Cosmetic
6 Act ((21 U.S.C. 379j–52(f)(3)) is amended by striking
7 “2018 through 2022” and inserting “2023 through
8 2027”.

9 (e) WRITTEN REQUESTS FOR WAIVERS AND RE-
10 FUNDS.—Subsection (h) of section 744H of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52) is
12 amended to read as follows:

13 “(h) WRITTEN REQUESTS FOR WAIVERS AND RE-
14 TURNS; DISPUTES CONCERNING FEES.—To qualify for
15 consideration for a waiver under subsection (d), or the re-
16 turn of any fee paid under this section, including if the
17 fee is claimed to have been paid in error, a person shall
18 submit to the Secretary a written request justifying such
19 waiver or return and, except as otherwise specified in this
20 section, such written request shall be submitted to the Sec-
21 retary not later than 180 days after such fee is due. A
22 request submitted under this paragraph shall include any
23 legal authorities under which the request is made.”.

1 **SEC. 404. REAUTHORIZATION; REPORTING REQUIREMENTS.**

2 Section 744I of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 379j–53) is amended—

4 (1) by striking “2018” each place it appears
5 and inserting “2023”;

6 (2) by striking “Biosimilar User Fee Amend-
7 ments of 2017” each place it appears and inserting
8 “Biosimilar User Fee Amendments of 2022”;

9 (3) in subsection (a)(4), by striking “2020” and
10 inserting “2023”; and

11 (4) in subsection (f), by striking “2022” each
12 place it appears and inserting “2027”.

13 **SEC. 405. SUNSET DATES.**

14 (a) **AUTHORIZATION.**—Sections 744G and 744H of
15 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 379j–51, 379j–52) shall cease to be effective October 1,
17 2027.

18 (b) **REPORTING REQUIREMENTS.**—Section 744I of
19 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 379j–53) shall cease to be effective January 31, 2028.

21 (c) **PREVIOUS SUNSET PROVISION.**—Effective Octo-
22 ber 1, 2022, subsections (a) and (b) of section 405 of the
23 FDA Reauthorization Act of 2017 (Public Law 115–52)
24 are repealed.

1 **SEC. 406. EFFECTIVE DATE.**

2 The amendments made by this title shall take effect
3 on October 1, 2022, or the date of the enactment of this
4 Act, whichever is later, except that fees under part 8 of
5 subchapter C of chapter VII of the Federal Food, Drug,
6 and Cosmetic Act (21 U.S.C. 379j–51 et seq.) shall be
7 assessed for all biosimilar biological product applications
8 received on or after October 1, 2022, regardless of the
9 date of the enactment of this Act.

10 **SEC. 407. SAVINGS CLAUSE.**

11 Notwithstanding the amendments made by this title,
12 part 8 of subchapter C of chapter VII of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 379j–51 et seq.), as
14 in effect on the day before the date of the enactment of
15 this title, shall continue to be in effect with respect to bio-
16 similar biological product applications and supplements
17 (as defined in such part as of such day) that were accepted
18 by the Food and Drug Administration for filing on or after
19 October 1, 2017, but before October 1, 2022, with respect
20 to assessing and collecting any fee required by such part
21 for a fiscal year prior to fiscal year 2023.

1 **TITLE V—IMPROVING REGULA-**
2 **TION OF DRUGS AND BIO-**
3 **LOGICAL PRODUCTS**

4 **SEC. 501. ALTERNATIVES TO ANIMAL TESTING.**

5 (a) IN GENERAL.—Section 505 of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

7 (1) in subsection (i)—

8 (A) in paragraph (1)(A), by striking “pre-
9 clinical tests (including tests on animals)” and
10 inserting “nonclinical tests”; and

11 (B) in paragraph (2)(B), by striking “ani-
12 mal” and inserting “nonclinical tests”; and

13 (2) after subsection (y), by inserting the fol-
14 lowing:

15 “(z) NONCLINICAL TEST DEFINED.—For purposes
16 of this section, the term ‘nonclinical test’ means a test con-
17 ducted in vitro, in silico, or in chemico, or a non-human
18 in vivo test that occurs before or during the clinical trial
19 phase of the investigation of the safety and effectiveness
20 of a drug, and may include animal tests, or non-animal
21 or human biology-based test methods, such as cell-based
22 assays, microphysiological systems, or bioprinted or com-
23 puter models.”.

24 (b) BIOSIMILAR BIOLOGICAL PRODUCT APPLICA-
25 TIONS.—Item (bb) of section 351(k)(2)(A)(i)(I) of the

1 Public Health Service Act (42 U.S.C. 262(k)(2)(A)(i)(I))
2 is amended to read as follows:

3 “(bb) an assessment of tox-
4 icity (which may rely on, or con-
5 sist of, a study or studies de-
6 scribed in item (aa) or (cc));
7 and”.

8 **SEC. 502. SAFER DISPOSAL OF OPIOIDS.**

9 Section 505–1(e)(4)(B) of the Federal Food, Drug,
10 and Cosmetic Act (21 U.S.C. 355–1(e)(4)(B)) is amended
11 by striking “for purposes of rendering drugs nonretriev-
12 able (as defined in section 1300.05 of title 21, Code of
13 Federal Regulations (or any successor regulation))”.

14 **SEC. 503. CLARIFICATIONS TO EXCLUSIVITY PROVISIONS**
15 **FOR FIRST INTERCHANGEABLE BIOSIMILAR**
16 **BIOLOGICAL PRODUCTS.**

17 Section 351(k)(6) of the Public Health Service Act
18 (42 U.S.C. 262(k)(6)) is amended—

19 (1) in the matter preceding subparagraph (A)—

20 (A) by striking “Upon review of” and in-
21 sserting “The Secretary shall not make approval
22 as an interchangeable biological product effec-
23 tive with respect to”;

24 (B) by striking “relying on” and inserting
25 “that relies on”; and

1 (C) by striking “the Secretary shall not
2 make a determination under paragraph (4) that
3 the second or subsequent biological product is
4 interchangeable for any condition of use”; and
5 (2) in the flush text that follows subparagraph
6 (C), by striking the period and inserting “, and the
7 term ‘first interchangeable biosimilar biological prod-
8 uct’ means any interchangeable biosimilar biological
9 product that is approved on the first day on which
10 such a product is approved as interchangeable with
11 the reference product.”.

12 **SEC. 504. IMPROVEMENTS TO THE PURPLE BOOK.**

13 (a) IN GENERAL.—Section 506I of the Federal Food,
14 Drug, and Cosmetic Act (21 U.S.C. 356i) is amended—

15 (1) in subsection (a)—

16 (A) by striking “The holder of an applica-
17 tion approved under subsection (c) or (j) of sec-
18 tion 505” and inserting “The holder of an ap-
19 plication approved under subsection (c) or (j) of
20 section 505 of this Act or subsection (a) or (k)
21 of section 351 of the Public Health Service
22 Act”;

23 (B) in paragraph (2), by inserting “(in the
24 case of a biological product, the proper name)”
25 after “established name”; and

1 (C) in paragraph (3), by striking “or ab-
2 breviated application number” and inserting “,
3 abbreviated application number, or biologics li-
4 cense application number”; and

5 (2) in subsection (b)—

6 (A) in the matter preceding paragraph (1),
7 by striking “The holder of an application ap-
8 proved under subsection (c) or (j)” and insert-
9 ing “The holder of an application approved
10 under subsection (c) or (j) of section 505 of
11 this Act or subsection (a) or (k) of section 351
12 of the Public Health Service Act”;

13 (B) in paragraph (1), by inserting “(in the
14 case of a biological product, the proper name)”
15 after “established name”; and

16 (C) in paragraph (2), by striking “or ab-
17 breviated application number” and inserting “,
18 abbreviated application number, or biologics li-
19 cense application number”.

20 (b) **ADDITIONAL ONE-TIME REPORT.**—Subsection
21 (c) of section 506I of the Federal Food, Drug, and Cos-
22 metic Act (21 U.S.C. 356i) is amended to read as follows:

23 “(c) **ADDITIONAL ONE-TIME REPORT.**—Within 180
24 days of the date of enactment of the Food and Drug Ad-
25 ministration Safety and Landmark Advancements Act of

1 2022, all holders of applications approved under sub-
2 section (a) or (k) of section 351 of the Public Health Serv-
3 ice Act shall review the information in the list published
4 under section 351(k)(9)(A) and shall submit a written no-
5 tice to the Secretary—

6 “(1) stating that all of the application holder’s
7 biological products in the list published under sec-
8 tion 351(k)(9)(A) that are not listed as discontinued
9 are available for sale; or

10 “(2) including the information required pursu-
11 ant to subsection (a) or (b), as applicable, for each
12 of the application holder’s biological products that
13 are in the list published under section 351(k)(9)(A)
14 and not listed as discontinued, but have been discon-
15 tinued from sale or never have been available for
16 sale.”.

17 (c) PURPLE BOOK.—Section 506I of the Federal
18 Food, Drug, and Cosmetic Act (21 U.S.C. 356i) is amend-
19 ed—

20 (1) in subsection (d)—

21 (A) by striking “or (c), the Secretary” and
22 inserting “or (c)—

23 “(1) the Secretary”;

24 (B) by striking the period at the end, and
25 inserting “; and”; and

1 (C) by adding at the end the following:

2 “(2) the Secretary may identify the application
3 holder’s biological products as discontinued in the
4 list published under section 351(k)(9)(A) of the
5 Public Health Service Act, except that the Secretary
6 shall remove from the list in accordance with section
7 351(k)(9)(B) of such Act any biological product for
8 which a license has been revoked or suspended for
9 reasons of safety, purity, or potency.”; and

10 (2) in subsection (e)—

11 (A) by inserting after the first sentence the
12 following: “The Secretary shall update the list
13 published under section 351(k)(9)(A) of the
14 Public Health Service Act based on information
15 provided under subsections (a), (b), and (c) by
16 identifying as discontinued biological products
17 that are not available for sale, except that any
18 biological product for which the license has been
19 revoked or suspended for reasons of safety, pu-
20 rity, or potency shall be removed from the list
21 in accordance with section 351(k)(9)(B) of the
22 Public Health Service Act.”; and

23 (B) in the last sentence—

24 (i) by striking “updates to the list”
25 and inserting “updates to the lists pub-

1 lished under section 505(j)(7)(A) of this
2 Act and section 351(k)(9)(A) of the Public
3 Health Service Act”; and

4 (ii) by striking “update the list” and
5 inserting “update such lists”.

6 **SEC. 505. THERAPEUTIC EQUIVALENCE EVALUATIONS.**

7 Section 505(j)(7)(A) of the Federal Food, Drug, and
8 Cosmetic Act (21 U.S.C. 355(j)(7)(A)) is amended by
9 adding at the end the following:

10 “(v)(I) With respect to an application submitted pur-
11 suant to subsection (b)(2) for a drug that is subject to
12 section 503(b) for which the sole difference from a listed
13 drug relied upon in the application is a difference in inac-
14 tive ingredients not permitted under clause (iii) or (iv) of
15 section 314.94(a)(9) of title 21, Code of Federal Regula-
16 tions (or any successor regulations), the Secretary shall
17 make an evaluation with respect to whether such drug is
18 a therapeutic equivalent (as defined in section 314.3 of
19 title 21, Code of Federal Regulations (or any successor
20 regulations)) to another approved drug product in the pre-
21 scription drug product section of the list under this para-
22 graph as follows:

23 “(aa) With respect to such an application sub-
24 mitted after the date of enactment of the Food and
25 Drug Administration Safety and Landmark Ad-

1 vancements Act of 2022, the evaluation shall be
2 made with respect to a listed drug relied upon in the
3 application pursuant to subsection (b)(2) that is a
4 pharmaceutical equivalent (as defined in section
5 314.3 of title 21, Code of Federal Regulations (or
6 any successor regulations)) to the drug in the appli-
7 cation pursuant to subsection (b)(2) at the time of
8 approval of such application or not later than 180
9 days after the date of such approval, provided that
10 the request for such an evaluation is made in the
11 original application (or in a resubmission to a com-
12 plete response letter), and all necessary data and in-
13 formation are submitted in the original application
14 (or in a resubmission in response to a complete re-
15 sponse letter) for the therapeutic equivalence evalua-
16 tion, including information to demonstrate bio-
17 equivalence, in a form and manner prescribed by the
18 Secretary.

19 “(bb) With respect to such an application ap-
20 proved prior to or on the date of enactment of the
21 Food and Drug Administration Safety and Land-
22 mark Advancements Act of 2022, the evaluation
23 shall be made not later than 180 days after receipt
24 of a request for a therapeutic equivalence evaluation
25 submitted as part of a supplement to such applica-

1 tion; or with respect to an application that was sub-
2 mitted prior to the date of enactment of the Food
3 and Drug Administration Safety and Landmark Ad-
4 vancements Act of 2022 but not approved as of the
5 date of enactment of such Act, the evaluation shall
6 be made not later than 180 days after the date of
7 approval of such application if a request for such
8 evaluation is submitted as an amendment to the ap-
9 plication, provided that—

10 “(AA) such request for a therapeutic
11 equivalence evaluation is being sought with re-
12 spect to a listed drug relied upon in the applica-
13 tion, and the relied upon listed drug is in the
14 prescription drug product section of the list
15 under this paragraph and is a pharmaceutical
16 equivalent (as defined in section 314.3 of title
17 21, Code of Federal Regulations (or any suc-
18 cessor regulations)) to the drug for which a
19 therapeutic equivalence evaluation is sought;
20 and

21 “(BB) the amendment or supplement, as
22 applicable, containing such request, or the rel-
23 evant application, includes all necessary data
24 and information for the therapeutic equivalence
25 evaluation, including information to dem-

1 “(B) STUDIES NOT REQUIRED.—If the
2 Secretary does not require that the sponsor of
3 a product approved under accelerated approval
4 conduct a postapproval study under this para-
5 graph, the Secretary shall publish on the
6 website of the Food and Drug Administration
7 the rationale for why such study is not appro-
8 priate or necessary.

9 “(C) POSTAPPROVAL STUDY CONDI-
10 TIONS.—Not later than the date of approval of
11 a product under accelerated approval, the Sec-
12 retary shall specify the conditions for a post-
13 approval study or studies required to be con-
14 ducted under this paragraph with respect to
15 such product, which may include enrollment
16 targets, the study protocol, and milestones, in-
17 cluding the target date of study completion.

18 “(D) STUDIES BEGUN BEFORE AP-
19 PROVAL.—The Secretary may require such
20 study or studies to be underway prior to ap-
21 proval of the applicable product.”; and

22 (2) in paragraph (3)—

23 (A) by redesignating subparagraphs (A)
24 through (D) as clauses (i) through (iv), respec-
25 tively and adjusting the margins accordingly;

1 (B) by striking “The Secretary may” and
2 inserting the following:

3 “(A) IN GENERAL.—The Secretary may”;

4 (C) in clause (i) of such subparagraph (A),
5 as so redesignated, by striking “drug with due
6 diligence” and inserting “product with due dili-
7 gence, including with respect to conditions spec-
8 ified by the Secretary under paragraph (2)(C)”;

9 (D) in clause (iii) of such subparagraph
10 (A), as so redesignated, by inserting “shown to
11 be” after “product is not”; and

12 (E) by adding at the end the following:

13 “(B) EXPEDITED PROCEDURES DE-
14 SCRIBED.—Expedited procedures described in
15 this subparagraph shall consist of, prior to the
16 withdrawal of accelerated approval—

17 “(i) providing the sponsor with—

18 “(I) due notice;

19 “(II) an explanation for the pro-
20 posed withdrawal;

21 “(III) an opportunity for a meet-
22 ing with the Commissioner or the
23 Commissioner’s designee; and

24 “(IV) an opportunity for written
25 appeal to—

- 1 “(aa) the Commissioner; or
- 2 “(bb) a designee of the
- 3 Commissioner who has not par-
- 4 ticipated in the proposed with-
- 5 drawal of approval (other than a
- 6 meeting pursuant to subclause
- 7 (III)) and is not subordinate of
- 8 an individual (other than the
- 9 Commissioner) who participated
- 10 in such proposed withdrawal;
- 11 “(ii) providing an opportunity for
- 12 public comment on the proposal to with-
- 13 draw approval;
- 14 “(iii) the publication of a summary of
- 15 the public comments received, and the Sec-
- 16 retary’s response to such comments, on the
- 17 website of the Food and Drug Administra-
- 18 tion; and
- 19 “(iv) convening and consulting an ad-
- 20 visory committee on issues related to the
- 21 proposed withdrawal, if requested by the
- 22 sponsor and if no such advisory committee
- 23 has previously advised the Secretary on
- 24 such issues with respect to the withdrawal

1 of the product prior to the sponsor’s re-
2 quest.”.

3 (b) REPORTS OF POSTMARKETING STUDIES.—Sec-
4 tion 506B(a) of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 356b(a)) is amended—

6 (1) by redesignating paragraph (2) as para-
7 graph (3); and

8 (2) by inserting after paragraph (1) the fol-
9 lowing:

10 “(2) ACCELERATED APPROVAL.—Notwith-
11 standing paragraph (1), a sponsor of a drug ap-
12 proved pursuant to accelerated approval shall submit
13 to the Secretary a report of the progress of any
14 study required under section 506(c), including
15 progress toward enrollment targets, milestones, and
16 other information as required by the Secretary, not
17 later than 180 days after the approval of such drug
18 and not less frequently than every 180 days there-
19 after, until the study is completed or terminated.
20 The Secretary shall promptly publish on the website
21 of the Food and Drug Administration, in an easily
22 searchable format, the information reported under
23 this paragraph.”.

1 (c) ENFORCEMENT.—Section 301 of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
3 ed by adding at the end the following:

4 “(fff) The failure of a sponsor of a product approved
5 under accelerated approval pursuant to section 506(c)—

6 “(1) to conduct with due diligence any post-
7 approval study required under section 506(c) with
8 respect to such product; or

9 “(2) to submit timely reports with respect to
10 such product in accordance with section
11 506B(a)(2).”.

12 (d) GUIDANCE.—

13 (1) IN GENERAL.—The Secretary of Health and
14 Human Services (referred to in this section as the
15 “Secretary”) shall issue guidance describing—

16 (A) how sponsor questions related to the
17 identification of novel surrogate or intermediate
18 clinical endpoints may be addressed in early-
19 stage development meetings with the Food and
20 Drug Administration;

21 (B) the use of novel clinical trial designs
22 that may be used to conduct appropriate post-
23 approval studies as may be required under sec-
24 tion 506(c)(2)(A) of the Federal Food, Drug,

1 and Cosmetic Act, as amended by subsection
2 (a);

3 (C) the expedited procedures described in
4 section 506(e)(3)(B) of the Federal Food,
5 Drug, and Cosmetic Act; and

6 (D) considerations related to the use of
7 surrogate or intermediate clinical endpoints
8 that may support the accelerated approval of an
9 application under 506(e)(1)(A), including con-
10 siderations in evaluating the evidence related to
11 any such endpoints.

12 (2) FINAL GUIDANCE.—The Secretary shall
13 issue—

14 (A) draft guidance under paragraph (1)
15 not later than 18 months after the date of en-
16 actment of this Act; and

17 (B) final guidance not later than 1 year
18 after the close of the public comment period on
19 such draft guidance.

20 (e) ACCELERATED APPROVAL COUNCIL.—

21 (1) GENERAL.—Not later than 1 year after the
22 date of enactment of this Act, the Secretary shall es-
23 tablish an intra-agency coordinating council within
24 the Food and Drug Administration to ensure the
25 consistent and appropriate use of accelerated ap-

1 proval across the Food and Drug Administration,
2 pursuant to section 506(c) of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 356(c)).

4 (2) MEMBERSHIP.—The members of the Coun-
5 cil shall consist of the following senior officials, or
6 a designee of such official, from the Food and Drug
7 Administration and relevant Centers:

8 (A) The Director of the Center for Drug
9 Evaluation and Research.

10 (B) The Director of the Center for Bio-
11 logics Evaluation and Research.

12 (C) The Director of the Oncology Center
13 of Excellence.

14 (D) The Director of the Office of New
15 Drugs.

16 (E) The Director of the Office of Orphan
17 Products Development.

18 (F) The Director of the Office of Tissues
19 and Advanced Therapies.

20 (G) The Director of the Office of Medical
21 Policy.

22 (H) At least 3 directors of review divisions
23 or offices overseeing products approved under
24 accelerated approval, including at least one di-
25 rector within the Office of Neuroscience.

1 (3) DUTIES OF THE COUNCIL.—

2 (A) MEETINGS.—The Council shall con-
3 vene not fewer than 3 times per calendar year
4 to discuss issues related to accelerated approval,
5 including any relevant cross-disciplinary ap-
6 proaches related to product review with respect
7 to accelerated approval.

8 (B) POLICY DEVELOPMENT.—The Council
9 shall directly engage with product review teams
10 to support the consistent and appropriate use of
11 accelerated approval across the Food and Drug
12 Administration. Such activities may include—

13 (i) developing guidance for Food and
14 Drug Administration staff and best prac-
15 tices for, and across, product review teams,
16 including with respect to communication
17 between sponsors and the Food and Drug
18 Administration and the review of products
19 under accelerated approval;

20 (ii) providing training for product re-
21 view teams; and

22 (iii) advising review divisions on prod-
23 uct-specific development, review, and with-
24 drawal of products under accelerated ap-
25 proval.

1 (4) PUBLICATION OF A REPORT.—Not later
2 than 1 year after the date of enactment of this Act,
3 and annually thereafter, the council shall publish on
4 the public website of the Food and Drug Adminis-
5 tration a report on the activities of the council.

6 (f) RULE OF CONSTRUCTION.—Nothing in this sec-
7 tion (including the amendments made by this section)
8 shall be construed to affect products approved pursuant
9 to section 506(c) of the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C. 356(c)) prior to the date of enactment of
11 this Act.

12 **SEC. 507. RARE DISEASE PILOT PROGRAM.**

13 (a) IN GENERAL.—The Secretary of Health and
14 Human Services (referred to in this section as the “Sec-
15 retary”) shall establish a pilot program under which the
16 Secretary establishes procedures to provide increased
17 interaction with sponsors of rare disease drug development
18 programs for purposes of advancing the development of
19 efficacy endpoints, including surrogate and intermediate
20 endpoints, for drugs intended to treat rare diseases, in-
21 cluding through—

22 (1) determining eligibility of participants for
23 such program; and

24 (2) developing and implementing a process for
25 applying to, and participating in, such a program.

1 (b) PUBLIC WORKSHOPS.—The Secretary shall con-
2 duct up to 3 public workshops, which shall be completed
3 not later than September 30, 2026, to discuss topics rel-
4 evant to the development of endpoints for rare diseases,
5 which may include discussions about—

6 (1) novel endpoints developed through the pilot
7 program established under this section; and

8 (2) as appropriate, the use of real world evi-
9 dence and real world data to support the validation
10 of efficacy endpoints, including surrogate and inter-
11 mediate endpoints, for rare diseases.

12 (c) REPORT.—Not later than September 30, 2026,
13 the Secretary shall submit to the Committee on Health,
14 Education, Labor, and Pensions of the Senate and the
15 Committee on Energy and Commerce of the House of
16 Representatives a report describing the outcomes of the
17 pilot program established under this section.

18 (d) GUIDANCE.—Not later than September 30, 2027,
19 the Secretary shall issue guidance describing best prac-
20 tices and strategies for development of efficacy endpoints,
21 including surrogate and intermediate endpoints, for rare
22 diseases.

23 (e) SUNSET.—The Secretary may not accept any new
24 application or request to participate in the program estab-
25 lished by this section on or after October 1, 2027.

1 **SEC. 508. SUPPORTING REVIEW AND DEVELOPMENT OF**
2 **DRUGS TO TREAT RARE DISEASES.**

3 (a) GAO REPORT.—

4 (1) IN GENERAL.—Not later than 18 months
5 after the date of enactment of this Act, the Comp-
6 troller General of the United States shall submit to
7 the Committee on Health, Education, Labor, and
8 Pensions of the Senate and the Committee on En-
9 ergy and Commerce of the House of Representa-
10 tives, a report assessing the policies, practices, and
11 programs of the Food and Drug Administration with
12 respect to the review of applications for drugs and
13 biological products intended to treat rare diseases
14 and conditions (as defined in section 526(a)(2) of
15 the Federal Food, Drug, and Cosmetic Act (21
16 U.S.C. 360bb(a)(2))).

17 (2) CONTENT OF REPORT.—The report under
18 paragraph (1) shall—

19 (A) describe the activities of the Food and
20 Drug Administration dedicated to the develop-
21 ment and review of drugs and biological prod-
22 ucts intended to treat rare diseases and condi-
23 tions;

24 (B) describe challenges with developing
25 and obtaining approval or licensure of drugs
26 and biological products intended to treat rare

1 diseases and conditions, such as challenges re-
2 lated to designing and conducting clinical trials,
3 clinical trial subject recruitment and enroll-
4 ment, study endpoints, and ensuring data qual-
5 ity, assessing the benefit-risk profile of drugs
6 and biological products intended to treat rare
7 diseases and conditions, and meeting require-
8 ments for approval or licensure;

9 (C) assess the effectiveness of policies and
10 practices of the Food and Drug Administration
11 related to the review of applications for drugs
12 and biological products intended to treat rare
13 diseases and conditions, including—

14 (i) initiatives to support the develop-
15 ment and review of drugs and biological
16 products intended to treat rare diseases
17 and conditions, including initiatives related
18 to regulatory science, clinical trial design,
19 statistical analysis, and other relevant top-
20 ics;

21 (ii) consideration of relevant patient-
22 focused drug development data and infor-
23 mation, including patient experience data
24 and the views of patients, pursuant to sec-

1 tion 569C of the Federal Food, Drug, and
2 Cosmetic Act (21 U.S.C. 360bbb–8c);

3 (iii) training and other efforts to en-
4 sure the expertise of personnel of the Food
5 and Drug Administration regarding the re-
6 view of applications for drugs and biologi-
7 cal products intended to treat rare diseases
8 and conditions; and

9 (iv) consultations and engagement
10 with stakeholders and external experts pur-
11 suant to section 569 of the Federal Food,
12 Drug, and Cosmetic Act (21 U.S.C.
13 360bbb–8);

14 (D) assess the extent to which the Food
15 and Drug Administration is applying the poli-
16 cies and practices described in subparagraph
17 (C) consistently across review divisions, and the
18 factors that influence the extent to which such
19 application is consistent; and

20 (E) include recommendations to address
21 challenges and deficiencies identified, including
22 recommendations to improve the effectiveness,
23 consistency, and coordination of policies, prac-
24 tices, and programs of the Food and Drug Ad-
25 ministration related to the review of applica-

1 tions for drugs and biological products intended
2 to treat rare diseases and conditions.

3 (b) FDA REPORT.—

4 (1) IN GENERAL.—Not later than March 31,
5 2026, the Secretary of Health and Human Services
6 (referred to in this subsection as the “Secretary”)
7 shall submit to the Committee on Health, Edu-
8 cation, Labor, and Pensions of the Senate and the
9 Committee on Energy and Commerce of the House
10 of Representatives a report assessing the policies,
11 practices, and programs of the Food and Drug Ad-
12 ministration with respect to the review of applica-
13 tions for drugs and biological products intended to
14 treat rare diseases and conditions (as defined in sec-
15 tion 526(a)(2) of the Federal Food, Drug, and Cos-
16 metic Act (21 U.S.C. 360bb(a)(2))).

17 (2) CONTENT OF REPORT.—The report under
18 paragraph (1) shall include, with respect to the pe-
19 riod of fiscal years 2023 through 2025, broken down
20 by fiscal year and by the responsible review division
21 of the Food and Drug Administration—

22 (A) the number of drugs that have been
23 designated as a drug for a rare disease or con-
24 dition under section 526 of the Federal Food,
25 Drug, and Cosmetic Act (21 U.S.C. 360bb);

1 (B) the number of applications under sec-
2 tion 505(b) of the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 355(b)) or section
4 351(a) of the Public Health Service Act (42
5 U.S.C. 262(a)) for a drug designated under sec-
6 tion 526 for a rare disease or condition that
7 were submitted, the number of such applica-
8 tions that were approved, and the average size
9 of the affected population in the United States
10 upon which the designation pursuant to section
11 526 of the Federal Food, Drug, and Cosmetic
12 Act (21 U.S.C. 360bb) was granted for each
13 such submitted and approved application;

14 (C) the number of applications for a drug
15 or biological product for which the sponsor re-
16 quested written recommendations pursuant to
17 section 525 of the Federal Food, Drug, and
18 Cosmetic Act (21 U.S.C. 360aa), and the num-
19 ber of such applications for which the sponsor
20 received such written recommendations;

21 (D) the number of applications for which
22 the Secretary consulted experts pursuant to sec-
23 tion 569(a)(2) of the Federal Food, Drug, and
24 Cosmetic Act (21 U.S.C. 360bbb–8c); and

1 (E) the number of applications for which
2 the Secretary allowed the sponsor to rely upon
3 data and information pursuant to section 529A
4 of the Federal Food, Drug, and Cosmetic Act
5 (21 U.S.C. 360ff–1).

6 (3) CLARIFICATION.—Nothing in this sub-
7 section shall be construed to authorize the disclosure
8 of confidential commercial information or other in-
9 formation considered proprietary or trade secret, as
10 prohibited under section 301(j) of the Federal Food,
11 Drug, and Cosmetic Act (21 U.S.C. 331(j)) or sec-
12 tion 1905 of title 18, United States Code.

13 (c) GUIDANCE.—Not later than 9 months after the
14 date of enactment of this Act, the Secretary shall publish
15 final guidance related to the draft guidance titled, “Rare
16 Diseases: Common Issues in Drug Development” issued
17 on February 1, 2019.

18 **SEC. 509. GENERIC DRUG LABELING CHANGES.**

19 Section 505(j)(10)(A) of the Federal Food, Drug,
20 and Cosmetic Act (21 U.S.C. 355(j)(10)(A)) is amended
21 by striking clauses (i) through (iii) and inserting the fol-
22 lowing:

23 “(i) a revision to the labeling of the listed drug
24 has been approved by the Secretary within 90 days

1 of when the application is otherwise eligible for ap-
2 proval under this subsection;

3 “(ii) the sponsor of the application agrees to
4 submit revised labeling for the drug that is the sub-
5 ject of the application not later than 60 days after
6 approval under this subsection of the application;

7 “(iii) the labeling revision described under
8 clause (i) does not include a change to the ‘Warn-
9 ings’ section of the labeling; and”.

10 **TITLE VI—OTHER** 11 **REAUTHORIZATIONS**

12 **SEC. 601. REAUTHORIZATION OF THE CRITICAL PATH PUB-** 13 **LIC-PRIVATE PARTNERSHIP.**

14 Section 566(f) of the Federal Food, Drug, and Cos-
15 metic Act (21 U.S.C. 360bbb–5(f)) is amended by striking
16 “2018 through 2022” and inserting “2023 through
17 2027”.

18 **SEC. 602. REAUTHORIZATION OF THE BEST PHARMA-** 19 **CEUTICALS FOR CHILDREN PROGRAM.**

20 Section 409I(d)(1) of the Public Health Service Act
21 (42 U.S.C. 284m(d)(1)) is amended by striking “2018
22 through 2022” and inserting “2023 through 2027”.

1 **SEC. 603. REAUTHORIZATION OF THE HUMANITARIAN DE-**
2 **VICE EXEMPTION INCENTIVE.**

3 Section 520(m)(6)(A)(iv) of the Federal Food, Drug,
4 and Cosmetic Act (21 U.S.C. 360j(m)(6)(A)(iv)) is
5 amended by striking “2022” and inserting “2027”.

6 **SEC. 604. REAUTHORIZATION OF THE PEDIATRIC DEVICE**
7 **CONSORTIA PROGRAM.**

8 Section 305(e) of the Food and Drug Administration
9 Amendments Act of 2007 (Public Law 110–85; 42 U.S.C.
10 282 note) is amended by striking “\$5,250,000 for each
11 of fiscal years 2018 through 2022” and inserting
12 “\$7,000,000 for each of fiscal years 2023 through 2027”.

13 **SEC. 605. REAUTHORIZATION OF PROVISION PERTAINING**
14 **TO DRUGS CONTAINING SINGLE**
15 **ENANTIOMERS.**

16 Section 505(u) of the Federal Food, Drug, and Cos-
17 metic Act (21 U.S.C. 355(u)) is amended by—

18 (1) in paragraph (1)(A)(ii)(II), by adding
19 “(other than bioavailability studies)” after “any clin-
20 ical investigations”; and

21 (2) in paragraph (4), by striking “October 1,
22 2022” and inserting “October 1, 2027”.

23 **SEC. 606. REAUTHORIZATION OF ORPHAN DRUG GRANTS.**

24 Section 5(c) of the Orphan Drug Act (21 U.S.C.
25 360ee(c)) is amended by striking “2018 through 2022”
26 and inserting “2023 through 2027”.

1 **SEC. 607. REAUTHORIZATION OF CERTAIN DEVICE INSPEC-**
2 **TIONS.**

3 Section 704(g)(11) of the Federal Food, Drug, and
4 Cosmetic Act (21 U.S.C. 374(g)(11)) is amended by strik-
5 ing “2022” and inserting “2027”.

6 **TITLE VII—ENHANCING FDA**
7 **HIRING AUTHORITIES**

8 **SEC. 701. ENHANCING FDA HIRING AUTHORITY FOR SCI-**
9 **ENTIFIC, TECHNICAL, AND PROFESSIONAL**
10 **PERSONNEL.**

11 Section 714A of the Federal Food, Drug, and Cos-
12 metic Act (21 U.S.C. 379d–3a) is amended—

13 (1) in subsection (a)—

14 (A) by inserting “, including cross-cutting
15 operational positions,” after “professional posi-
16 tions”; and

17 (B) by inserting “and the regulation of
18 food” after “medical products”; and

19 (2) in subsection (d)(1)—

20 (A) in the matter preceding subparagraph

21 (A)—

22 (i) by striking “the 21st Century
23 Cures Act” and inserting “the Food and
24 Drug Administration Safety and Land-
25 mark Advancements Act of 2022”; and

1 (ii) by striking “that examines the ex-
2 tent” and all that follows through “, in-
3 cluding” and inserting “that addresses”;

4 (B) in subparagraph (A)—

5 (i) by inserting “updated” before
6 “analysis”; and

7 (ii) by striking “; and” and inserting
8 a semicolon;

9 (C) by redesignating subparagraph (B) as
10 subparagraph (C);

11 (D) by inserting after subparagraph (A)
12 the following:

13 “(B) an analysis of how the Secretary has
14 used the authorities provided under this section,
15 and a plan for how the Secretary will use the
16 authority under this section, and other applica-
17 ble hiring authorities, for employees of the
18 Food and Drug Administration; and”;

19 (E) in the matter preceding clause (i) of
20 subparagraph (C), as so redesignated, by strik-
21 ing “a recruitment” and inserting “an updated
22 recruitment”.

1 **SEC. 702. STRATEGIC WORKFORCE PLAN AND REPORT.**

2 Chapter VII of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 371 et seq.) is amended by inserting
4 after section 714A the following:

5 **“SEC. 714B. STRATEGIC WORKFORCE PLAN AND REPORT.**

6 “(a) IN GENERAL.—Not later than September 30,
7 2023, and at least every 4 years thereafter, the Secretary
8 shall develop and submit to the appropriate committees
9 of Congress and post on the website of the Food and Drug
10 Administration, a coordinated strategy and report to pro-
11 vide direction for the activities and programs of the Sec-
12 retary to recruit, hire, train, develop, and retain the work-
13 force needed to fulfill the public health mission of the
14 Food and Drug Administration, including to facilitate col-
15 laboration across centers, to keep pace with new bio-
16 medical, technological, and scientific advancements, and
17 support the development, review, and regulation of med-
18 ical products. Each such report shall be known as the
19 ‘Food and Drug Administration Strategic Workforce
20 Plan’.

21 “(b) USE OF THE FOOD AND DRUG ADMINISTRATION
22 STRATEGIC WORKFORCE PLAN.—Each center within the
23 Food and Drug Administration shall develop and update,
24 as appropriate, a strategic plan that will be informed by
25 the Food and Drug Administration Strategic Workforce
26 Plan developed and updated under this subsection.

1 “(c) CONTENTS OF THE FOOD AND DRUG ADMINIS-
2 TRATION STRATEGIC WORKFORCE PLAN.—Each Food
3 and Drug Administration Strategic Workforce Plan under
4 subsection (a) shall—

5 “(1) include agency-wide strategic goals and
6 priorities for recruiting, hiring, training, developing,
7 and retaining a qualified workforce for the Food and
8 Drug Administration;

9 “(2) establish specific activities the Secretary
10 will take to achieve its strategic goals and priorities
11 and address the workforce needs of the Food and
12 Drug Administration in the forthcoming fiscal years;

13 “(3) identify challenges and risks the Secretary
14 will face in meeting its strategic goals and priorities,
15 and the activities the Secretary will undertake to
16 overcome those challenges and mitigate those risks;

17 “(4) establish metrics and milestones that the
18 Secretary will use to measure progress in achieving
19 its strategic goals and priorities; and

20 “(5) define functions, capabilities, and gaps in
21 such workforce and identify strategies to recruit,
22 hire, train, develop, and retain such workforce.

23 “(d) CONSIDERATIONS.—In developing each Food
24 and Drug Administration Strategic Workforce Plan under
25 subsection (a), the Secretary shall consider—

1 “(1) the number of employees, employee exper-
2 tise, and employing center of employees, including
3 senior leadership and non-senior leadership employ-
4 ees, eligible for retirement;

5 “(2) the vacancy and turnover rates for employ-
6 ees with different types of expertise and from dif-
7 ferent centers, including any changes or trends re-
8 lated to such rates;

9 “(3) the results of the Federal Employee View-
10 point Survey for employees of the Food and Drug
11 Administration, including any changes or trends re-
12 lated to such results;

13 “(4) rates of pay for different types of posi-
14 tions, including rates for different types of expertise
15 within the same field (such as differences in pay be-
16 tween different medical specialists), and how such
17 rates of pay impact the ability of the Secretary to
18 achieve strategic goals and priorities; and

19 “(5) the statutory hiring authorities used to
20 hire Food and Drug Administration employees, and
21 the time to hire across different hiring authorities.

22 “(e) EVALUATION OF PROGRESS.—Each Food and
23 Drug Administration Strategic Workforce Plan issued
24 pursuant to subsection (a), with the exception of the first
25 such Food and Drug Administration Strategic Workforce

1 Plan, shall include an evaluation of the progress the Sec-
2 retary has made, based on the metrics, benchmarks, and
3 other milestones that measure successful recruitment, hir-
4 ing, training, development, and retention activities; and
5 whether such actions improved the capacity of the Food
6 and Drug Administration to achieve the strategic goals
7 and priorities set forth in the previous Food and Drug
8 Administration Strategic Workforce Plan.

9 “(f) ADDITIONAL CONSIDERATIONS.—The Food and
10 Drug Administration Strategic Workforce Plan issued in
11 fiscal year 2023 shall address the effect of the COVID-
12 19 pandemic on hiring, retention, and other workforce
13 challenges for the Food and Drug Administration, includ-
14 ing protecting such workforce during public health emer-
15 gencies.”.

16 **TITLE VIII—ADVANCING REGU-**
17 **LATION OF COSMETICS, DIE-**
18 **TARY SUPPLEMENTS, AND IN**
19 **VITRO CLINICAL TESTS**
20 **Subtitle A—Cosmetics**

21 **SEC. 801. SHORT TITLE.**

22 This subtitle may be cited as the “Modernization of
23 Cosmetics Regulation Act of 2022”.

1 **SEC. 802. AMENDMENTS TO COSMETIC REQUIREMENTS.**

2 Chapter VI of the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 361 et seq.) is amended by adding at the
4 end the following:

5 **“SEC. 604. DEFINITIONS.**

6 “In this chapter:

7 “(1) ADVERSE EVENT.—The term ‘adverse
8 event’ means any health-related event associated
9 with the use of a cosmetic product that is adverse.

10 “(2) COSMETIC PRODUCT.—The term ‘cosmetic
11 product’ means a preparation of cosmetic ingredi-
12 ents with a qualitatively and quantitatively set com-
13 position for use in a finished product.

14 “(3) FACILITY.—

15 “(A) IN GENERAL.—The term ‘facility’ in-
16 cludes any establishment (including an estab-
17 lishment of an importer) that manufactures or
18 processes cosmetic products distributed in the
19 United States.

20 “(B) Such term does not include any of
21 the following:

22 “(i) Beauty shops and salons, unless
23 such establishment manufactures or proc-
24 esses cosmetic products at that location.

25 “(ii) Cosmetic product retailers, in-
26 cluding individual sales representatives, di-

1 rect sellers (as defined in section
2 3508(b)(2) of the Internal Revenue Code
3 of 1986), retail distribution facilities, and
4 pharmacies, unless such establishment
5 manufactures or processes cosmetic prod-
6 ucts that are not sold directly to con-
7 sumers at that location.

8 “(iii) Hospitals, physicians’ offices,
9 and health care clinics.

10 “(iv) Public health agencies and other
11 nonprofit entities that provide cosmetic
12 products directly to the consumer.

13 “(v) Entities (such as hotels and air-
14 lines) that provide complimentary cosmetic
15 products to customers incidental to other
16 services.

17 “(vi) Trade shows and other venues
18 where cosmetic product samples are pro-
19 vided free of charge.

20 “(vii) An establishment that manufac-
21 tures or processes cosmetic products that
22 are solely for use in research or evaluation,
23 including for production testing and not of-
24 fered for retail sale.

1 “(iv) a persistent or significant dis-
2 ability or incapacity;

3 “(v) a congenital anomaly or birth de-
4 fect; or

5 “(vi) significant disfigurement (includ-
6 ing serious and persistent rashes or infec-
7 tions, second- or third-degree burns, sig-
8 nificant hair loss, or permanent or signifi-
9 cant alteration of appearance), other than
10 as intended, under conditions of use that
11 are customary or usual; or

12 “(B) requires, based on reasonable medical
13 judgment, a medical or surgical intervention to
14 prevent an outcome described in subparagraph
15 (A).

16 **“SEC. 605. ADVERSE EVENTS.**

17 “(a) SERIOUS ADVERSE EVENT REPORTING RE-
18 QUIREMENTS.—The responsible person shall submit to the
19 Secretary any report received of a serious adverse event
20 associated with the use, in the United States, of a cosmetic
21 product manufactured, packed, or distributed by such per-
22 son.

23 “(b) SUBMISSION OF REPORTS.—

24 “(1) SERIOUS ADVERSE EVENT REPORT.—The
25 responsible person shall submit to the Secretary a

1 serious adverse event report accompanied by a copy
2 of the label on or within the retail packaging of such
3 cosmetic product no later than 15 business days
4 after the report is received by the responsible per-
5 son.

6 “(2) NEW MEDICAL INFORMATION.—The re-
7 sponsible person shall submit to the Secretary any
8 new and material medical information, related to a
9 serious adverse event report submitted to the Sec-
10 retary in accordance with paragraph (1), that is re-
11 ceived by the responsible person within 1 year of the
12 initial report to the Secretary, no later than 15 busi-
13 ness days after such information is received by such
14 responsible person.

15 “(3) CONSOLIDATION OF REPORTS.—The Sec-
16 retary shall develop systems to enable responsible
17 persons to submit a single report that includes du-
18 plicate reports of, or new medical information re-
19 lated to, a serious adverse event.

20 “(c) EXEMPTIONS.—The Secretary may establish by
21 regulation an exemption to any of the requirements of this
22 section if the Secretary determines that such exemption
23 would have no significant adverse effect on public health.

24 “(d) CONTACT INFORMATION.—The responsible per-
25 son shall receive reports of adverse events through the do-

1 mestic address, domestic telephone number, or electronic
2 contact information included on the label in accordance
3 with section 609(a).

4 “(e) MAINTENANCE AND INSPECTION OF ADVERSE
5 EVENT RECORDS.—

6 “(1) MAINTENANCE.—The responsible person
7 shall maintain records related to each report of an
8 adverse event associated with the use, in the United
9 States, of a cosmetic product manufactured or dis-
10 tributed by such person received by such person, for
11 a period of 6 years.

12 “(2) INSPECTION.—

13 “(A) IN GENERAL.— The responsible per-
14 son shall permit an authorized person to have
15 access to records required to be maintained
16 under this section during an inspection pursu-
17 ant to section 704.

18 “(B) AUTHORIZED PERSON.—For pur-
19 poses of this paragraph, the term ‘authorized
20 person’ means an officer or employee of the De-
21 partment of Health and Human Services who
22 has—

23 “(i) appropriate credentials, as deter-
24 mined by the Secretary; and

1 “(ii) been duly designated by the Sec-
2 retary to have access to the records re-
3 quired under this section.

4 “(f) FRAGRANCE AND FLAVOR INGREDIENTS.—If
5 the Secretary has reasonable grounds to believe that an
6 ingredient or combination of ingredients in a fragrance or
7 flavor has caused or contributed to a serious adverse event
8 required to be reported under this section, the Secretary
9 may request in writing a list of ingredients or categories
10 of ingredients in the specific fragrances or flavors in the
11 cosmetic product, from the responsible person. The re-
12 sponsible person shall ensure that the requested informa-
13 tion is submitted to the Secretary within 30 days of such
14 request. In response to a request under section 552 of title
15 5, United States Code, information submitted to the Sec-
16 retary under this subsection shall be withheld under sec-
17 tion 552(b)(3) of title 5, United States Code.

18 “(g) PROTECTED INFORMATION.—A serious adverse
19 event report submitted to the Secretary under this section,
20 including any new medical information submitted under
21 subsection (b)(2), or an adverse event report, or any new
22 information, voluntarily submitted to the Secretary shall
23 be considered to be—

24 “(1) a safety report under section 756 and may
25 be accompanied by a statement, which shall be a

1 part of any report that is released for public disclo-
2 sure, that denies that the report or the records con-
3 stitute an admission that the product involved
4 caused or contributed to the adverse event; and

5 “(2) a record about an individual under section
6 552a of title 5, United States Code (commonly re-
7 ferred to as the ‘Privacy Act of 1974’) and a med-
8 ical or similar file the disclosure of which would con-
9 stitute a violation of section 552 of such title 5
10 (commonly referred to as the ‘Freedom of Informa-
11 tion Act’), and shall not be publicly disclosed unless
12 all personally identifiable information is redacted.

13 “(h) EFFECT OF SECTION.—

14 “(1) IN GENERAL.—Nothing in this section
15 shall affect the authority of the Secretary to provide
16 adverse event reports and information to any health,
17 food, or drug officer or employee of any State, terri-
18 tory, or political subdivision of a State or territory,
19 under a memorandum of understanding between the
20 Secretary and such State, territory, or political sub-
21 division.

22 “(2) PERSONALLY IDENTIFIABLE INFORMA-
23 TION.—Notwithstanding any other provision of law,
24 personally-identifiable information in adverse event
25 reports provided by the Secretary to any health,

1 food, or drug officer or employee of any State, terri-
2 tory, or political subdivision of a State or territory,
3 shall not—

4 “(A) be made publicly available pursuant
5 to any State or other law requiring disclosure
6 of information or records; or

7 “(B) otherwise be disclosed or distributed
8 to any party without the written consent of the
9 Secretary and the person submitting such infor-
10 mation to the Secretary.

11 “(3) USE OF REPORTS.—Nothing in this sec-
12 tion shall permit a State, territory, or political sub-
13 division of a State or territory, to use any safety re-
14 port received from the Secretary in a manner incon-
15 sistent with this section.

16 “(4) RULE OF CONSTRUCTION.—The submis-
17 sion of any report in compliance with this section
18 shall not be construed as an admission that the cos-
19 metic product involved caused or contributed to the
20 relevant adverse event.

21 **“SEC. 606. GOOD MANUFACTURING PRACTICE.**

22 “(a) IN GENERAL.—The Secretary shall by regula-
23 tion establish good manufacturing practices for facilities
24 that are consistent, to the extent practicable, and appro-
25 priate, with national and international standards, in ac-

1 cordance with section 601. Any such regulations shall be
2 intended to protect the public health and ensure that cos-
3 metic products are not adulterated. Such regulations may
4 allow for the Secretary to inspect records necessary to
5 demonstrate compliance with good manufacturing prac-
6 tices prescribed by the Secretary under this paragraph
7 during an inspection conducted under section 704.

8 “(b) CONSIDERATIONS.—In establishing regulations
9 for good manufacturing practices under this section, the
10 Secretary shall take into account the size and scope of the
11 businesses engaged in the manufacture of cosmetics, and
12 the risks to public health posed by such cosmetics, and
13 provide sufficient flexibility to be practicable for all sizes
14 and types of facilities to which such regulations will apply.
15 Such regulations shall include simplified good manufac-
16 turing practice requirements for smaller businesses, as ap-
17 propriate, to ensure that such regulations do not impose
18 undue economic hardship for smaller businesses, and may
19 include longer compliance times for smaller businesses.
20 Before issuing regulations to implement subsection (a),
21 the Secretary shall consult with cosmetics manufacturers,
22 including smaller businesses, consumer organizations, and
23 other experts selected by the Secretary.

24 “(c) TIMEFRAME.—The Secretary shall publish a no-
25 tice of proposed rulemaking not later than 2 years after

1 the date of enactment of the Modernization of Cosmetics
2 Regulation Act of 2022 and shall publish a final such rule
3 not later than 3 years after such date of enactment.

4 **“SEC. 607. REGISTRATION AND PRODUCT LISTING.**

5 “(a) SUBMISSION OF REGISTRATION.—

6 “(1) INITIAL REGISTRATION.—

7 “(A) EXISTING FACILITIES.—Every person
8 that, on the date of enactment of the Mod-
9 ernization of Cosmetics Regulation Act of 2022,
10 owns or operates a facility that engages in the
11 manufacturing or processing of a cosmetic
12 product for distribution in the United States
13 shall register each facility with the Secretary
14 not later than 1 year after date of enactment
15 of such Act.

16 “(B) NEW FACILITIES.—Every person that
17 owns or operates a facility that first engages,
18 after the date of enactment of the Moderniza-
19 tion of Cosmetics Regulation Act of 2022, in
20 manufacturing or processing of a cosmetic
21 product for distribution in the United States,
22 shall register with the Secretary such facility
23 within 60 days of first engaging in such activity
24 or 60 days after the deadline for registration
25 under subparagraph (A), whichever is later.

1 “(2) BIENNIAL RENEWAL OF REGISTRATION.—

2 A person required to register a facility under para-
3 graph (1) shall renew such registrations with the
4 Secretary biennially.

5 “(3) CONTRACT MANUFACTURERS.—If a facility
6 manufactures or processes cosmetic products on be-
7 half of a responsible person, the Secretary shall re-
8 quire only a single registration for such facility even
9 if such facility is manufacturing or processing its
10 own cosmetic products or cosmetic products on be-
11 half of more than one responsible person. Such sin-
12 gle registration may be submitted to the Secretary
13 by such facility or any responsible person whose
14 products are manufactured or processed at such fa-
15 cility.

16 “(4) UPDATES TO CONTENT.—A person that is
17 required to register under subsection (a)(1) shall no-
18 tify the Secretary within 60 days of any changes to
19 information required under subsection (b)(2).

20 “(5) ABBREVIATED RENEWAL REGISTRA-
21 TIONS.—The Secretary shall provide for an abbrevi-
22 ated registration renewal process for any person
23 that owns or operates a facility that has not been re-
24 quired to submit updates under paragraph (4) for a
25 registered facility since submission of the most re-

1 cent registration of such facility under paragraph
2 (1) or (2).

3 “(b) FORMAT; CONTENTS OF REGISTRATION.—

4 “(1) IN GENERAL.—Registration information
5 under this section may be submitted at such time
6 and in such manner as the Secretary may prescribe.

7 “(2) CONTENTS.—The registration under sub-
8 section (a) shall contain—

9 “(A) the facility’s name, physical address,
10 email address, and telephone number;

11 “(B) with respect to any foreign facility,
12 the contact for the United States agent of the
13 facility, and, if available, the electronic contact
14 information;

15 “(C) the facility registration number, if
16 any, previously assigned by the Secretary under
17 subsection (d);

18 “(D) all brand names under which cos-
19 metic products manufactured or processed in
20 the facility are sold; and

21 “(E) the product category or categories
22 and responsible person for each cosmetic prod-
23 uct manufactured or processed at the facility.

24 “(c) COSMETIC PRODUCT LISTING.—

1 “(1) IN GENERAL.—For each cosmetic product,
2 the responsible person shall submit to the Secretary
3 a cosmetic product listing, or ensure that such sub-
4 mission is made, at such time and in such manner
5 as the Secretary may prescribe.

6 “(2) COSMETIC PRODUCT LISTING.—The re-
7 sponsible person of a cosmetic product that is mar-
8 keted on the date of enactment of the Modernization
9 of Cosmetics Regulation Act of 2022 shall submit to
10 the Secretary a cosmetic product listing not later
11 than 1 year after the date of enactment of the Mod-
12 ernization of Cosmetics Regulation Act of 2022, or
13 for a cosmetic product that is first marketed after
14 the date of enactment of such Act, within 120 days
15 of marketing such product in interstate commerce.
16 Thereafter, any updates to such listing shall be
17 made annually, consistent with paragraphs (4) and
18 (5).

19 “(3) ABBREVIATED RENEWAL.—The Secretary
20 shall provide for an abbreviated process for the re-
21 newal of any cosmetic product listing under this sub-
22 section with respect to which there has been no
23 change since the responsible person submitted the
24 previous listing.

25 “(4) CONTENTS OF LISTING.—

1 “(A) IN GENERAL.—Each such cosmetic
2 product listing shall include—

3 “(i) the facility registration number of
4 each facility where the cosmetic product is
5 manufactured or processed;

6 “(ii) the name and contact number of
7 the responsible person and the name for
8 the cosmetic product, as such name ap-
9 pears on the label;

10 “(iii) the applicable cosmetic category
11 or categories for the cosmetic product;

12 “(iv) a list of ingredients in the cos-
13 metic product, including any fragrances,
14 flavors, or colors, with each ingredient
15 identified by the name, as required under
16 section 701.3 of title 21, Code of Federal
17 Regulations (or any successor regulations),
18 or by the common or usual name of the in-
19 gredient; and

20 “(v) the product listing number, if
21 any previously assigned by the Secretary
22 under subsection (d).

23 “(B) FLEXIBLE LISTINGS.—A single list-
24 ing submission for a cosmetic product may in-
25 clude multiple cosmetic products with identical

1 formulations, or formulations that differ only
2 with respect to colors, fragrances or flavors, or
3 quantity of contents.

4 “(5) UPDATES TO CONTENT.—A responsible
5 person that is required to submit a cosmetic product
6 listing shall submit any updates to such cosmetic
7 product listing annually.

8 “(6) SUBMISSION.—A responsible person may
9 submit product listing information as part of a facil-
10 ity registration or separately.

11 “(d) FACILITY REGISTRATION AND PRODUCT LIST-
12 ING NUMBERS.—At the time of the initial registration of
13 any facility under subsection (a)(1) or initial listing of any
14 cosmetic product under (c)(1), the Secretary shall assign
15 a facility registration number to the facility and a product
16 listing number to each cosmetic product. The Secretary
17 shall not make such product listing number publicly avail-
18 able.

19 “(e) CONFIDENTIALITY.—In response to a request
20 under section 552 of title 5, United States Code, informa-
21 tion described in subsection (b)(2)(D) or (c)(4)(A)(i) that
22 is derived from a registration or listing under this section
23 shall be withheld under section 552(b)(3) of title 5, United
24 States Code.

25 “(f) SUSPENSIONS.—

1 “(1) SUSPENSION OF REGISTRATION OF A FA-
2 CILITY.—The Secretary may suspend the registra-
3 tion of a facility if the Secretary determines that a
4 cosmetic product manufactured or processed by a
5 registered facility and distributed in the United
6 States has a reasonable probability of causing seri-
7 ous adverse health consequences or death to humans
8 and the Secretary has a reasonable belief that other
9 products manufactured or processed by the facility
10 may be similarly affected because of a failure that
11 cannot be isolated to a product or products, or is
12 sufficiently pervasive to raise concerns about other
13 products manufactured in the facility.

14 “(2) NOTICE OF SUSPENSION.—Before sus-
15 pending a facility registration under this section, the
16 Secretary shall provide—

17 “(A) notice to the facility registrant of the
18 cosmetic product or other responsible person, as
19 appropriate, of the intent to suspend the facility
20 registration, which shall specify the basis of the
21 determination by the Secretary that the facility
22 registration should be suspended; and

23 “(B) an opportunity, within 5 business
24 days of the notice provided under subparagraph
25 (A), for the responsible person to provide a plan

1 for addressing the reasons for possible suspen-
2 sion of the facility registration.

3 “(3) HEARING ON SUSPENSION.—The Secretary
4 shall provide the registrant subject to an order
5 under paragraph (1) or (2) with an opportunity for
6 an informal hearing, to be held as soon as possible
7 but not later than 5 business days after the issuance
8 of the order, or such other time period agreed upon
9 by the Secretary and the registrant, on the actions
10 required for reinstatement of registration and why
11 the registration that is subject to the suspension
12 should be reinstated. The Secretary shall reinstate a
13 registration if the Secretary determines, based on
14 evidence presented, that adequate grounds do not
15 exist to continue the suspension of the registration.

16 “(4) POST-HEARING CORRECTIVE ACTION
17 PLAN.—If, after providing opportunity for an infor-
18 mal hearing under paragraph (3), the Secretary de-
19 termines that the suspension of registration remains
20 necessary, the Secretary shall require the registrant
21 to submit a corrective action plan to demonstrate
22 how the registrant plans to correct the conditions
23 found by the Secretary. The Secretary shall review
24 such plan not later than 14 business days after the
25 submission of the corrective action plan or such

1 other time period as determined by the Secretary, in
2 consultation with the registrant.

3 “(5) VACATING OF ORDER; REINSTATEMENT.—

4 Upon a determination by the Secretary that ade-
5 quate grounds do not exist to continue the suspen-
6 sion actions, the Secretary shall promptly vacate the
7 suspension and reinstate the registration of the facil-
8 ity.

9 “(6) EFFECT OF SUSPENSION.—If the registra-
10 tion of the facility is suspended under this section,
11 no person shall introduce or deliver for introduction
12 into commerce in the United States cosmetic prod-
13 ucts from such facility.

14 “(7) NO DELEGATION.—The authority con-
15 ferred by this section to issue an order to suspend
16 a registration or vacate an order of suspension shall
17 not be delegated to any officer or employee other
18 than the Commissioner.

19 **“SEC. 608. SAFETY SUBSTANTIATION.**

20 “(a) SUBSTANTIATION OF SAFETY.—A responsible
21 person for a cosmetic product shall ensure, and maintain
22 records supporting, that there is adequate substantiation
23 of safety of such cosmetic product.

24 “(b) COAL-TAR HAIR DYE.—Subsection (a) shall not
25 apply to coal-tar hair dye that otherwise complies with the

1 requirements of section 601(a). A responsible person for
2 a coal-tar hair dye shall maintain records related to the
3 safety of such product.

4 “(c) DEFINITIONS.—For purposes of this section:

5 “(1) ADEQUATE SUBSTANTIATION OF SAFE-
6 TY.—The term ‘adequate substantiation of safety’
7 means tests or studies, research, analyses, or other
8 evidence or information that is considered, among
9 experts qualified by scientific training and experi-
10 ence to evaluate the safety of cosmetic products and
11 their ingredients, sufficient to support a reasonable
12 certainty that a cosmetic product is safe.

13 “(2) SAFE.—The term ‘safe’ means that the
14 cosmetic product, including any ingredient thereof,
15 is not injurious to users under the conditions of use
16 prescribed in the labeling thereof, or under such con-
17 ditions of use as are customary or usual. The Sec-
18 retary shall not consider a cosmetic ingredient or
19 cosmetic product injurious to users solely because it
20 can cause minor and transient reactions or minor
21 and transient skin irritations in some users. In de-
22 termining for purposes of this section whether a cos-
23 metic product is safe, the Secretary may consider, as
24 appropriate and available, the cumulative or other

1 relevant exposure to the cosmetic product, including
2 any ingredient thereof.

3 **“SEC. 609. LABELING.**

4 “(a) GENERAL REQUIREMENT.—Each cosmetic prod-
5 uct shall bear a label that includes a domestic address,
6 domestic phone number, or electronic contact information,
7 which may include a website, through which the respon-
8 sible person can receive adverse event reports with respect
9 to such cosmetic product.

10 “(b) FRAGRANCE ALLERGENS.—The responsible per-
11 son shall identify on the label of a cosmetic product each
12 fragrance allergen included in such cosmetic product. Sub-
13 stances that are fragrance allergens for purposes of this
14 subsection shall be determined by the Secretary by regula-
15 tion. The Secretary shall issue a notice of proposed rule-
16 making promulgating the regulation implementing this re-
17 quirement not later than 18 months after the date of en-
18 actment of the Modernization of Cosmetics Regulation Act
19 of 2022, and not later than 180 days after the date on
20 which the public comment period on the proposed rule-
21 making closes, shall issue a final rulemaking. In promul-
22 gating regulations implementing this subsection, the Sec-
23 retary shall consider international, State, and local re-
24 quirements for allergen disclosure, including the substance
25 and format of requirements in the European Union, and

1 may establish threshold levels of amounts of substances
2 subject to disclosure pursuant to such regulations.

3 “(c) COSMETIC PRODUCTS FOR PROFESSIONAL
4 USE.—

5 “(1) DEFINITION OF PROFESSIONAL.—For pur-
6 poses of this subsection, the term ‘professional’
7 means an individual who is licensed by an official
8 State authority to practice in the field of cosme-
9 tology, nail care, barbering, or esthetics.

10 “(2) PROFESSIONAL USE LABELING.—A cos-
11 metic product introduced into interstate commerce
12 and intended to be used only by a professional shall
13 bear a label that—

14 “(A) contains a clear and prominent state-
15 ment that the product shall be administered or
16 used only by licensed professionals; and

17 “(B) is in conformity with the require-
18 ments of the Secretary for cosmetics labeling
19 under this Act and section 4(a) of the Fair
20 Packaging and Labeling Act.

21 **“SEC. 610. RECORDS.**

22 “(a) IN GENERAL.—If the Secretary has a reasonable
23 belief that a cosmetic product, including an ingredient in
24 such cosmetic product, and any other cosmetic product
25 that the Secretary reasonably believes is likely to be af-

1 fected in a similar manner, is likely to be adulterated such
2 that the use or exposure to such product presents a threat
3 of serious adverse health consequences or death to hu-
4 mans, each responsible person and facility shall, at the re-
5 quest of an officer or employee duly designated by the Sec-
6 retary, permit such officer or employee, upon presentation
7 of appropriate credentials and a written notice to such
8 person, at reasonable times and within reasonable limits
9 and in a reasonable manner, to have access to and copy
10 all records relating to such cosmetic product, and to any
11 other cosmetic product that the Secretary reasonably be-
12 lieves is likely to be affected in a similar manner, that
13 are needed to assist the Secretary in determining whether
14 the cosmetic product is adulterated and presents a threat
15 of serious adverse health consequences or death to hu-
16 mans. This subsection shall not be construed to extend
17 to recipes or formulas for cosmetics, financial data, pricing
18 data, personnel data (other than data as to qualification
19 of technical and professional personnel performing func-
20 tions subject to this Act), research data (other than safety
21 substantiation data for cosmetic products and their ingre-
22 dients), or sales data (other than shipment data regarding
23 sales).

24 “(b) RULE OF CONSTRUCTION.—Nothing in this sec-
25 tion shall be construed to limit the authority of the Sec-

1 retary to inspect records or require establishment and
2 maintenance of records under any other provision of this
3 Act, including section 605 or 606.

4 **“SEC. 611. MANDATORY RECALL AUTHORITY.**

5 “(a) IN GENERAL.—If the Secretary determines that
6 there is a reasonable probability that a cosmetic is adulter-
7 ated under section 601 or misbranded under section 602
8 and the use of or exposure to such cosmetic will cause
9 serious adverse health consequences or death, the Sec-
10 retary shall provide the responsible person with an oppor-
11 tunity to voluntarily cease distribution and recall such ar-
12 ticle. If the responsible person refuses to or does not vol-
13 untarily cease distribution or recall such cosmetic within
14 the time and manner prescribed by the Secretary (if so
15 prescribed), the Secretary may, by order, require, as the
16 Secretary determines necessary, such person to imme-
17 diately cease distribution of such article.

18 “(b) HEARING.—The Secretary shall provide the re-
19 sponsible person who is subject to an order under sub-
20 section (a) with an opportunity for an informal hearing,
21 to be held not later than 10 days after the date of issuance
22 of the order, on whether adequate evidence exists to justify
23 the order.

1 “(c) ORDER RESOLUTION.—After an order is issued
2 according to the process under subsections (a) and (b),
3 the Secretary shall, except as provided in subsection (d)—

4 “(1) vacate the order, if the Secretary deter-
5 mines that inadequate grounds exist to support the
6 actions required by the order;

7 “(2) continue the order ceasing distribution of
8 the cosmetic until a date specified in such order; or

9 “(3) amend the order to require a recall of the
10 cosmetic, including any requirements to notify ap-
11 propriate persons, a timetable for the recall to occur,
12 and a schedule for updates to be provided to the
13 Secretary regarding such recall.

14 “(d) ACTION FOLLOWING ORDER.—Any person who
15 is subject to an order pursuant to paragraph (2) or (3)
16 of subsection (c) shall immediately cease distribution of
17 or recall, as applicable, the cosmetic and provide notifica-
18 tion as required by such order.

19 “(e) NOTICE TO PERSONS AFFECTED.—If the Sec-
20 retary determines necessary, the Secretary may require
21 the person subject to an order pursuant to subsection (a)
22 or an amended order pursuant to paragraph (2) or (3)
23 of subsection (c) to provide either a notice of a recall order
24 for, or an order to cease distribution of, such cosmetic,
25 as applicable, under this section to appropriate persons,

1 including persons who manufacture, distribute, import, or
2 offer for sale such product that is the subject of an order
3 and to the public.

4 “(f) PUBLIC NOTIFICATION.—In conducting a recall
5 under this section, the Secretary shall—

6 “(1) ensure that a press release is published re-
7 garding the recall, and that alerts and public notices
8 are issued, as appropriate, in order to provide notifi-
9 cation—

10 “(A) of the recall to consumers and retail-
11 ers to whom such cosmetic was, or may have
12 been, distributed; and

13 “(B) that includes, at a minimum—

14 “(i) the name of the cosmetic subject
15 to the recall;

16 “(ii) a description of the risk associ-
17 ated with such article; and

18 “(iii) to the extent practicable, infor-
19 mation for consumers about similar cos-
20 metics that are not affected by the recall;
21 and

22 “(2) ensure publication, as appropriate, on the
23 website of the Food and Drug Administration of an
24 image of the cosmetic that is the subject of the press
25 release described in paragraph (1), if available.

1 “(g) NO DELEGATION.—The authority conferred by
2 this section to order a recall or vacate a recall order shall
3 not be delegated to any officer or employee other than the
4 Commissioner.

5 “(h) EFFECT.—Nothing in this section shall affect
6 the authority of the Secretary to request or participate
7 in a voluntary recall, or to issue an order to cease distribu-
8 tion or to recall under any other provision of this chapter.

9 **“SEC. 612. SMALL BUSINESSES.**

10 “(a) IN GENERAL.—Responsible persons, and owners
11 and operators of facilities, whose average gross annual
12 sales in the United States of cosmetic products for the
13 previous 3-year period is less than \$1,000,000, adjusted
14 for inflation, and who do not engage in the manufacturing
15 or processing of the cosmetic products described in sub-
16 section (b), shall be considered small businesses and not
17 subject to the requirements of section 606 or 607.

18 “(b) REQUIREMENTS APPLICABLE TO ALL MANU-
19 FACTURERS AND PROCESSORS OF COSMETICS.—The ex-
20 emptions under subsection (a) shall not apply to any re-
21 sponsible person or facility engaged in the manufacturing
22 or processing of any of the following products:

23 “(1) Cosmetic products that regularly come into
24 contact with mucus membrane of the eye under con-
25 ditions of use that are customary or usual.

1 “(2) Cosmetic products that are injected.

2 “(3) Cosmetic products that are intended for
3 internal use.

4 “(4) Cosmetic products that are intended to
5 alter appearance for more than 24 hours under con-
6 ditions of use that are customary or usual and re-
7 moval by the consumer is not part of such conditions
8 of use that are customary or usual.

9 **“SEC. 613. EXEMPTION FOR CERTAIN PRODUCTS AND FA-**
10 **CILITIES.**

11 “(a) IN GENERAL.—Notwithstanding any other pro-
12 vision of law, except as provided in subsection (b), a cos-
13 metic product or facility that is also subject to the require-
14 ments of chapter V shall be exempt from the requirements
15 of sections 605, 606, 607, 608, 609(a), 610, and 611.

16 “(b) EXCEPTION.—A facility described in subsection
17 (a) that also manufactures or processes cosmetic products
18 that are not subject to the requirements of chapter V shall
19 not be exempt from the requirements of sections 605, 606,
20 607, 608, 609(a), 610, and 611, with respect to such cos-
21 metic products.

22 **“SEC. 614. PREEMPTION.**

23 “(a) IN GENERAL.—No State or political subdivision
24 of a State may establish or continue in effect any law,
25 regulation, order, or other requirement for cosmetics that

1 is different from or in addition to, or otherwise not iden-
2 tical with, any requirement applicable under this chapter
3 with respect to registration and product listing, good man-
4 ufacturing practice, recordkeeping, recalls, adverse event
5 reporting, or safety substantiation.

6 “(b) LIMITATION.—Nothing in the amendments to
7 this Act made by the Modernization of Cosmetics Regula-
8 tion Act of 2022 shall be construed to preempt any State
9 statute, public initiative, referendum, regulation, or other
10 State action, except as expressly provided in subsection
11 (a). Notwithstanding subsection (a), nothing in this sec-
12 tion shall be construed to prevent any State from prohib-
13 iting the use or limiting the amount of an ingredient in
14 a cosmetic product, or from continuing in effect a require-
15 ment of any State that is in effect at the time of enact-
16 ment of the Modernization of Cosmetics Regulation Act
17 of 2022 for the reporting to the State of an ingredient
18 in a cosmetic product.

19 “(c) SAVINGS.—Nothing in the amendments to this
20 Act made by the Modernization of Cosmetics Regulation
21 Act of 2022, nor any standard, rule, requirement, regula-
22 tion, or adverse event report shall be construed to modify,
23 preempt, or displace any action for damages or the liabil-
24 ity of any person under the law of any State, whether stat-
25 utory or based in common law.

1 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
2 tion shall be construed to amend, expand, or limit the pro-
3 visions under section 752.”.

4 **SEC. 803. ENFORCEMENT AND CONFORMING AMEND-**
5 **MENTS.**

6 (a) IN GENERAL.—

7 (1) PROHIBITED ACTS.—Section 301 of the
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 331), as amended by section 506, is further amend-
10 ed—

11 (A) by adding at the end the following:

12 “(ggg) The failure to register or submit listing infor-
13 mation in accordance with section 607.

14 “(hhh) The refusal or failure to follow an order under
15 section 611.”; and

16 (B) in paragraph (d), by striking “or 564”
17 and inserting “, 564, or 607”.

18 (2) ADULTERATED PRODUCTS.—Section 601 of
19 the Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 361) is amended by adding at the end the
21 following:

22 “(f) If it has been manufactured or processed under
23 conditions that do not meet good manufacturing practice
24 regulations, as prescribed by the Food and Drug Adminis-
25 tration in accordance with section 606.

1 “(g) If it is a cosmetic product, and the cosmetic
2 product, including each ingredient in the cosmetic product,
3 does not have adequate substantiation for safety, as de-
4 fined in section 608(c).”.

5 (3) MISBRANDED COSMETICS.—Section 602(b)
6 of the Federal Food, Drug, and Cosmetic Act (21
7 U.S.C. 362(b)) is amended—

8 (A) by striking “and (2)” and inserting
9 “(2)”; and

10 (B) by inserting after “numerical count”
11 the following: “; and (3) the information re-
12 quired under section 609”.

13 (4) ADVERSE EVENT REPORTING.—The Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
15 seq.) is amended—

16 (A) in section 301(e) (21 U.S.C. 331(e))—

17 (i) by striking “564, 703” and insert-
18 ing “564, 605, 703”; and

19 (ii) by striking “564, 760” and insert-
20 ing “564, 605, 611, 760”;

21 (B) in section 301(ii) (21 U.S.C.
22 331(ii))—

23 (i) by striking “760 or 761) or” and
24 inserting “604, 760, or 761) or”; and

1 (ii) by inserting “or required under
2 section 605(a)” after “report (as defined
3 under section 760 or 761”;

4 (C) in section 801(a) (21 U.S.C. 381(a))—

5 (i) by striking “under section 760 or
6 761” and inserting “under section 605,
7 760, or 761”;

8 (ii) by striking “defined in such sec-
9 tion 760 or 761” and inserting “defined in
10 section 604, 760, or 761”;

11 (iii) by striking “of such section 760
12 or 761” and inserting “of such section
13 605, 760, or 761”; and

14 (iv) by striking “described in such
15 section 760 or 761” and inserting “de-
16 scribed in such section 605, 760, or 761”;
17 and

18 (D) in section 801(b) (21 U.S.C.
19 381(b))—

20 (i) by striking “requirements of sec-
21 tions 760 or 761,” and inserting “require-
22 ments of section 605, 760, or 761”;

23 (ii) by striking “as defined in section
24 760 or 761” and inserting “as defined in
25 section 604, 760, or 761”; and

1 (iii) by striking “with section 760 or
2 761” and inserting “with section 605, 760,
3 or 761”.

4 (b) EFFECTIVE DATES.—

5 (1) IN GENERAL.—The amendments made by
6 subsection (a) shall take effect on the date that is
7 1 year after the date of enactment of this Act.

8 (2) LABELING REQUIREMENT.—Section 609(a)
9 of the Federal Food, Drug, and Cosmetic Act, as
10 added by section 802, shall take effect on the date
11 that is 2 years after the date of enactment of this
12 Act.

13 (c) CONFIDENTIALITY.—

14 (1) IN GENERAL.—The Secretary shall take ap-
15 propriate measures to ensure that there are in effect
16 effective procedures to prevent the unauthorized dis-
17 closure of any trade secret or confidential commer-
18 cial information that is obtained by the Secretary of
19 Health and Human Services pursuant to this sub-
20 title, including the amendments made by this sub-
21 title.

22 (2) CLARIFICATION.—Nothing in this subtitle,
23 including the amendments made by this subtitle,
24 shall be construed to authorize the disclosure of in-
25 formation that is prohibited from disclosure under

1 section 301(j) of the Federal Food, Drug, and Cos-
2 metic Act (21 U.S.C. 331(j)) or section 1905 of title
3 18, United States Code, or that is subject to with-
4 holding under section 552(b)(4) of title 5, United
5 States Code.

6 **SEC. 804. RECORDS INSPECTION.**

7 Section 704(a)(1) of the Federal Food, Drug, and
8 Cosmetic Act (21 U.S.C. 374(a)(1)) is amended by insert-
9 ing after the second sentence the following: “In the case
10 of a facility (as defined in section 604) that manufactures
11 or processes cosmetic products, the inspection shall extend
12 to all records and other information described in sections
13 605, 606, and 610, when the standard for records inspec-
14 tion under such section applies.”.

15 **SEC. 805. TALC-CONTAINING COSMETICS.**

16 The Secretary of Health and Human Services—

17 (1) not later than one year after the date of en-
18 actment of this Act, shall promulgate proposed regu-
19 lations to establish and require standardized testing
20 methods for detecting and identifying asbestos in
21 talc-containing cosmetic products; and

22 (2) not later than 180 days after the date on
23 which the public comment period on the proposed
24 regulations closes, shall issue such final regulations.

1 **SEC. 806. PFAS IN COSMETICS.**

2 (a) IN GENERAL.—The Secretary of Health and
3 Human Services (referred to in this section as the “Sec-
4 retary”) shall assess the use of perfluoroalkyl and
5 polyfluoroalkyl substances in cosmetic products and the
6 scientific evidence regarding the safety of such use in cos-
7 metic products, including any risks associated with such
8 use. In conducting such assessment, the Secretary may,
9 as appropriate, consult with the National Center for Toxi-
10 cological Research.

11 (b) REPORT.—Not later than 3 years after enactment
12 of this Act, the Secretary shall publish on the website of
13 the Food and Drug Administration a report summarizing
14 the results of the assessment conducted under subsection
15 (a).

16 **SEC. 807. SENSE OF THE SENATE ON ANIMAL TESTING.**

17 It is the sense of the Senate that animal testing
18 should not be used for the purposes of safety testing on
19 cosmetic products and should be phased out with the ex-
20 ception of appropriate allowances.

21 **SEC. 808. FUNDING.**

22 There is authorized to be appropriated \$14,200,000
23 for fiscal year 2023, \$25,960,000 for fiscal year 2024, and
24 \$41,890,000 for each of fiscal years 2025 through 2027,
25 for purposes of conducting the activities under this sub-
26 title (including the amendments made by this subtitle) and

1 hiring personnel required to carry out this subtitle (includ-
2 ing the amendments made by this subtitle).

3 **Subtitle B—Dietary Supplements**

4 **SEC. 811. REGULATION OF DIETARY SUPPLEMENTS.**

5 (a) IN GENERAL.—Chapter IV of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amend-
7 ed by adding after section 403C of such Act (21 U.S.C.
8 343–3) the following:

9 **“SEC. 403D. DIETARY SUPPLEMENT LISTING REQUIRE-** 10 **MENT.**

11 “(a) IN GENERAL.—Beginning on the date specified
12 in subsection (b)(4), each dietary supplement marketed in
13 the United States shall be listed with the Secretary in ac-
14 cordance with this section. Each such listing shall include,
15 with respect to the dietary supplement, the information
16 specified in subsection (b)(1).

17 “(b) REQUIREMENTS.—

18 “(1) IN GENERAL.—The manufacturer, packer,
19 or distributor of a dietary supplement whose name
20 (pursuant to section 403(e)(1)) appears on the label
21 of a dietary supplement marketed in the United
22 States (referred to in this section as the ‘responsible
23 person’), or if the responsible person is a foreign en-
24 tity, the United States agent of such person, shall
25 submit to the Secretary in accordance with this sec-

1 tion the following information for a dietary supple-
2 ment that is marketed:

3 “(A) Any name of the dietary supplement
4 and the statement of identity, including brand
5 name and specified flavors, if applicable.

6 “(B) The name and address of the respon-
7 sible person and the name and email address of
8 the owner, operator, or agent in charge of the
9 responsible person.

10 “(C) The name, domestic address, and
11 email address for the United States agent, if
12 the responsible person is a foreign entity.

13 “(D) The business name and full address
14 of all locations at which the responsible person
15 manufactures, packages, labels, or holds the di-
16 etary supplement.

17 “(E) A list of all ingredients in each such
18 dietary supplement required under sections
19 101.4 and 101.36, title 21, Code of Federal
20 Regulations (or any successor regulations) to
21 appear on the label of a dietary supplement, in-
22 cluding—

23 “(i) where applicable, ingredients in a
24 proprietary blend as described in section

1 101.36(c) of title 21, Code of Federal Reg-
2 ulations (or any successor regulations);

3 “(ii) the amount per serving of each
4 listed dietary ingredient;

5 “(iii) if required by section 101.36 of
6 title 21, Code of Federal Regulations (or
7 any successor regulations), the percent of
8 the daily value of each listed dietary ingre-
9 dient; and

10 “(iv) the amount per serving of die-
11 tary ingredients within a proprietary blend.

12 “(F) The number of servings per container
13 for each container size.

14 “(G) The directions for use.

15 “(H) Warnings, notice, and safe handling
16 statements, as required by section 101.17 of
17 title 21, Code of Federal Regulations (or any
18 successor regulations).

19 “(I) Allergen statements for major food al-
20 lergens (pursuant to sections 403(w) and
21 403(x)).

22 “(J) The form of the dietary supplement
23 (such as tablets, capsules, powders, liquids,
24 softgels, and gummies).

1 listing for each such dietary supplement in-
2 troduced or delivered for introduction into
3 interstate commerce shall be submitted by
4 the responsible person to the Secretary
5 under this subsection not later than 18
6 months after the date of enactment of the
7 Food and Drug Administration Safety and
8 Landmark Advancements Act of 2022.

9 “(ii) NEW DIETARY SUPPLEMENTS.—
10 In the case of a dietary supplement that is
11 not being offered in interstate commerce
12 on or before January 1, 2024, a listing for
13 each such dietary supplement introduced
14 or delivered for introduction into interstate
15 commerce that has not been included in
16 any listing previously submitted by the re-
17 sponsible person to the Secretary under
18 this subsection shall be submitted to the
19 Secretary at the time of introduction into
20 interstate commerce.

21 “(B) DISCONTINUED DIETARY SUPPLE-
22 MENTS.—The responsible person shall notify
23 the Secretary within one year of the date of dis-
24 continuance of a dietary supplement required to
25 be listed with the Secretary under paragraph

1 (1) for which the responsible person has discon-
2 tinued commercial marketing.

3 “(C) CHANGES TO EXISTING LISTINGS.—

4 The responsible person shall submit to the Sec-
5 retary a change or modification to listing infor-
6 mation submitted under paragraph (1) included
7 on the label for a dietary supplement at the
8 time the dietary supplement with the change or
9 modification is introduced into interstate com-
10 merce.

11 “(5) ADDITIONAL INFORMATION.—The respon-
12 sible person shall provide upon request from the Sec-
13 retary, within 10 calendar days of such request, the
14 full business name and physical and mailing address
15 from which the responsible person receives a dietary
16 ingredient or combination of dietary ingredients that
17 the responsible person uses in the manufacture of
18 the dietary supplement or, if applicable, from which
19 the responsible person receives the dietary supple-
20 ment.

21 “(c) PRODUCT LISTING NUMBER AND DIETARY SUP-
22 PLEMENT ELECTRONIC DATABASE.—

23 “(1) DIETARY SUPPLEMENT PRODUCT LISTING
24 NUMBER.—The Secretary shall provide each dietary
25 supplement listed in accordance with subsection

1 (b)(1) a dietary supplement product listing number,
2 which may apply to multiple dietary supplements
3 with identical formulations, or formulations that dif-
4 fer only with respect to color, excipients, or
5 flavorings, including dietary supplements offered in
6 a single package size or in multiple package sizes.
7 The Secretary shall provide a process for a respon-
8 sible person to reserve dietary supplement listing
9 numbers in advance of listing under subsection
10 (b)(1).

11 “(2) ELECTRONIC DATABASE.—Not later than
12 2 years after the date of enactment of the Food and
13 Drug Administration Safety and Landmark Ad-
14 vancements Act of 2022, the Secretary shall estab-
15 lish and maintain an electronic database that is pub-
16 licly available and contains information submitted
17 under subsection (b)(1) (except for the information
18 submitted under subparagraphs (D) and (E)(iv) of
19 such subsection). The Secretary shall make such in-
20 formation maintained in the electronic database pub-
21 licly searchable, including by dietary supplement
22 product listing number, and by any field of informa-
23 tion or combination of fields of information provided
24 under subsection (b)(1).

1 “(3) CONFIDENTIAL INFORMATION.—In re-
2 sponse to a request under section 552 of title 5,
3 United States Code, information described in sub-
4 paragraph (D) or (E)(iv) of subsection (b)(1) that is
5 derived from a listing under this section shall be
6 withheld under section 552(b)(3) of title 5, United
7 States Code.

8 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
9 tion shall be construed—

10 “(1) to limit the authority of the Secretary to
11 inspect or copy records or to require the establish-
12 ment and maintenance of records under any other
13 provision of this Act;

14 “(2) to authorize the disclosure of information
15 that is prohibited from disclosure under section
16 301(j) of this Act or section 1905 of title 18, United
17 States Code, or that is subject to withholding under
18 section 552(b)(4) of title 5, United States Code; or

19 “(3) to grant the Secretary authority to require
20 the approval of a dietary supplement prior to mar-
21 keting.

22 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
23 is authorized to be appropriated \$7,498,080 for fiscal year
24 2023, and \$6,300,000 for each of fiscal years 2024
25 through 2027, for purposes of conducting the activities

1 under this section and hiring personnel required to carry
2 out this section.”.

3 (b) GUIDANCE.—Not later than 18 months after the
4 date of enactment of this Act, the Secretary of Health and
5 Human Services shall publish final guidance related to the
6 draft guidance titled, “Dietary Supplements: New Dietary
7 Ingredient Notifications and Related Issues; Revised
8 Draft Guidance for Industry”, issued August 12, 2016,
9 consistent with section 403D of the Federal Food, Drug,
10 and Cosmetic Act, as added by subsection (a).

11 (c) INSPECTIONS FOR CERTAIN DIETARY SUPPLE-
12 MENTS.—The Secretary of Health and Human Services
13 shall direct resources to inspections of facilities, suppliers,
14 and dietary supplement types that present a high risk to
15 public health (as identified by the Secretary).

16 (d) MISBRANDING.—Section 403 of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amend-
18 ed by adding at the end the following:

19 “(z) If it is a dietary supplement for which a respon-
20 sible person or the United States agent of such a person
21 is required under section 403D to file a listing, file a
22 change to an existing listing, or provide additional infor-
23 mation to the Secretary, and such person or agent has
24 failed to comply with any such requirements under section
25 403D with respect to such dietary supplement.”.

1 (e) NEW PROHIBITED ACT.—Section 301 of the Fed-
2 eral Food, Drug, and Cosmetic Act (21 U.S.C. 331), as
3 amended by section 803(a), is further amended by adding
4 at the end the following:

5 “(iii) The introduction or delivery for introduction
6 into interstate commerce of any product marketed as a
7 dietary supplement that does not meet the definition of
8 a dietary supplement under section 201(ff).

9 “(jjj) The introduction or delivery for introduction
10 into interstate commerce of a dietary supplement that has
11 been prepared, packed, or held using the assistance of, or
12 at the direction of, a person debarred under section 306.”.

13 **Subtitle C—In Vitro Clinical Tests**

14 **SEC. 821. SHORT TITLE.**

15 (a) SHORT TITLE.—This subtitle may be cited as the
16 “Verifying Accurate Leading-edge IVCT Development Act
17 of 2022” or the “VALID Act of 2022”.

18 **SEC. 822. DEFINITIONS.**

19 (a) IN GENERAL.—Section 201 of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 321) is amended—

21 (1) by adding at the end the following:

22 “(ss)(1) The term ‘in vitro clinical test’ means an ar-
23 ticle specified in subparagraph (2) that is intended to be
24 used in the collection, preparation, analysis, or in vitro

1 clinical examination of specimens taken or derived from
2 the human body for the purpose of—

3 “(A) identifying or diagnosing a disease or con-
4 dition;

5 “(B) providing information for diagnosing,
6 screening, measuring, detecting, predicting,
7 prognosing, analyzing, or monitoring a disease or
8 condition, including by making a determination of
9 an individual’s state of health; or

10 “(C) selecting, monitoring, or informing ther-
11 apy or treatment for a disease or condition.

12 “(2) An article specified in this subparagraph is—

13 “(A) a test kit;

14 “(B) a test system;

15 “(C) a test protocol or laboratory test protocol;

16 “(D) an instrument (as defined in section
17 587(11));

18 “(E) a specimen receptacle (as defined in sec-
19 tion 587(16));

20 “(F) software, excluding software that is ex-
21 cluded by section 520(o) from the definition of a de-
22 vice under section 201(h), that—

23 “(i) is a component or part of another in
24 vitro clinical test or analyzes, processes, or in-

1 terprets a signal or pattern from another in
2 vitro clinical test; and

3 “(ii) does not analyze, process, or interpret
4 a signal, pattern, or medical image from a de-
5 vice; and

6 “(G) subject to subparagraph (3), a component
7 or part of a test, a test protocol, an instrument, an
8 article, or software described in any of clauses (A)
9 through (D) of such subparagraph, whether alone or
10 in combination, including reagents, calibrators, and
11 controls.

12 “(3) Notwithstanding subparagraph (2)(G), an arti-
13 cle intended to be used as a component or part of an in
14 vitro clinical test described in subparagraph (1) is ex-
15 cluded from the definition in subparagraph (1) if the arti-
16 cle consists of any of the following:

17 “(A) Blood, blood components, or human cells
18 or tissues, from the time of acquisition, donation, or
19 recovery of such article, including determination of
20 donor eligibility, as applicable, until such time as the
21 article is released as a component or part of an in
22 vitro clinical test by the establishment that collected
23 such article.

24 “(B) An article used for invasive sampling, a
25 needle, or a lancet, except to the extent such article,

1 needle, or lancet is an integral component of an arti-
2 cle for holding, storing, or transporting a specimen.

3 “(C) General purpose laboratory equipment.”;

4 (2) by adding at the end of section 201(g) the
5 following:

6 “(3) The term ‘drug’ does not include an in vitro clin-
7 ical test.”; and

8 (3) in section 201(h)(1), in the matter following
9 clause (C), by striking “section 520(o)” and insert-
10 ing “section 520(o) or an in vitro clinical test”.

11 (b) EXCLUSION FROM DEFINITION OF BIOLOGICAL
12 PRODUCT.—Section 351(i)(1) of the Public Health Serv-
13 ices Act (42 U.S.C. 262(i)(1)) is amended—

14 (1) by striking “(1) The term ‘biological prod-
15 uct’ means” and inserting “(1)(A) The term ‘biologi-
16 cal product’ means”; and

17 (2) by adding at the end the following:

18 “(B) The term ‘biological product’ does not in-
19 clude an in vitro clinical test as defined in section
20 201(ss) of the Federal Food, Drug, and Cosmetic
21 Act.”.

22 (c) IN VITRO CLINICAL TEST DEFINITION.—In this
23 subtitle, the term “in vitro clinical test” has the meaning
24 given such term in section 201(ss) of the Federal Food,
25 Drug, and Cosmetic Act, as added by subsection (a).

1 **SEC. 823. REGULATION OF IN VITRO CLINICAL TESTS.**

2 The Federal Food, Drug, and Cosmetic Act (21
3 U.S.C. 301 et seq.) is amended—

4 (1) by amending the heading of chapter V to
5 read as follows: “**DRUGS, DEVICES, AND IN**
6 **VITRO CLINICAL TESTS**”; and

7 (2) by adding at the end of chapter V the fol-
8 lowing:

9 **“Subchapter J—In Vitro Clinical Tests**

10 **“SEC. 587. DEFINITIONS.**

11 “In this subchapter:

12 “(1) ANALYTICAL VALIDITY.—The term ‘ana-
13 lytical validity’ means, with respect to an in vitro
14 clinical test, the ability of the in vitro clinical test,
15 to identify, measure, detect, calculate, or analyze (or
16 assist in such identification, measurement, detection,
17 calculation, or analysis of) one or more analytes, bio-
18 markers, substances, or other targets intended to be
19 identified, measured, detected, calculated, or ana-
20 lyzed by the test.

21 “(2) APPLICABLE STANDARD.—The term ‘ap-
22 plicable standard’, with respect to an in vitro clinical
23 test, means a reasonable assurance of analytical and
24 clinical validity for its indications for use, and a rea-
25 sonable assurance of safety for individuals who come
26 into contact with such in vitro clinical test, except

1 that such term, with respect to specimen receptacles
2 and test instruments, means a reasonable assurance
3 of analytical validity for its indications for use and
4 safety for individuals who come into contact with
5 such specimen receptacle or test instrument.

6 “(3) CLINICAL USE.—The term ‘clinical use’
7 means the operation, application, or functioning of
8 an in vitro clinical test for the purpose for which it
9 is intended as described in section 201(ss)(1).

10 “(4) CLINICAL VALIDITY.—The term ‘clinical
11 validity’ means the ability of an in vitro clinical test
12 to achieve the purpose for which it is intended as de-
13 scribed in section 201(ss)(1).

14 “(5) COMPONENT OR PART.—The term ‘compo-
15 nent or part’ means a substance, piece, part, raw
16 material, software, firmware, labeling, or assembly,
17 including reagents, that is intended to be included as
18 an aspect of an in vitro clinical test described in sec-
19 tion 201(ss)(1).

20 “(6) DEVELOP.—The term ‘develop’, with re-
21 spect to an in vitro clinical test, means—

22 “(A) designing, validating, producing,
23 manufacturing, remanufacturing, labeling, ad-
24 vertising, propagating, importing, or assembling
25 an in vitro clinical test;

1 “(B) modifying an in vitro clinical test, in-
2 cluding modifying the indications for use of the
3 in vitro clinical test, or modifying an article to
4 be an in vitro clinical test; or

5 “(C) establishing a test system as de-
6 scribed or included in a test protocol developed
7 by another entity unless such test protocol is
8 listed as an in vitro clinical test in the com-
9 prehensive test information system established
10 under section 587T by that other entity.

11 “(7) DEVELOPER.—The term ‘developer’ means
12 a person who engages in development as described in
13 paragraph (6), except the term does not include a
14 laboratory that—

15 “(A) is certified by the Secretary under
16 section 353 of the Public Health Service Act;
17 and

18 “(B) assembles for use solely within that
19 laboratory, without otherwise developing, an in
20 vitro clinical test appropriately listed in the
21 comprehensive test information system estab-
22 lished under section 587T by a different person.

23 “(8) FIRST-OF-A-KIND.—The term ‘first-of-a-
24 kind’, with respect to an in vitro clinical test, means
25 that such test has any novel combination of the ele-

1 ments specified in paragraph (10) that differs from
2 in vitro clinical tests that already are legally avail-
3 able in the United States, except for such tests of-
4 fered under section 587C(a)(3), 587C(a)(4), or
5 587G.

6 “(9) HIGH-RISK.—The term ‘high-risk’, with
7 respect to an in vitro clinical test or category of in
8 vitro clinical tests, means that an undetected inac-
9 curate result from such test, or such category of
10 tests, when used as intended—

11 “(A)(i) has the substantial likelihood to re-
12 sult in serious or irreversible harm or death to
13 a patient or patients, or would otherwise cause
14 serious harm to the public health; or

15 “(ii) is reasonably likely to result in the
16 absence, significant delay, or discontinuation of
17 life-supporting or life-sustaining medical treat-
18 ment; and

19 “(B) sufficient mitigating measures are
20 not able to be established and applied to pre-
21 vent, mitigate, or detect the inaccurate result,
22 or otherwise mitigate the risk resulting from an
23 undetected inaccurate result described in sub-
24 paragraph (A), such that the test would be
25 moderate-risk or low-risk.

1 “(10) INDICATIONS FOR USE.—The term ‘indi-
2 cations for use’, with respect to an in vitro clinical
3 test, means the following elements:

4 “(A) Substance or substances measured by
5 the in vitro clinical test, such as an analyte,
6 protein, or pathogen.

7 “(B) Test method.

8 “(C) Test purpose or purposes, as de-
9 scribed in section 201(ss)(1).

10 “(D) Diseases or conditions for which the
11 in vitro clinical test is intended for use, includ-
12 ing intended patient populations.

13 “(E) Context of use, such as in a clinical
14 laboratory, in a health care facility, prescription
15 home use, over-the-counter use, or direct-to-
16 consumer testing.

17 “(11) INSTRUMENT.—

18 “(A) IN GENERAL.—The term ‘instrument’
19 means an analytical or pre-analytical instru-
20 ment.

21 “(B) ANALYTIC INSTRUMENT.—The term
22 ‘analytic instrument’ means an in vitro clinical
23 test that is hardware intended by the hardware
24 developer to be used with one or more other in
25 vitro clinical tests to generate a clinical test re-

1 sult, including software used to effectuate the
2 functionality of the hardware.

3 “(C) PRE-ANALYTICAL INSTRUMENT.—The
4 term ‘pre-analytical instrument’ means an in
5 vitro clinical test that is hardware intended by
6 the hardware developer solely to generate an
7 output for use exclusively with one or more ana-
8 lytical instruments as defined in subparagraph
9 (B) and which does not itself generate a clinical
10 test result. Such term may include software
11 used to effectuate the hardware’s functionality.

12 “(12) INSTRUMENT FAMILY.—The term ‘instru-
13 ment family’ means more than one instrument devel-
14 oped by the same developer for which the developer
15 demonstrates and documents, with respect to all
16 such instruments, that all—

17 “(A) have the same basic architecture, de-
18 sign, and performance characteristics;

19 “(B) have the same indications for use and
20 capabilities;

21 “(C) share the same measurement prin-
22 ciples, detection methods, and reaction condi-
23 tions, as applicable; and

1 “(D) produce the same or similar analyt-
2 ical results from samples of the same specimen
3 type or types.

4 “(13) LABORATORY OPERATIONS.—The term
5 ‘laboratory operations’—

6 “(A) means the conduct of a laboratory ex-
7 amination or other laboratory procedure on ma-
8 terials derived from the human body, including
9 the conduct of an in vitro clinical test and asso-
10 ciated activities within or under the oversight of
11 a laboratory and not related to the design of an
12 in vitro clinical test; and

13 “(B) includes—

14 “(i) performing pre-analytical and
15 post-analytical processes for an in vitro
16 clinical test;

17 “(ii) standard operating procedures
18 and the conduct thereof; and

19 “(iii) preparing reagents or other test
20 materials that do not meet the definition of
21 an in vitro clinical test for clinical use
22 under section 201(ss).

23 “(14) LOW-RISK.—The term ‘low-risk’, with re-
24 spect to an in vitro clinical test or category of in
25 vitro clinical tests, means that an undetected inac-

1 curate result from such in vitro clinical test, or such
2 category of in vitro clinical tests, when used as in-
3 tended—

4 “(A) would cause only minimal or imme-
5 diately reversible harm, and would lead to only
6 a remote risk of adverse patient impact or ad-
7 verse public health impact; or

8 “(B) sufficient mitigating measures are
9 able to be established and applied such that the
10 in vitro clinical test meets the standard de-
11 scribed in subparagraph (A).

12 “(15) MITIGATING MEASURES.—The term
13 ‘mitigating measures’—

14 “(A) means controls, standards, and other
15 requirements that the Secretary determines,
16 based on evidence, are necessary—

17 “(i) for an in vitro clinical test, or a
18 category of in vitro clinical tests, to meet
19 the applicable standard; or

20 “(ii) to mitigate the risk of harm en-
21 suing from an undetected inaccurate result
22 or misinterpretation of a result; and

23 “(B) may include, as required by the Sec-
24 retary, as appropriate, applicable requirements
25 regarding labeling, conformance to performance

1 standards and consensus standards, perform-
2 ance testing, submission of clinical data, adver-
3 tising, website posting of information, clinical
4 studies, postmarket surveillance, user com-
5 prehension studies, training, and confirmatory
6 laboratory, clinical findings, the role of a health
7 professional in the testing process, or testing.

8 “(16) MODERATE-RISK.—The term ‘moderate-
9 risk’, with respect to an in vitro clinical test or cat-
10 egory of in vitro clinical tests, means a test or cat-
11 egory of tests—

12 “(A) that, when used as intended, meets
13 the criteria specified in paragraph (9)(A) for
14 classification as high-risk, but one or more miti-
15 gating measures are able to be established and
16 applied to prevent or detect an inaccurate result
17 or otherwise sufficiently mitigate such risk, but
18 are not sufficient such that the test is low-risk
19 under the criteria in paragraph (13); or

20 “(B) for which, when used as intended—

21 “(i) an undetected inaccurate result
22 would cause only non-life-threatening
23 harm, harm that is medically reversible, or
24 the absence, significant delay, or dis-

1 continuation of necessary treatment that is
2 not life-supporting or life-sustaining; and

3 “(ii) mitigating measures are not able
4 to be established and applied to prevent or
5 detect such inaccurate result or otherwise
6 sufficiently mitigate the risk of such inac-
7 curate result such that the test would be
8 low-risk under the criteria in paragraph
9 (13).

10 “(17) SPECIMEN RECEPTACLE.—The term
11 ‘specimen receptacle’ means an in vitro clinical test
12 intended for taking, collecting, holding, storing, or
13 transporting of specimens derived from the human
14 body or for in vitro examination for purposes de-
15 scribed in subparagraph (A) or (B) of section
16 201(ss)(1).

17 “(18) TECHNOLOGY.—The term ‘technology’—
18 “(A) means a set of control mechanisms,
19 energy sources, or operating principles—

20 “(i) that do not differ significantly
21 among multiple in vitro clinical tests; and

22 “(ii) for which design and develop-
23 ment (including analytical and clinical vali-
24 dation, as applicable) of the tests would be

1 addressed in a similar manner or through
2 similar procedures; and

3 “(B) may include clot detection, colorimetric (non-immunoassay), electrochemical
4 (non-immunoassay), enzymatic (non-immunoassay), flow cytometry, fluorometry
5 (non-immunoassay), immunoassay, mass spectrometry or chromatography, microbial culture,
6 next generation sequencing, nephelometric or turbidimetric (non-immunoassay), singleplex or
7 multiplex non-NGS nucleic acid analysis, slide-based technology, spectroscopy, and any other
8 technology, as the Secretary determines appropriate.
9
10
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13
14

15 “(19) TEST.—The term ‘test’, unless otherwise
16 provided, means an in vitro clinical test.

17 “(20) VALID SCIENTIFIC EVIDENCE.—The term
18 ‘valid scientific evidence’—

19 “(A) means, with respect to an in vitro
20 clinical test, evidence that—

21 “(i) has been generated and evaluated
22 by persons qualified by training or experience to do so, using procedures generally
23 accepted by other persons so qualified; and
24

1 “(ii) forms an appropriate basis for
2 concluding by qualified experts whether the
3 applicable standard has been met by the in
4 vitro clinical test; and

5 “(B) may include evidence described in
6 subparagraph (A) consisting of—

7 “(i) peer-reviewed literature;

8 “(ii) clinical guidelines;

9 “(iii) reports of significant human ex-
10 perience with an in vitro clinical test;

11 “(iv) bench studies;

12 “(v) case studies or histories;

13 “(vi) clinical data;

14 “(vii) consensus standards;

15 “(viii) reference standards;

16 “(ix) data registries;

17 “(x) postmarket data;

18 “(xi) real world data;

19 “(xii) clinical trials; and

20 “(xiii) data collected in countries
21 other than the United States if such data
22 are demonstrated to be appropriate for the
23 purpose of making a regulatory determina-
24 tion under this subchapter.

1 **“SEC. 587A. REGULATION OF IN VITRO CLINICAL TESTS.**

2 “(a) IN GENERAL.—No person shall introduce or de-
3 liver for introduction into interstate commerce any in vitro
4 clinical test, unless—

5 “(1) an approval of an application filed pursu-
6 ant to subsection (a) or (b) of section 587B is effec-
7 tive with respect to such in vitro clinical test;

8 “(2) the in vitro clinical test is offered under a
9 technology certification order in effect under section
10 587D(b)(1); or

11 “(3) the test is exempt under sections 587C or
12 587G from the requirements of section 587B.

13 “(b) TRANSFER OR SALE OF IN VITRO CLINICAL
14 TESTS.—

15 “(1) TRANSFER AND ASSUMPTION OF REGU-
16 LATORY OBLIGATIONS.—If ownership of an in vitro
17 clinical test is sold or transferred in such manner
18 that the developer transfers the regulatory submis-
19 sions and obligations applicable under this sub-
20 chapter with respect to the test, the transferee or
21 purchaser becomes the developer of the test and
22 shall have all regulatory obligations applicable to
23 such a test under this subchapter. The transferee or
24 purchaser shall update the registration and listing
25 information under section 587J for the in vitro clin-
26 ical test.

1 “(2) TRANSFER OR SALE OF PREMARKET AP-
2 PROVAL.—

3 “(A) NOTICE REQUIRED.—If a developer
4 of an in vitro clinical test transfers or sells the
5 approval of the in vitro clinical test, the trans-
6 feror or seller shall—

7 “(i) submit a notice of the transfer or
8 sale to the Secretary and update the reg-
9 istration and listing information under sec-
10 tion 587J for the in vitro clinical test; and

11 “(ii) submit a supplement to an appli-
12 cation if required under section 587B(h).

13 “(B) EFFECTIVE DATE OF APPROVAL
14 TRANSFER.—A transfer or sale described in
15 subparagraph (A) shall become effective upon
16 completion of a transfer or sale described in
17 paragraph (1) or the approval of a supplement
18 to an application under section 587B(h) if re-
19 quired, whichever is later. The transferee or
20 purchaser shall update the registration and list-
21 ing information under section 587J for the in
22 vitro clinical test within 15 calendar days of the
23 effective date of the transfer or sale.

24 “(3) TRANSFER OR SALE OF TECHNOLOGY CER-
25 TIFICATION.—

1 “(A) REQUIREMENTS FOR TRANSFER OR
2 SALE OF TECHNOLOGY CERTIFICATION.—An
3 unexpired technology certification can be trans-
4 ferred or sold if the transferee or purchaser—

5 “(i) is an eligible person under section
6 587D(a)(2); and

7 “(ii) maintains, upon such transfer or
8 sale, test design and quality requirements,
9 processes and procedures under the scope
10 of technology certification, and scope of the
11 technology certification identified in the
12 applicable technology certification order.

13 “(B) NOTICE REQUIRED.—If a developer
14 of an in vitro clinical test transfers or sells a
15 technology certification order that has not ex-
16 pired, the transferor or seller shall submit a no-
17 tice of the transfer or sale to the Secretary and
18 shall update the registration and listing infor-
19 mation under section 587J for all in vitro clin-
20 ical tests covered by the technology certifi-
21 cation.

22 “(C) EFFECTIVE DATE OF TECHNOLOGY
23 CERTIFICATION TRANSFER.—The transfer of a
24 technology certification shall become effective
25 upon completion of a transfer or sale described

1 in subparagraph (A). The transferee or pur-
2 chaser shall update the registration and listing
3 information under section 587J for the in vitro
4 clinical test within 30 calendar days of the ef-
5 fective date of the technology certification
6 transfer.

7 “(D) NEW TECHNOLOGY CERTIFICATION
8 REQUIRED.—If the requirements of subpara-
9 graph (A)(ii) are not met, the technology cer-
10 tification order may not be transferred and the
11 transferee or purchaser of an in vitro clinical
12 test is required to submit an application for
13 technology certification and obtain a technology
14 certification order prior to offering the test for
15 clinical use.

16 “(c) REGULATIONS.—The Secretary may issue regu-
17 lations to implement this subchapter.

18 **“SEC. 587B. PREMARKET REVIEW.**

19 “(a) APPLICATION.—

20 “(1) FILING.—Any developer may file with the
21 Secretary an application for premarket approval of
22 an in vitro clinical test under this subsection.

23 “(2) TRANSPARENCY AND PREDICTABILITY.—If
24 a developer files a premarket application under this
25 section and provides any additional documentation

1 required under section 587D, the in vitro clinical
2 test that is the subject of the premarket application
3 may be utilized as the representative in vitro clinical
4 test reviewed by the Secretary to support a tech-
5 nology certification order under section 587D.

6 “(3) APPLICATION CONTENT.—An application
7 submitted under paragraph (1) shall include the fol-
8 lowing, in such format as the Secretary specifies:

9 “(A) General information regarding the in
10 vitro clinical test, including—

11 “(i) the name and address of the ap-
12 plicant;

13 “(ii) the table of contents for the ap-
14 plication and the identification of the infor-
15 mation the applicant claims as trade secret
16 or confidential commercial or financial in-
17 formation;

18 “(iii) a description of the test’s design
19 and intended use, including the indications
20 for use; and

21 “(iv) a description regarding test
22 function and performance characteristics.

23 “(B) A summary of the data and informa-
24 tion in the application for the in vitro clinical
25 test, including—

1 “(i) a brief description of the foreign
2 and domestic marketing history of the test,
3 if any, including a list of all countries in
4 which the test has been marketed and a
5 list of all countries in which the test has
6 been withdrawn from marketing for any
7 reason related to the ability of the in vitro
8 clinical test to meet the applicable stand-
9 ard, if known by the applicant;

10 “(ii) a description of benefit and risk
11 considerations related to the in vitro clin-
12 ical test, including a description of any ap-
13 plicable adverse effects of the test on
14 health and how such adverse effects have
15 been, or will be, mitigated;

16 “(iii) a risk assessment of the test;
17 and

18 “(iv) a description of how the data
19 and information in the application con-
20 stitute valid scientific evidence and support
21 a showing that the test meets the applica-
22 ble standard under section 587(2).

23 “(C) The signature of the developer filing
24 the premarket application or an authorized rep-
25 resentative.

1 “(D) A bibliography of applicable pub-
2 lished reports relied upon by the applicant and
3 a description of any studies conducted, includ-
4 ing any unpublished studies related to such
5 test, that are known or that should reasonably
6 be known to the applicant, and a description of
7 data and information relevant to the evaluation
8 of whether the test meets the applicable stand-
9 ard.

10 “(E) Applicable information regarding the
11 methods used in, and the facilities or controls
12 used for, the development of the test to dem-
13 onstrate compliance with the applicable quality
14 requirements under section 587K.

15 “(F) Information demonstrating compli-
16 ance with any relevant and applicable—

17 “(i) mitigating measures under sec-
18 tion 587E; and

19 “(ii) standards established or recog-
20 nized under section 514 prior to the date
21 of enactment of the VALID Act of 2022,
22 or, after applicable standards are estab-
23 lished or recognized under section 587Q,
24 with such standards.

1 “(G) Valid scientific evidence to support
2 that the test meets the applicable standard,
3 which shall include—

4 “(i) summary information for all sup-
5 porting validation studies performed, in-
6 cluding a description of the objective of the
7 study, a description of the experimental de-
8 sign of the study, a description of any limi-
9 tations of the study, a brief description of
10 how the data were collected and analyzed,
11 a brief description of the results of each
12 study, and conclusions drawn from each
13 study;

14 “(ii) raw data for each study, which
15 may include, as applicable, tabulations of
16 data and results; and

17 “(iii) for nonclinical laboratory studies
18 involving the test, if applicable, a state-
19 ment that studies were conducted in com-
20 pliance with applicable good laboratory
21 practices.

22 “(H) To the extent the application seeks
23 authorization to make modifications to the test
24 within the scope of the approval that are not
25 otherwise permitted without premarket review

1 under this subchapter, a proposed change pro-
2 tocol that includes validation procedures and
3 acceptance criteria for anticipated modifications
4 that could be made to the test within the scope
5 of the approval.

6 “(I) Proposed labeling, in accordance with
7 the requirements of section 587L.

8 “(J) Such other data or information as the
9 Secretary may require in accordance with the
10 least burdensome requirements under section
11 587AA(c).

12 “(4) GUIDANCE FOR PREMARKET AND ABBRE-
13 VIATED PREMARKET APPLICATIONS.—In accordance
14 with section 825 of the VALID Act of 2022, the
15 Secretary shall issue draft guidance detailing the in-
16 formation to be provided in a premarket application
17 and abbreviated premarket application under this
18 section. The Secretary shall issue final guidance de-
19 tailing the information to be provided in a pre-
20 market application and abbreviated premarket appli-
21 cation under this section not later than 1 year prior
22 to the effective date of such Act.

23 “(5) REFUSE TO FILE A PREMARKET OR AB-
24 BREVIATED PREMARKET APPLICATION.—The Sec-
25 retary may refuse to file an application under this

1 section only for lack of completeness or legibility of
2 the application. If, after receipt of an application
3 under this section, the Secretary refuses to file such
4 an application, the Secretary shall provide to the de-
5 veloper, within 45 calendar days of receipt of such
6 application submitted under this subsection or with-
7 in 30 calendar days of receipt of an application sub-
8 mitted under subsection (b), a description of the rea-
9 son for such refusal, and identify the information re-
10 quired, if any, to allow for the filing of the applica-
11 tion.

12 “(6) SUBSTANTIVE REVIEW FOR DEFICIENT AP-
13 PPLICATION.—If, after receipt of an application under
14 this section, the Secretary determines that any por-
15 tion of such application is materially deficient, the
16 Secretary shall provide to the applicant a description
17 of such material deficiencies and the information re-
18 quired to resolve such deficiencies.

19 “(7) INSPECTIONS.—With respect to an appli-
20 cation under paragraph (1), preapproval inspections
21 authorized by an employee of the Food and Drug
22 Administration or a person accredited under section
23 587Q need not occur unless requested by the Sec-
24 retary.

25 “(b) ABBREVIATED PREMARKET REVIEW.—

1 “(1) IN GENERAL.—Any developer may file
2 with the Secretary an application for abbreviated
3 premarket approval for—

4 “(A) an instrument;

5 “(B) a specimen receptacle;

6 “(C) an in vitro clinical test that is mod-
7 erate-risk; or

8 “(D) an in vitro clinical test that is deter-
9 mined by the Secretary to be eligible for abbrevi-
10 ated premarket review under section
11 587F(a)(1)(B).

12 “(2) APPLICATION CONTENT.—An application
13 under paragraph (1) shall include—

14 “(A) the information required for applica-
15 tions submitted under subsection (a)(3), except
16 that applications under paragraph (1) need not
17 include—

18 “(i) quality requirement information;

19 or

20 “(ii) raw data, unless explicitly re-
21 quested by the Secretary; and

22 “(B) data, as applicable, to support soft-
23 ware validation, electromagnetic compatibility,
24 and electrical safety, and information dem-

1 onstrating compliance with maintaining quality
2 systems documentation.

3 “(3) SAFETY INFORMATION.—The developer of
4 an in vitro clinical test specimen receptacle reviewed
5 under this subsection shall maintain safety informa-
6 tion for such specimen receptacle.

7 “(4) INSPECTIONS.—With respect to an appli-
8 cation under paragraph (1), preapproval inspections
9 authorized by an employee of the Food and Drug
10 Administration or a person accredited under section
11 587Q need not occur unless requested by the Sec-
12 retary.

13 “(c) INSTRUMENTS AND INSTRUMENT FAMILIES.—

14 “(1) IN GENERAL.—A developer of an instru-
15 ment family shall file with the Secretary an applica-
16 tion for premarket approval of one version of an in-
17 strument under this subsection. Any modified
18 versions of the instrument that generate a new in-
19 strument within the same instrument family shall be
20 exempt from premarket review requirements of this
21 section, provided that the developer of such instru-
22 ment or instrument family—

23 “(A) maintains documentation that the
24 new instrument is part of the instrument fam-
25 ily, as defined in section 587;

1 claims regarding an instrument or instru-
2 ments that can be used with such test kit
3 or test protocol;

4 “(ii) adversely affect performance of
5 the test kit or test protocol; or

6 “(iii) cause the test kit or test pro-
7 tocol to no longer conform with perform-
8 ance standards required under section
9 587R or comply with any applicable miti-
10 gating measures under section 587E, con-
11 ditions of approval under subsection
12 (e)(2)(B), or restrictions under section
13 587O;

14 “(B) the test developer does not identify
15 any new risks for the test kit or test protocol
16 when using the new instrument;

17 “(C) the test developer validates the use of
18 the new instrument with the test kit or test
19 protocol and maintains validation documenta-
20 tion;

21 “(D) the test kit or test protocol is not in-
22 tended for use—

23 “(i) in settings for which a certificate
24 of waiver is in effect under section 353 of
25 the Public Health Service Act;

1 “(ii) without a prescription;

2 “(iii) at home; or

3 “(iv) in testing donors, donations, and
4 recipients of blood, blood components,
5 human cells, tissues, cellular-based prod-
6 ucts, or tissue-based products;

7 “(E) the test developer makes the docu-
8 mentation described under subparagraph (C)
9 available to the Secretary upon request; and

10 “(F) the test developer updates the listing
11 information for the test kit or test protocol, as
12 applicable.

13 “(d) AMENDMENTS TO AN APPLICATION.—An appli-
14 cant shall amend an application submitted under sub-
15 section (a), (b), or (f) if the applicant becomes aware of
16 information that could reasonably affect an evaluation
17 under subsection (e) of whether the approval standard has
18 been met.

19 “(e) ACTION ON AN APPLICATION FOR PREMARKET
20 APPROVAL.—

21 “(1) REVIEW.—

22 “(A) DISPOSITION.—As promptly as pos-
23 sible, but not later than 90 calendar days after
24 an application under subsection (a) is accepted
25 for submission (unless the Secretary determines

1 that an extension is necessary to review one or
2 more major amendments to the application), or
3 not later than 60 calendar days after an appli-
4 cation under subsection (b) is accepted for sub-
5 mission or a supplemental application under
6 subsection (f) is accepted for submission, the
7 Secretary, after considering any applicable re-
8 port and recommendations pursuant to advisory
9 committees under section 587H, shall issue an
10 order approving the application, unless the Sec-
11 retary finds that the grounds for approval in
12 paragraph (2) are not met.

13 “(B) RELIANCE ON PROPOSED LABEL-
14 ING.—In determining whether to approve or
15 deny an application under paragraph (1), the
16 Secretary shall rely on the indications for use
17 included in the proposed labeling, provided that
18 such labeling is not false or misleading based on
19 a fair evaluation of all material facts.

20 “(2) APPROVAL OF AN APPLICATION.—

21 “(A) IN GENERAL.—The Secretary shall
22 approve an application submitted under sub-
23 section (a) or (b) with respect to an in vitro
24 clinical test if the Secretary finds that the ap-
25 plicable standard is met, and—

1 “(i) the applicant is in compliance
2 with applicable quality requirements in sec-
3 tion 587K;

4 “(ii) the application does not contain
5 a false statement or misrepresentation of
6 material fact;

7 “(iii) based on a fair evaluation of all
8 material facts, the proposed labeling is
9 truthful and non-misleading and complies
10 with the requirements of section 587L;

11 “(iv) the applicant permits, if re-
12 quested, authorized employees of the Food
13 and Drug Administration and persons ac-
14 credited under section 587Q an oppor-
15 tunity to inspect pursuant to section 704;

16 “(v) the test conforms with any appli-
17 cable performance standards required
18 under section 587R and any applicable
19 mitigating measures under section 587E;

20 “(vi) all nonclinical laboratory studies
21 and clinical investigations involving human
22 subjects that are described in the applica-
23 tion were conducted in a manner that
24 meets the applicable requirements of this
25 subchapter; and

1 “(vii) other data and information the
2 Secretary may require under subsection
3 (a)(3)(J) support approval.

4 “(B) CONDITIONS OF APPROVAL.—An
5 order approving an application pursuant to this
6 section may require reasonable conditions of ap-
7 proval for the in vitro clinical test, which may
8 include conformance with applicable mitigating
9 measures under section 587E, restrictions
10 under section 587O, and performance standards
11 under section 587R.

12 “(C) PUBLICATION.—The Secretary shall
13 publish an order for each application approved
14 pursuant to this paragraph on the public
15 website of the Food and Drug Administration
16 and make publicly available a summary of the
17 data used to approve such application. In mak-
18 ing the order and summary publicly available,
19 the Secretary shall not disclose any information
20 that—

21 “(i) is confidential commercial infor-
22 mation or trade secret information subject
23 to section 552(b)(4) of title 5, United
24 States Code, or section 1905 of title 18,
25 United States Code; or

1 “(ii) could compromise national secu-
2 rity.

3 “(3) REVIEW OF DENIALS.—An applicant
4 whose application submitted under this section has
5 been denied approval under this subsection may, by
6 petition filed not more than 60 calendar days after
7 the date on which the applicant receives notice of
8 such denial, obtain review of the denial in accord-
9 ance with section 587P.

10 “(f) SUPPLEMENTS TO AN APPROVED APPLICA-
11 TION.—

12 “(1) RISK ANALYSIS.—Prior to implementing
13 any modification to an in vitro clinical test, the hold-
14 er of the application approved under subsection (e)
15 for such test shall perform risk analyses in accord-
16 ance with this subsection, unless such modification is
17 included in the change protocol submitted by the ap-
18 plicant and approved under this section or exempt
19 under section 587C.

20 “(2) SUPPLEMENT REQUIREMENT.—

21 “(A) IN GENERAL.—If the holder of an ap-
22 plication of an approved in vitro clinical test
23 makes a modification to such in vitro clinical
24 test, except as provided in subparagraph (C), or
25 otherwise specified by the Secretary, the holder

1 of the application approved under subsection (e)
2 for an in vitro clinical test shall submit a sup-
3 plemental application to the Secretary. The
4 holder of the application may not implement
5 such modification to the in vitro clinical test
6 until such supplemental application is approved.
7 The information required in a supplemental ap-
8 plication is limited to what is needed to support
9 the change.

10 “(B) ADJUSTMENTS TO CHANGE PRO-
11 TOCOL.—The holder of an approved application
12 may submit under this paragraph a supple-
13 mental application to modify the change pro-
14 tocol of the test at any time after the applica-
15 tion is submitted under subsection (a) or (b).

16 “(C) EXCEPTIONS.—Notwithstanding sub-
17 paragraphs (A) and (B), and so long as the
18 holder of an approved application submitted
19 under subsection (a) or (b) for an in vitro clin-
20 ical test does not add a manufacturing site, or
21 change activities at an existing manufacturing
22 site, with respect to the test, the holder of an
23 approved application may, without submission
24 of a supplemental application, implement the
25 following modifications to the test:

1 “(i) Modifications in accordance with
2 an approved change protocol under sub-
3 section (a)(3)(H).

4 “(ii) Modifications that are exempt
5 under section 587C(a)(6).

6 “(iii) Labeling changes that are ap-
7 propriate to address a safety concern, ex-
8 cept such labeling changes that include any
9 of the following remain subject to subpara-
10 graph (A):

11 “(I) A change to the indications
12 for use of the test.

13 “(II) A change to the perform-
14 ance claims made with respect to the
15 test.

16 “(III) A change that adversely
17 affects performance of the test.

18 “(D) REPORTING FOR CERTAIN MODIFICA-
19 TIONS MADE PURSUANT TO A CHANGE PRO-
20 TOCOL.—The holder of an application approved
21 under subsection (e), with an approved change
22 protocol under subsection (a)(2)(H) for such in
23 vitro clinical test shall—

24 “(i) report any modification to such
25 test made pursuant to such change pro-

1 tocol approved under subsection (a)(3)(H)
2 in a submission under section
3 587J(c)(2)(B); and

4 “(ii) include in such report—

5 “(I) a description of the modi-
6 fication;

7 “(II) the rationale for imple-
8 menting such modification; and

9 “(III) as applicable, a summary
10 of the evidence supporting that the
11 test, as modified, meets the applicable
12 standard, complies with performance
13 standards required under section
14 587Q, and complies with any miti-
15 gating measures established under
16 section 587E and any restrictions
17 under section 587O.

18 “(E) REPORTING FOR CERTAIN SAFETY
19 RELATED LABELING CHANGES.—The holder of
20 the application for an in vitro clinical test ap-
21 proved under subsection (e) shall—

22 “(i) report to the Secretary any modi-
23 fication to the test described in subpara-
24 graph (C)(iii) not more than 30 days after
25 the date on which the test, with the modi-

1 fication, is introduced into interstate com-
2 merce; and

3 “(ii) include in the report—

4 “ (I) a description of the change
5 or changes;

6 “ (II) the rationale for imple-
7 menting such change or changes; and

8 “ (III) a description of how the
9 change or changes were evaluated.

10 “(3) CONTENTS OF SUPPLEMENT.—Unless oth-
11 erwise specified by the Secretary, a supplement
12 under this subsection shall include—

13 “(A) for modifications other than manufac-
14 turing site changes requiring a supplement—

15 “(i) a description of the modification;

16 “(ii) data relevant to the modification
17 to demonstrate that the applicable stand-
18 ard is met, not to exceed data require-
19 ments for the original submission;

20 “(iii) acceptance criteria; and

21 “(iv) any revised labeling; and

22 “(B) for manufacturing site changes—

23 “(i) the information listed in subpara-
24 graph (A); and

1 “(ii) information regarding the meth-
2 ods used in, or the facilities or controls
3 used for, the development of the test to
4 demonstrate compliance with the applicable
5 quality requirements under section 587K.

6 “(4) ADDITIONAL DATA.—The Secretary may
7 require, when necessary, data to evaluate a modifica-
8 tion to an in vitro clinical test that is in addition to
9 the data otherwise required under the preceding
10 paragraphs if the data request is in accordance with
11 the least burdensome requirements under section
12 587AA(c).

13 “(5) CONDITIONS OF APPROVAL.—In an order
14 approving a supplement under this subsection, the
15 Secretary may require conditions of approval for the
16 in vitro clinical test, including compliance with re-
17 strictions under section 587O and conformance to
18 performance standards under section 587R.

19 “(6) APPROVAL.—The Secretary shall approve
20 a supplement under this subsection if—

21 “(A) the data demonstrate that the modi-
22 fied in vitro clinical test meets the applicable
23 standard; and

24 “(B) the holder of the application approved
25 under subsection (e) for the test has dem-

1 onstrated compliance with applicable quality
2 and inspection requirements, as applicable and
3 appropriate.

4 “(7) PUBLICATION.—The Secretary shall pub-
5 lish on the public website of the Food and Drug Ad-
6 ministration notice of any order approving a supple-
7 ment under this subsection provided that doing so
8 does not disclose any information that—

9 “(A) is trade secret or confidential com-
10 mercial or financial information; or

11 “(B) could compromise national security.

12 “(8) REVIEW OF DENIAL.—An applicant whose
13 supplement under this subsection has been denied
14 approval may, by petition filed on or before the 60th
15 calendar day after the date upon which the applicant
16 receives notice of such denial, obtain review of the
17 denial in accordance with section 587P.

18 “(g) WITHDRAWAL AND TEMPORARY SUSPENSION
19 OF APPROVAL.—

20 “(1) ORDER WITHDRAWING APPROVAL.—

21 “(A) IN GENERAL.—The Secretary may,
22 after providing due notice and an opportunity
23 for an informal hearing to the holder of an ap-
24 proved application for an in vitro clinical test
25 under this section, issue an order withdrawing

1 approval of the application if the Secretary
2 finds that—

3 “(i) the grounds for approval under
4 subsection (e) are no longer met;

5 “(ii) there is a reasonable likelihood
6 that the test would cause death or serious
7 adverse health consequences, including by
8 causing the absence, significant delay, or
9 discontinuation of life-saving or life sus-
10 taining medical treatment;

11 “(iii) the holder of the approved appli-
12 cation—

13 “(I) has failed to, or repeatedly
14 or deliberately failed to, maintain
15 records to make reports, as required
16 under section 587M;

17 “(II) has refused to permit ac-
18 cess to, or copying or verification of
19 such records, as required under sec-
20 tion 704;

21 “(III) has not complied with the
22 requirements of section 587K; or

23 “(IV) has not complied with any
24 mitigating measure required under

1 section 587E or restriction under sec-
2 tion 587O; or

3 “(iv) the labeling of such in vitro clin-
4 ical test, based on a fair evaluation of all
5 material facts, is false or misleading in any
6 particular and was not corrected within a
7 reasonable time after receipt of written no-
8 tice from the Secretary of such fact.

9 “(B) CONTENT.—An order under subpara-
10 graph (A) withdrawing approval of an applica-
11 tion shall state each ground for withdrawal and
12 shall notify the holder of such application 60
13 calendar days prior to issuing such order.

14 “(C) PUBLICATION.—The Secretary shall
15 publish any order under subparagraph (A) on
16 the public website of the Food and Drug Ad-
17 ministration provided that doing so does not
18 disclose—

19 “(i) any information that is trade se-
20 cret or confidential commercial or financial
21 information; or

22 “(ii) any other information that the
23 Secretary determines, if published, could
24 compromise national security.

1 “(2) ORDER OF TEMPORARY SUSPENSION.—If,
2 after providing due notice and an opportunity for an
3 informal hearing to the holder of an approved appli-
4 cation for an in vitro clinical test under this section,
5 the Secretary determines, based on scientific evi-
6 dence, that there is a reasonable likelihood that the
7 in vitro clinical test would cause death or serious ad-
8 verse health consequences, such as by causing the
9 absence, significant delay, or discontinuation of life-
10 saving or life-sustaining medical treatment, the Sec-
11 retary shall, by order, temporarily suspend the ap-
12 proval of the application. If the Secretary issues
13 such an order, the Secretary shall proceed expedi-
14 tiously under paragraph (1) to withdraw approval of
15 such application.

16 “(3) APPEAL WITHDRAWING APPROVAL AND
17 ORDERS OF TEMPORARY SUSPENSIONS.—An order of
18 withdrawal or an order of temporary suspension may
19 be appealed under 587P.

20 **“SEC. 587C. EXEMPTIONS.**

21 “(a) IN GENERAL.—The following in vitro clinical
22 tests are exempt from premarket review under section
23 587B, and may be lawfully marketed subject to other ap-
24 plicable requirements of this Act:

25 “(1) TESTS EXEMPT FROM SECTION 510(k).—

1 “(A) EXEMPTION.—An in vitro clinical
2 test is exempt from premarket review under
3 section 587B and may be lawfully marketed
4 subject to the other applicable requirements of
5 this Act, if the developer of the in vitro clinical
6 test—

7 “(i) maintains documentation dem-
8 onstrating that the test meets and con-
9 tinues to meet the criteria set forth in sub-
10 paragraph (B); and

11 “(ii) makes such documentation avail-
12 able to the Secretary upon request.

13 “(B) CRITERIA FOR EXEMPTION.—An in
14 vitro clinical test is exempt as specified in sub-
15 paragraph (A) if such test—

16 “(i)(I)(aa) was offered for clinical use
17 prior to the date of enactment of the
18 VALID Act of 2022; and

19 “(bb) immediately prior to such date
20 of enactment was exempt pursuant to sub-
21 section (l) or (m)(2) of section 510 from
22 the requirements for submission of a re-
23 port under section 510(k); or

24 “(II)(aa) was not offered for clinical
25 use prior to such date of enactment;

1 “(bb) is not an instrument; and

2 “(cc) falls within a category of tests
3 that was exempt from the requirements for
4 submission of a report under section
5 510(k) as of such date of enactment (in-
6 cluding class II devices and excluding class
7 I devices described in section 510(l));

8 “(ii) meets the applicable standard as
9 described in section 587(2);

10 “(iii) is not offered with labeling and
11 advertising that is false or misleading; and

12 “(iv) is not likely to cause or con-
13 tribute to serious adverse health con-
14 sequences.

15 “(C) EFFECT ON SPECIAL CONTROLS.—

16 For any in vitro clinical test, or category of in
17 vitro clinical tests, that is exempt from pre-
18 market review based on the criteria in subpara-
19 graph (B), any special control that applied to a
20 device within a predecessor category imme-
21 diately prior to the date of enactment of the
22 VALID Act of 2022 shall be deemed a miti-
23 gating measure applicable under section 587E
24 to an in vitro clinical test within the successor
25 category, except to the extent such mitigating

1 measure is withdrawn or changed in accordance
2 with section 587E.

3 “(D) NEAR-PATIENT TESTING.—Not later
4 than 1 year after the date of enactment of the
5 VALID Act of 2022, the Secretary shall issue
6 draft guidance indicating categories of tests
7 that shall be exempt from premarket review
8 under section 587B when offered for near-pa-
9 tient testing (point of care), which were not ex-
10 empt from submission of a report under section
11 510(k) pursuant to subsection (l) or (m)(2) of
12 section 510 and regulations imposing limita-
13 tions on exemption for in vitro devices intended
14 for near-patient testing (point of care).

15 “(2) LOW-RISK TESTS.—

16 “(A) EXEMPTION.—An in vitro clinical
17 test is exempt from premarket review under
18 section 587B and may be lawfully marketed
19 subject to the other applicable requirements of
20 this Act, including section 587J(b), if such test
21 meets the definition of low-risk under section
22 587 and if the developer of the test—

23 “(i) maintains documentation dem-
24 onstrating that the in vitro clinical test

1 meets and continues to meet the criteria
2 set forth in subparagraph (B); and

3 “(ii) makes such documentation avail-
4 able to the Secretary upon request.

5 “(B) CRITERIA FOR EXEMPTION.—An in
6 vitro clinical test is exempt as specified in sub-
7 paragraph (A) if—

8 “(i) the in vitro clinical test meets the
9 applicable standard as described in 587(2);

10 “(ii) the labeling and advertising are
11 not false or misleading;

12 “(iii) the in vitro clinical test is not
13 likely to cause or contribute to serious ad-
14 verse health consequences; and

15 “(iv) the in vitro clinical test falls
16 within a category of tests listed as de-
17 scribed in subparagraph (C).

18 “(C) LIST OF LOW-RISK TESTS.—

19 “(i) IN GENERAL.—The Secretary
20 shall maintain, and make publicly available
21 on the website of the Food and Drug Ad-
22 ministration, a list of in vitro clinical tests,
23 and categories of in vitro clinical tests,
24 that are low-risk in vitro clinical tests for

1 purposes of the exemption under this para-
2 graph.

3 “(ii) INCLUSION.—The list under
4 clause (i) shall consist of—

5 “(I) all in vitro clinical tests and
6 categories of in vitro clinical tests that
7 are exempt from premarket review
8 pursuant to paragraph (1) or this
9 paragraph; and

10 “(II) all in vitro clinical tests and
11 categories of in vitro clinical tests that
12 are designated by the Secretary pur-
13 suant to subparagraph (D) as low-risk
14 for purposes of this paragraph.

15 “(D) DESIGNATION OF TESTS AND CAT-
16 EGORIES.—Without regard to subchapter II of
17 chapter 5 of title 5, United States Code, the
18 Secretary may designate, in addition to the
19 tests and categories described in subparagraph
20 (C)(i), additional in vitro clinical tests, and cat-
21 egories of in vitro clinical tests, as low-risk in
22 vitro clinical tests for purposes of the exemption
23 under this paragraph. The Secretary may make
24 such a designation on the Secretary’s own ini-
25 tiative or in response to a request by a devel-

1 oper pursuant to subsection (a) or (b) of section
2 587F. In making such a designation for a test
3 or category of tests, the Secretary shall con-
4 sider—

5 “(i) whether the test, or category of
6 tests, is low-risk;

7 “(ii) the existence of and ability to de-
8 velop mitigating measures sufficient for
9 such test category to meet the low-risk
10 standard; and

11 “(iii) such other factors as the Sec-
12 retary determines to be appropriate for the
13 protection of the public health.

14 “(3) HUMANITARIAN TEST EXEMPTION.—

15 “(A) IN GENERAL.—An in vitro clinical
16 test that meets the criteria under subparagraph
17 (B) is exempt from premarket review under sec-
18 tion 587B and may be lawfully offered subject
19 to the other applicable requirements of this sub-
20 chapter, if the developer of the test—

21 “(i) maintains documentation (which
22 may include literature citations in special-
23 ized medical journals, textbooks, special-
24 ized medical society proceedings, and gov-
25 ernmental statistics publications, or, if no

1 such studies or literature citations exist,
2 credible conclusions from appropriate re-
3 search or surveys) demonstrating that such
4 test meets and continues to meet the cri-
5 teria described in this subsection; and

6 “(ii) makes such documentation avail-
7 able to the Secretary upon request.

8 “(B) CRITERIA FOR EXEMPTION.—An in
9 vitro clinical test is exempt as described in sub-
10 paragraph (A) if—

11 “(i) the in vitro clinical test is in-
12 tended by the developer for use for a diag-
13 nostic purpose for a disease or condition
14 that affects not more than 10,000 (or such
15 other higher number determined by the
16 Secretary) individuals in the United States
17 per year;

18 “(ii) the in vitro clinical test meets
19 the applicable standard described in sec-
20 tion 587(2);

21 “(iii) the labeling and advertising for
22 the in vitro clinical test are not false or
23 misleading;

1 “(iv) the in vitro clinical test is not
2 likely to cause or contribute to serious ad-
3 verse health consequences; and

4 “(v) the in vitro clinical test is not in-
5 tended for screening.

6 “(C) EXCEPTION FOR CERTAIN TESTS.—

7 An in vitro clinical test intended to inform the
8 use of a specific individual or specific type of bi-
9 ological product, drug, or device shall be eligible
10 for an exemption from premarket review under
11 this subsection only if, the developer submits a
12 request under section 587F(e) for informal
13 feedback and the Secretary determines that
14 such in vitro clinical test is eligible for an ex-
15 emption from premarket review under this sub-
16 section.

17 “(4) CUSTOM TESTS AND LOW-VOLUME
18 TESTS.—An in vitro clinical test is exempt from pre-
19 market review under section 587B, quality require-
20 ments under section 587K, and listing requirements
21 under section 587J, and may be lawfully marketed
22 subject to the other applicable requirements of this
23 Act, if—

24 “(A) such in vitro clinical test—

1 “(i) is a test protocol performed for
2 not more than 5 patients per year (or such
3 other higher number determined by the
4 Secretary), in a laboratory certified by the
5 Secretary under section 353 of the Public
6 Health Service Act that—

7 “(I) meets the requirements to
8 perform tests of high-complexity in
9 which the test protocol was developed;
10 or

11 “(II) meets the requirements to
12 perform tests of high-complexity with-
13 in the same corporate organization
14 and having common ownership by the
15 same parent corporation as the lab-
16 oratory in which such test protocol
17 was developed; or

18 “(ii) is an in vitro clinical test devel-
19 oped or modified to diagnose a unique pa-
20 thology or physical condition of a specific
21 patient or patients, upon order of a health
22 professional or other specially qualified
23 person designated under regulations, for
24 which no other in vitro clinical test is com-

1 mercially available in the United States,
2 and is—

3 “(I) not intended for use with re-
4 spect to more than 5 (or such other
5 higher number determined by the Sec-
6 retary) other patients; and

7 “(II) after the development of
8 such test, not included in any test
9 menu or template test report or other
10 promotional materials, and is not oth-
11 erwise advertised; and

12 “(B) the developer of the in vitro clinical
13 test—

14 “(i) maintains documentation dem-
15 onstrating that such test meets the appli-
16 cable criteria described in subparagraph
17 (A);

18 “(ii) makes such documentation, such
19 as a prescription order requesting the cus-
20 tom test for an individual patient, available
21 to the Secretary upon request; and

22 “(iii) informs the Secretary, on an an-
23 nual basis, in a manner prescribed by the
24 Secretary by guidance, that such test was
25 offered.

1 offered under section 587S, and the
2 modified test is performed—

3 “(aa) in the same clinical
4 laboratory in which it was devel-
5 oped for which a certification is
6 still in effect under section 353
7 that meets the requirements to
8 perform tests of high complexity;

9 “(bb) by another clinical lab-
10 oratory for which a certificate is
11 in effect under section 353 that
12 meets the requirements to per-
13 form tests of high complexity, is
14 within the same corporate organi-
15 zation, and has common owner-
16 ship by the same parent corpora-
17 tion as the laboratory in which
18 the test was developed; or

19 “(cc) by a clinical laboratory
20 for which a certificate is in effect
21 under section 353 that meets the
22 requirements to perform tests of
23 high complexity and is within a
24 public health laboratory network
25 coordinated or managed by the

1 Centers for Disease Control and
2 Prevention, if the test was devel-
3 oped by the Centers for Disease
4 Control and Prevention or an-
5 other laboratory within such pub-
6 lic health laboratory network;
7 and

8 “(ii) the modification does not—

9 “(I) constitute a significant
10 change to the indications for use;

11 “(II) cause the test to no longer
12 comply with applicable mitigating
13 measures under section 587E or re-
14 strictions under section 587O;

15 “(III) significantly and adversely
16 change performance claims or signifi-
17 cantly and adversely change perform-
18 ance, unless provided for under an ap-
19 proved change protocol under section
20 587B(a)(3)(H); or

21 “(IV) constitute an adverse
22 change in the safety of the in vitro
23 clinical test for individuals who come
24 in contact with the in vitro clinical
25 test;

1 changes individually and collectively, is a
2 type of modification described in subpara-
3 graph (A), (B), or (C); and

4 “(ii) provide such documentation to
5 the Secretary upon request or inspection.

6 “(E) GUIDANCE.—Not later than 30
7 months after the date of enactment of the
8 VALID Act of 2022, the Secretary shall issue
9 guidance regarding the in vitro clinical tests
10 that are modified and exempt from premarket
11 review under section 587B pursuant to this
12 paragraph.

13 “(b) MANUAL TESTS.—

14 “(1) EXEMPTION.—An in vitro clinical test is
15 exempt from all requirements of this subchapter if
16 the output of such in vitro clinical test is the result
17 of direct, manual observation, without the use of
18 automated instrumentation or software for inter-
19 mediate or final interpretation, by a qualified labora-
20 tory professional, and such in vitro clinical test—

21 “(A) is developed and used within a single
22 clinical laboratory for which a certificate is in
23 effect under section 353 of the Public Health
24 Service Act that meets the requirements under

1 section 353 for performing high-complexity test-
2 ing;

3 “(B) is not a specimen receptacle, instru-
4 ment, or an in vitro clinical test that includes
5 an instrument or specimen receptacle that is
6 not approved under or exempt from section
7 587B;

8 “(C) is not a high-risk test, or is a high-
9 risk test that the Secretary has determined
10 meets at least one condition in paragraph (2)
11 and is otherwise appropriate for this exemption;
12 and

13 “(D) is not intended for testing donors,
14 donations, or recipients of blood, blood compo-
15 nents, human cells, tissues, cellular-based prod-
16 ucts, or tissue-based products.

17 “(2) HIGH-RISK TEST LIMITATION OR CONDI-
18 TION.—A high-risk test may be exempt under para-
19 graph (1) from the requirements of this subchapter
20 only if—

21 “(A) no components or parts of such test,
22 including any reagent, is introduced into inter-
23 state commerce under the exemption under sub-
24 section (e), and any article for taking or deriv-
25 ing specimens from the human body used in

1 conjunction with the test remains subject to the
2 requirements of this subchapter; or

3 “(B) the test has been developed in accord-
4 ance with the applicable test design and quality
5 requirements under section 587K.

6 “(c) PUBLIC HEALTH SURVEILLANCE ACTIVITIES.—

7 “(1) IN GENERAL.—The provisions of this sub-
8 chapter shall not apply to a test intended by the de-
9 veloper to be used solely for public health surveil-
10 lance activities.

11 “(2) EXCLUSION.—An in vitro clinical test used
12 for public health surveillance activities is not ex-
13 cluded from the provisions of this subchapter pursu-
14 ant to this subsection if such test is intended for use
15 in making clinical decisions for individual patients.

16 “(d) GENERAL LABORATORY EQUIPMENT.—Any in-
17 strument that does not produce an analytical result, and
18 that functions as a component of pre-analytical procedures
19 related to in vitro clinical tests, is not subject to the re-
20 quirements of this subchapter, provided that the instru-
21 ment is operating in a clinical laboratory that is certified
22 under section 353 of the Public Health Service Act.

23 “(e) COMPONENTS AND PARTS.—

1 “(1) IN GENERAL.—Subject to paragraph (2), a
2 component or part described in section
3 201(ss)(2)(G) is—

4 “(A) exempt from the requirements of this
5 subchapter if it is intended for further develop-
6 ment as described in paragraph (3); or

7 “(B) subject to the requirements of this
8 subchapter and regulated based on its risk
9 when used as intended by the developer, not-
10 withstanding its subsequent use by a developer
11 as a component, part, or raw material of an-
12 other in vitro clinical test.

13 “(2) INAPPLICABILITY TO OTHER TESTS.—Not-
14 withstanding paragraph (1), an in vitro clinical test
15 that is described in section 201(ss)(1)(B) and that
16 uses a component or part described in such subpara-
17 graph shall be subject to the requirements of this
18 subchapter, unless the test is otherwise exempt
19 under this section.

20 “(3) FURTHER DEVELOPMENT.—A component,
21 part, or raw material (as described in paragraph
22 (1)) is intended for further development (for pur-
23 poses of such paragraph) if—

24 “(A) it is intended solely for use in the de-
25 velopment of another in vitro clinical test; and

1 “(B) in the case of such a test that is in-
2 troduced or delivered for introduction into
3 interstate commerce after the date of enactment
4 of the VALID Act of 2022, the labeling of such
5 test bears the following statement: ‘This prod-
6 uct is intended solely for further development of
7 an in vitro clinical test and is exempt from
8 FDA regulation. This product must be evalu-
9 ated by the in vitro clinical test developer if it
10 is used with or in the development of an in vitro
11 clinical test.’.

12 “(f) GENERAL EXEMPTION AUTHORITY.—The Sec-
13 retary may, by order published in the Federal Register
14 following notice and an opportunity for comment, exempt
15 a class of persons from any section under this subchapter
16 upon a finding that such exemption is appropriate for the
17 protection of the public health and other relevant consider-
18 ations.

19 “(g) EXEMPTION.—An in vitro clinical test that is in-
20 tended solely for use in forensic analysis or law enforce-
21 ment activity is exempt from the requirements of this sub-
22 chapter. An in vitro clinical test that is intended for use
23 in making clinical decisions for individual patients, or
24 whose individually identifiable results may be reported
25 back to an individual patient or the patient’s health care

1 provider, even if also intended for forensic analysis or law
2 enforcement purposes, is not intended solely for forensic
3 analysis or law enforcement for purposes of this sub-
4 section.

5 “(h) REVOCATION.—

6 “(1) IN GENERAL.—The Secretary may revoke
7 any exemption under this section with respect to in
8 vitro clinical tests with the same indications for use
9 if new clinical information indicates that the exemp-
10 tion of an in vitro clinical test or tests from pre-
11 market review under section 587B has a reasonable
12 probability of severe adverse health consequences, in-
13 cluding the absence, delay, or discontinuation of ap-
14 propriate medical treatment.

15 “(2) PROCESS.—Any action under paragraph
16 (1) shall be made by publication of a notice of such
17 proposed action on the website of the Food and
18 Drug Administration, the consideration of comments
19 to a public docket on such proposal, and publication
20 of a final action on such website within 60 calendar
21 days of the close of the comment period posted to
22 such public docket, notwithstanding subchapter II of
23 chapter 5 of title 5, United States Code.

24 “(i) PRE-ANALYTICAL INSTRUMENT.—A pre-analyt-
25 ical instrument is exempt from premarket review under

1 section 587B and may be lawfully offered subject to the
2 other applicable requirements of this Act, if either of the
3 following applies:

4 “(1) Such instrument provides additional infor-
5 mation regarding the sample or performs an action
6 on the sample but is not preparing or processing the
7 sample and does not perform any function of an an-
8 alytical instrument. Such types of pre-analytical in-
9 struments include barcode readers, sample movers,
10 and sample identifiers.

11 “(2) Such instrument processes or prepares the
12 sample prior to use on an analytical instrument,
13 does not perform any function of an analytical in-
14 strument, and does not select, isolate, or prepare a
15 part of a sample based on specific properties. Such
16 types of pre-analytical instruments may include sam-
17 ple mixers, DNA extractors and those used to dilute
18 samples.

19 **“SEC. 587D. TECHNOLOGY CERTIFICATION.**

20 “(a) DEFINITIONS.—In this section:

21 “(1) ELIGIBLE IN VITRO CLINICAL TEST.—The
22 term ‘eligible in vitro clinical test’ means an in vitro
23 clinical test that is not—

24 “(A) a component or part of an in vitro
25 clinical test as described in section

1 201(ss)(2)(G) unless it is a component or part
2 and is regulated based on its own risk under
3 section 587C(e)(1)(B) or as part of an other-
4 wise eligible in vitro clinical test;

5 “(B) an instrument under section
6 201(ss)(2)(D) or an in vitro clinical test that
7 includes an instrument that is subject to section
8 587B, but is not approved under, or exempt
9 from, section 587B;

10 “(C) a specimen receptacle under section
11 201(ss)(2)(E) or an in vitro clinical test that
12 includes a specimen receptacle that is subject to
13 section 587B, but is not approved under, or ex-
14 empt from, section 587B;

15 “(D) an in vitro clinical test, including re-
16 agents used in such tests, intended for use for
17 testing donors, donations, and recipients of
18 blood, blood components, human cells, tissues,
19 cellular-based products, or tissue-based prod-
20 ucts;

21 “(E) high-risk;

22 “(F) a combination product unless such
23 test has been determined to be eligible to be in-
24 troduced into interstate commerce under a tech-
25 nology certification order pursuant to the regu-

1 latory pathway designation process described in
2 section 587F, or as described in subsection (k);
3 or

4 “(G) a first-of-a-kind in vitro clinical test,
5 unless such test has been determined to be eli-
6 gible to be introduced into interstate commerce
7 under a technology certification order pursuant
8 to the regulatory pathway designation process
9 described in section 587F, or as described in
10 subsection (k).

11 “(2) ELIGIBLE PERSON.—The term ‘eligible
12 person’ means an in vitro clinical test developer un-
13 less such developer—

14 “(A) is a laboratory subject to section 353
15 of the Public Health Service Act and does not
16 have in effect a certificate applicable to the cat-
17 egory of laboratory examination or other proce-
18 dure;

19 “(B) was a laboratory, or an owner or op-
20 erator or any employee of a laboratory, found
21 to have committed a significant violation of sec-
22 tion 353 of the Public Health Service Act that
23 resulted in a suspended, revoked, or limited cer-
24 tificate within the 2-year period preceding the
25 date of the submission of the application for a

1 technology certificate under subsection (c) and
2 such violation has not been resolved; or

3 “(C) has been found to have submitted in-
4 formation to the Secretary, or otherwise dis-
5 seminated information, that—

6 “(i) made false or misleading state-
7 ments relevant to the requirements of this
8 subchapter; or

9 “(ii) violated any requirement of this
10 Act, where such violation exposed individ-
11 uals to serious risk of illness, injury, or
12 death, unless—

13 “(I) such violation has been re-
14 solved; or

15 “(II) such violation is not perti-
16 nent to any in vitro clinical test within
17 the scope of the technology certifi-
18 cation that such developer seeks.

19 “(b) APPLICABILITY.—

20 “(1) IN GENERAL.—An in vitro clinical test is
21 not subject to section 587B and may be introduced
22 into interstate commerce if the in vitro clinical
23 test—

24 “(A) is an eligible in vitro clinical test;

25 “(B) is developed by an eligible person;

1 “(C) falls within the scope of a technology
2 certification order issued under this section and
3 that is in effect;

4 “(D) complies with the conditions of the
5 technology certification order, including with
6 applicable mitigating measures under section
7 587E, restrictions under section 587O, and per-
8 formance standards under section 587R; and

9 “(E) meets the applicable standard de-
10 scribed in section 587(2).

11 “(2) SCOPE.—

12 “(A) IN GENERAL.—Subject to subpara-
13 graph (B), the scope of a technology certifi-
14 cation order issued under this section shall
15 apply to one or more technologies with multiple
16 in vitro clinical tests utilizing a technology that
17 does not significantly differ in control mecha-
18 nisms, energy sources, or operating principles
19 and for which development, including design,
20 and analytical and clinical validation, of the in
21 vitro clinical tests would be addressed through
22 similar procedures, and be no broader than—

23 “(i) a single technology type; or

24 “(ii) a fixed combination of tech-
25 nologies.

1 “(B) TECHNOLOGY TYPE.—A technology
2 type described in this paragraph may include
3 clot detection, colorimetric (non-immunoassay),
4 electrochemical (non-immunoassay), enzymatic
5 (non-immunoassay), flow cytometry,
6 fluorometry (non-immunoassay), immunoassay,
7 mass spectrometry or chromatography, micro-
8 bial culture, next generation sequencing,
9 nephelometric or turbidimetric (non-
10 immunoassay), singleplex or multiplex non-NGS
11 nucleic acid analysis, slide-based technology,
12 spectroscopy, and any other technology, as the
13 Secretary determines appropriate.

14 “(c) APPLICATION FOR TECHNOLOGY CERTIFI-
15 CATION.—

16 “(1) IN GENERAL.—A developer seeking a tech-
17 nology certification order shall submit an application
18 under this subsection, which shall contain the infor-
19 mation specified under paragraph (2).

20 “(2) CONTENT OF APPLICATION.—A developer
21 that submits an application for a technology certifi-
22 cation shall include all necessary information to
23 make a showing that all eligible in vitro clinical tests
24 developed within the scope of the technology certifi-

1 cation order will meet the applicable standard, in-
2 cluding—

3 “(A) the name and address of the devel-
4 oper;

5 “(B) a table of contents for the application
6 and the identification of the information the de-
7 veloper claims as trade secret or confidential
8 commercial or financial information;

9 “(C) the signature of the individual filing
10 the application or an authorized representative;

11 “(D) a statement identifying the scope of
12 the proposed technology certification intended
13 to be introduced into interstate commerce under
14 the application;

15 “(E) information establishing that the de-
16 veloper submitting the application is an eligible
17 person;

18 “(F) quality procedures showing that eligi-
19 ble in vitro clinical tests covered under the tech-
20 nology certification will conform to the applica-
21 ble quality requirements of section 587K with
22 respect to—

23 “(i) design controls, including related
24 purchasing controls and acceptance activi-
25 ties;

1 “(ii) complaint investigation, adverse
2 event reporting, and corrections and re-
3 movals; and

4 “(iii) process validation, as applicable;
5 “(G) procedures for analytical and clinical
6 validation, including all procedures for valida-
7 tion, verification, and acceptance criteria, and
8 an explanation as to how such procedures, when
9 used, provide a showing that eligible in vitro
10 clinical tests within the proposed scope of the
11 technology certification order are analytically
12 and clinically valid;

13 “(H) procedures that provide a showing
14 that in vitro clinical tests covered by the pro-
15 posed scope of the technology certification order
16 will be safe for individuals who come into con-
17 tact with in vitro clinical tests covered by such
18 order;

19 “(I) a proposed listing submission under
20 section 587J(b) for in vitro clinical tests that
21 the developer intends to introduce into inter-
22 state commerce upon receiving a technology cer-
23 tification order, which shall not be construed to
24 limit the developer from introducing additional

1 tests not included in such submission under the
2 same technology certification order;

3 “(J) information concerning one or more
4 representative in vitro clinical tests, including—

5 “(i) a test within the scope of the
6 technology certification application with
7 the appropriate analytical complexity at
8 the time of the submission of the applica-
9 tion under this section to serve as the rep-
10 resentative test;

11 “(ii) the information specified in sub-
12 section (a) or (b) of section 587B, as ap-
13 plicable, for the representative in vitro clin-
14 ical test or tests, including information and
15 data required pursuant to subsection
16 (a)(2)(G) of section 587B, unless the Sec-
17 retary determines that such information is
18 not necessary;

19 “(iii) a summary of a risk assessment
20 of the in vitro clinical test;

21 “(iv) an explanation of the choice of
22 the representative in vitro clinical test or
23 tests for the technology certification appli-
24 cation and how such test adequately dem-
25 onstrates the range of procedures that the

1 developer includes in the application under
2 subparagraphs (F), (G), (H), and (I); and

3 “(v) a brief explanation of the ways in
4 which the procedures included in the appli-
5 cation under subparagraphs (F), (G), (H),
6 and (I) have been applied to the represent-
7 ative in vitro clinical test or tests; and

8 “(K) such other information necessary to
9 make a determination on a technology certifi-
10 cation application as the Secretary may deter-
11 mine necessary.

12 “(3) REFERENCE TO EXISTING APPLICA-
13 TIONS.—With respect to the content requirements in
14 the technology certification application described in
15 paragraph (2), a developer may incorporate by ref-
16 erence any content of an application previously sub-
17 mitted by the developer.

18 “(d) ACTION ON AN APPLICATION FOR TECHNOLOGY
19 CERTIFICATION.—

20 “(1) SECRETARY RESPONSE.—

21 “(A) IN GENERAL.—As promptly as prac-
22 ticable, and not later than 90 days after receipt
23 of an application under subsection (c), the Sec-
24 retary shall—

1 “(i) issue a technology certification
2 order granting the application, which shall
3 specify the scope of the technology certifi-
4 cation, if the Secretary finds that all of the
5 grounds in paragraph (3) are met; or

6 “(ii) deny the application if the Sec-
7 retary finds (and sets forth the basis of
8 such finding as part of or accompanying
9 such denial) that one or more grounds for
10 granting the application specified in para-
11 graph (3) are not met.

12 “(B) EXTENSION.—The timeline described
13 in subparagraph (A) may be extended by mu-
14 tual agreement between the Secretary and the
15 applicant.

16 “(2) DEFICIENT APPLICATIONS.—

17 “(A) IN GENERAL.—If, after receipt of an
18 application under this section, the Secretary de-
19 termines that any portion of such application is
20 deficient, the Secretary, not later than 60 days
21 after receipt of such application, shall provide
22 to the applicant a description of such defi-
23 ciencies and identify the information required to
24 resolve such deficiencies.

1 “(B) CONVERTING TO PREMARKET APPLI-
2 CATIONS.—When responding to the deficiency
3 letter, the developer may convert the application
4 for technology certification under subsection (c)
5 into a premarket application under section
6 587B.

7 “(3) TECHNOLOGY CERTIFICATION ORDER.—
8 The Secretary shall issue an order granting a tech-
9 nology certification under this section if, on the
10 basis of the information submitted to the Secretary
11 as part of the application and any other information
12 with respect to such applicant, the Secretary finds
13 that—

14 “(A) there is a showing that in vitro clin-
15 ical tests within the scope of the technology cer-
16 tification order will meet the applicable stand-
17 ard;

18 “(B) the methods used in, and the facili-
19 ties or controls used for, the development of eli-
20 gible in vitro clinical tests covered by the pro-
21 posed scope of the technology certification con-
22 form to the applicable requirements of section
23 587K with respect to—

1 “(i) design controls, including related
2 purchasing controls and acceptance activi-
3 ties;

4 “(ii) complaint investigation, adverse
5 event reporting, and corrections and re-
6 movals; and

7 “(iii) process validation, as applicable;

8 “(C) based on a fair evaluation of all mate-
9 rial facts, the applicant’s proposed labeling and
10 advertising are not false or misleading in any
11 particular;

12 “(D) the application does not contain a
13 false statement of material fact;

14 “(E) there is a showing that the represent-
15 ative in vitro clinical test or tests—

16 “(i) meet the applicable standard; and

17 “(ii) reasonably represent the range of
18 procedures required to be submitted in the
19 application;

20 “(F) the applicant has agreed to permit,
21 upon request, authorized employees of the Food
22 and Drug Administration or persons accredited,
23 or recognized under this Act, an opportunity to
24 inspect at a reasonable time and in a reason-
25 able manner the facilities and all pertinent

1 equipment, finished and unfinished materials,
2 containers, and labeling therein, including all
3 things (including records, files, papers, and con-
4 trols) bearing on whether an in vitro clinical
5 test is adulterated, misbranded, or otherwise in
6 violation of this Act, and permits such author-
7 ized employees or persons accredited under this
8 Act to view and to copy and verify all records
9 pertinent to the application and the in vitro
10 clinical test; and

11 “(G) based on other data and information
12 the Secretary may require under subsection
13 (c)(2)(K), the Secretary finds that such data
14 and information support granting a technology
15 certification order.

16 “(4) REVIEW OF DENIALS.—An applicant
17 whose application has been denied under this sub-
18 section may obtain review of such denial under sec-
19 tion 587P.

20 “(e) SUPPLEMENTS.—

21 “(1) SUPPLEMENTAL APPLICATIONS.—

22 “(A) IN GENERAL.—With respect to any of
23 the following changes related to an in vitro clin-
24 ical test under a technology certification order,
25 a supplemental application to a technology cer-

1 tification order shall be submitted by the holder
2 of the technology certification order describing
3 such proposed changes, prior to introducing the
4 in vitro clinical test that is the subject of the
5 technology certification order into interstate
6 commerce—

7 “(i) any significant change to the pro-
8 cedures provided in support of the applica-
9 tion for technology certification submitted
10 under subparagraph (G) or (H) of sub-
11 section (c)(2); or

12 “(ii) any significant change to the
13 procedures provided in support of the ap-
14 plication for technology certification sub-
15 mitted under subparagraph (F) of sub-
16 section (c)(2).

17 “(B) SECRETARY ACTION ON SUPPLE-
18 MENTAL APPLICATIONS.—Any action by the
19 Secretary on a supplemental application shall
20 be in accordance with subsection (d), and any
21 order resulting from such supplement shall be
22 treated as an amendment to a technology cer-
23 tification order.

24 “(2) CONTENT OF APPLICATION.—

1 “(A) IN GENERAL.—A supplemental appli-
2 cation for a change to an in vitro clinical test
3 under a technology certification order shall—

4 “(i) contain all necessary information
5 to make a showing that any in vitro clin-
6 ical test affected by such change that is
7 within the scope of the technology certifi-
8 cation order will meet the applicable stand-
9 ard; and

10 “(ii) be limited to such information
11 that is needed to support the change.

12 “(B) CONTENT.—Unless otherwise speci-
13 fied by the Secretary, a supplemental applica-
14 tion under this subsection shall include—

15 “(i) a description of the change, in-
16 cluding a rationale for implementing such
17 change;

18 “(ii) a description of how the change
19 was evaluated;

20 “(iii) data from a representative in
21 vitro clinical test or tests that supports a
22 showing that, in using the modified proce-
23 dure or procedures, all eligible in vitro clin-
24 ical tests within the scope of the tech-

1 nology certification will meet the applicable
2 standard;

3 “(iv) as applicable, information to
4 demonstrate that the modified procedure
5 or procedures submitted under subsection
6 (c)(2)(F) continue to conform to applicable
7 requirements under section 587K; and

8 “(v) any other information requested
9 by the Secretary.

10 “(3) CHANGES IN RESPONSE TO A PUBLIC
11 HEALTH RISK.—

12 “(A) IN GENERAL.—If the holder of a
13 technology certification makes a change to an
14 in vitro clinical test or tests to address a poten-
15 tial risk to public health by adding a new speci-
16 fication or test method, such holder may imme-
17 diately implement such change and shall submit
18 a notification for such change to the Secretary
19 within 30 days.

20 “(B) CONTENT.—Any notification to the
21 Secretary under this paragraph shall include—

22 “(i) a summary of the relevant
23 change;

24 “(ii) the rationale for implementing
25 such change;

1 “(iii)(I) if such a change necessitates
2 a change to the procedures reviewed as
3 part of the granted technology certification
4 order, the modified procedures; or

5 “(II) if the procedures were not
6 changed, an explanation as to why they
7 were not changed; and

8 “(iv) if such a change necessitates a
9 change to the procedures reviewed as part
10 of the granted technology certification
11 order, data from a representative in vitro
12 clinical test or tests that support a showing
13 that, in using the modified procedures, all
14 eligible in vitro clinical tests within the
15 scope of the technology certification will
16 meet the applicable standard.

17 “(f) TEMPORARY HOLD.—

18 “(1) IN GENERAL.—Subject to the process
19 specified in paragraph (2), and based on one or
20 more findings under paragraph (4), the Secretary
21 may issue a temporary hold prohibiting any holder
22 of a technology certification order issued under this
23 section from introducing into interstate commerce
24 an in vitro clinical test that was not previously the
25 subject of a listing under section 587J. The tem-

1 porary hold shall identify the grounds for the tem-
2 porary hold under paragraph (4) and the rationale
3 for such finding.

4 “(2) PROCESS FOR ISSUING A TEMPORARY
5 HOLD.—If the Secretary makes a finding that a
6 temporary hold may be warranted based on one or
7 more grounds specified in paragraph (4), the Sec-
8 retary shall promptly notify the holder of the tech-
9 nology certification order of such finding and pro-
10 vide 30 calendar days for the developer to come into
11 compliance with or otherwise resolve the finding.

12 “(3) WRITTEN REQUESTS.—Any written re-
13 quest to the Secretary from the holder of a tech-
14 nology certification order that a temporary hold
15 under paragraph (1) be removed shall receive a deci-
16 sion, in writing and specifying the reasons therefore,
17 within 90 days after receipt of such request. Any
18 such request shall include information to support the
19 removal of the temporary hold.

20 “(4) GROUNDS FOR TEMPORARY HOLD.—The
21 Secretary may initiate a temporary hold under this
22 subsection upon a finding that the holder of a tech-
23 nology certification order—

1 “(A) is not in compliance with the condi-
2 tions of the technology certification order pur-
3 suant to subsection (b)(1)(D);

4 “(B) offers one or more in vitro clinical
5 tests with advertising or labeling that is false or
6 misleading;

7 “(C) has reported a correction or removal
8 of an in vitro clinical test that is offered under
9 a technology certification order under this sec-
10 tion and has failed to demonstrate that the
11 issue or issues causing the correction or re-
12 moval does not adversely impact the ability of
13 other in vitro clinical tests offered under the
14 same technology certification order to meet the
15 applicable standard; or

16 “(D) has introduced into interstate com-
17 merce an in vitro clinical test under a tech-
18 nology certification order and such test is adul-
19 terated or misbranded, based on a determina-
20 tion by the Secretary, and has failed to dem-
21 onstrate that the issue or issues causing the
22 adulteration or misbranding does not adversely
23 impact the ability of other in vitro clinical tests
24 offered under the same technology certification

1 granted under this section to meet the applica-
2 ble standard.

3 “(g) WITHDRAWAL.—The Secretary may, after due
4 notice and opportunity for an informal hearing, issue an
5 order withdrawing a technology certification order includ-
6 ing all tests introduced into interstate commerce under the
7 technology certification order if the Secretary finds that—

8 “(1) the application, supplement, or report
9 under subsection (h) contains false or misleading in-
10 formation or fails to reveal a material fact;

11 “(2) such holder fails to correct false or mis-
12 leading labeling or advertising upon the request of
13 the Secretary;

14 “(3) in connection with a technology certifi-
15 cation, the holder provides false or misleading infor-
16 mation to the Secretary; or

17 “(4) the holder of such technology certification
18 order fails to correct the grounds for a temporary
19 hold within a timeframe specified in the temporary
20 hold order.

21 “(h) REPORTS TO CONGRESS.—

22 “(1) IN GENERAL.—Not later than 1 year after
23 the effective date of the VALID Act of 2022, and
24 annually thereafter for the next 4 years, the Sec-
25 retary shall submit to the Committee on Health,

1 Education, Labor, and Pensions of the Senate and
2 the Committee on Energy and Commerce of the
3 House of Representatives, and make publicly avail-
4 able, including through posting on the website of the
5 Food and Drug Administration, a report containing
6 the information described in paragraph (2).

7 “(2) CONTENT.—

8 “(A) IN GENERAL.—Each report under
9 paragraph (1) shall address, at a minimum—

10 “(i) the total number of applications
11 for technology certifications filed, issued,
12 withdrawn, and denied;

13 “(ii) the total number of technology
14 certification orders the Secretary put on
15 temporary hold under subsection (h) and
16 the number of technology certification or-
17 ders withdrawn under subsection (i);

18 “(iii) the types of technologies for
19 which the Secretary issued technology cer-
20 tification orders;

21 “(iv) the total number of holders of
22 technology certification orders that are in
23 effect; and

24 “(v) the total number of in vitro clin-
25 ical test categories that required premarket

1 review under section 587B that were reded-
2 igned as eligible in vitro clinical tests
3 under this section.

4 “(B) FINAL REPORT.—The fifth report
5 submitted under paragraph (1) shall include a
6 summary of, and responses to, comments raised
7 in the docket.

8 “(C) PERFORMANCE REPORTS.—The re-
9 ports required under this section may be issued
10 with performance reports as required under sec-
11 tion 829 of the VALID Act of 2022.

12 “(i) PUBLIC MEETING AND INPUT.—

13 “(1) PUBLIC DOCKET.—Not later than 30 days
14 after the date of enactment of the VALID Act of
15 2022, the Secretary shall establish a public docket to
16 receive comments concerning recommendations for
17 implementation of this section, including criteria and
18 procedures for subsections (c) through (h). The pub-
19 lic docket shall remain open for at least 1 year after
20 the establishment of the public docket.

21 “(2) PUBLIC MEETING.—Not later than 180
22 days after the date of enactment of the VALID Act
23 of 2022, the Secretary shall convene a public meet-
24 ing to which stakeholders from organizations rep-
25 resenting patients and consumers, academia, and the

1 in vitro clinical test industry are invited to discuss
2 the technology certification process including appli-
3 cation requirements, inspections, alignment with
4 third-party accreditors, and the definition of the
5 term ‘technology’ under section 587.

6 “(j) REGULATIONS.—The Secretary shall issue regu-
7 lations regarding the technology certification process, in-
8 cluding describing criteria or procedures relating to tech-
9 nology certification under this section, which shall be sub-
10 ject to public comment for a minimum of 60 days from
11 issuance prior to finalizing such regulations after consid-
12 ering the comments received. The regulation shall include
13 an outline of the application process, opportunities to meet
14 with officials of the Food and Drug Administration, and
15 plans to streamline inspections.

16 “(k) NOTIFICATION.—

17 “(1) IN GENERAL.—Notwithstanding subsection
18 (a)(1), a first-of-a-kind in vitro clinical test or a
19 combination product that meets the definition of a
20 moderate-risk test under section 587A may be intro-
21 duced into interstate commerce under a technology
22 certification order that has been issued by the Sec-
23 retary, subject to other applicable requirements if—

24 “(A) the developer provides notification to
25 the Secretary 60 days prior to introducing such

1 tests into interstate commerce that includes in-
2 formation demonstrating that the test is mod-
3 erate-risk and within the scope of the applicable
4 technology certification order; and

5 “(B) the Secretary has not issued a notifi-
6 cation to the developer under paragraph (2) be-
7 fore such time has elapsed.

8 “(2) NOTIFICATION FROM SECRETARY.—The
9 Secretary shall issue a notification to the developer
10 that such test may not be introduced into interstate
11 commerce under such order if the Secretary deter-
12 mines that—

13 “(A) such test—

14 “(i) does not meet the definition of a
15 moderate-risk test under section 587A;

16 “(ii) is not eligible to be introduced
17 into interstate commerce under any of sub-
18 paragraphs (A) through (E) of subsection
19 (a)(1); or

20 “(iii) is not eligible to be introduced
21 into interstate commerce under the ref-
22 erenced technology certification order
23 issued by the Secretary because it is not
24 within the scope of the technology certifi-
25 cation order under subsection (b)(2); or

1 “(B) based on the information included in
2 the notification submitted by the developer pur-
3 suant to this subsection, there is insufficient in-
4 formation for the Secretary to make the deter-
5 minations described in clauses (i), (ii), and (iii)
6 of subparagraph (A).

7 **“SEC. 587E. MITIGATING MEASURES.**

8 “(a) ESTABLISHMENT OF MITIGATING MEASURES.—

9 “(1) ESTABLISHING, CHANGING, OR WITH-
10 DRAWING.—

11 “(A) ESTABLISHMENT.—The Secretary
12 may establish and require, on the basis of evi-
13 dence, mitigating measures for any in vitro clin-
14 ical test or category of in vitro clinical tests
15 with the same indications for use that is intro-
16 duced or delivered for introduction into inter-
17 state commerce after the establishment of such
18 mitigating measures.

19 “(B) METHODS OF ESTABLISHMENT.—The
20 Secretary may establish mitigating measures—

21 “(i) under the process set forth in
22 subparagraph (D);

23 “(ii) as provided under section 587F;

24 or

1 “(iii) through a premarket approval or
2 technology certification order, which may
3 establish mitigating measures for an indi-
4 vidual in vitro clinical test or a category of
5 in vitro clinical tests.

6 “(C) METHODS OF CHANGE OR WITH-
7 DRAWAL.—The Secretary may change or with-
8 draw mitigating measures—

9 “(i) under the process set forth in
10 subparagraph (D); or

11 “(ii) as provided under section 587F.

12 “(D) PROCESS FOR ESTABLISHMENT,
13 CHANGE, OR WITHDRAWAL.—Notwithstanding
14 subchapter II of chapter 5 of title 5, United
15 States Code, the Secretary may, upon the ini-
16 tiative of the Secretary or upon petition of an
17 interested person—

18 “(i) establish, change, or withdraw
19 mitigating measures for an in vitro clinical
20 test or category of in vitro clinical tests
21 by—

22 “(I) publishing a proposed order
23 in the Federal Register;

1 “(II) providing an opportunity
2 for public comment for a period of not
3 less than 30 60 calendar days; and

4 “(III) after consideration of any
5 comments submitted, publishing a
6 final order in the Federal Register
7 that responds to the comments sub-
8 mitted, and which shall include a rea-
9 sonable transition period.

10 “(E) EFFECT OF MITIGATING MEASURES
11 ON GRANDFATHERED TESTS.—A mitigating
12 measure shall not be required by the Secretary
13 for an in vitro clinical test subject to section
14 587G(a).

15 “(2) IN VITRO CLINICAL TESTS PREVIOUSLY
16 CLEARED OR EXEMPT AS DEVICES WITH SPECIAL
17 CONTROLS.—

18 “(A) IN GENERAL.—Any special controls
19 applicable to an in vitro clinical test previously
20 cleared or exempt under section 510(k), or clas-
21 sified under section 513(f)(2) prior to date of
22 enactment of the VALID Act of 2022, including
23 any such special controls established during the
24 period beginning on the date of enactment of
25 the VALID Act of 2022 and ending on the ef-

1 fective date of such Act (as described in section
2 5(b) of such Act)—

3 “(i) shall continue to apply to such in
4 vitro clinical test after such effective date;
5 and

6 “(ii) are deemed to be mitigating
7 measures as of the effective date specified
8 in section 825(a)(1)(A) of the VALID Act
9 of 2022.

10 “(B) CHANGES.—Notwithstanding sub-
11 paragraph (A), the Secretary may establish,
12 change, or withdraw mitigating measures for
13 such tests or category of tests using the proce-
14 dures under paragraph (1).

15 “(b) DOCUMENTATION.—

16 “(1) IN VITRO CLINICAL TESTS SUBJECT TO
17 PREMARKET REVIEW.—The developer of an in vitro
18 clinical test subject to premarket review under sec-
19 tion 587B and to which mitigating measures apply
20 shall—

21 “(A) in accordance with section
22 587B(c)(2)(G)(i), submit documentation to the
23 Secretary as part of the application for the test
24 under subsection (c) or (d) of section 587B

1 demonstrating that such mitigating measures
2 have been met;

3 “(B) if such application is approved, main-
4 tain documentation demonstrating that such
5 mitigating measures continue to be met fol-
6 lowing a test modification by the developer; and

7 “(C) make such documentation available to
8 the Secretary upon request or inspection.

9 “(2) OTHER TESTS.—The developer of an in
10 vitro clinical test that is offered under a technology
11 certification order or other exemption from pre-
12 market review under section 587B and to which
13 mitigating measures apply shall—

14 “(A) maintain documentation in accord-
15 ance with the applicable quality requirements
16 under section 587J demonstrating that such
17 mitigating measures continue to be met fol-
18 lowing a test modification by the developer;

19 “(B) make such documentation available to
20 the Secretary upon request or inspection; and

21 “(C) include in the performance summary
22 for such test a brief description of how such
23 mitigating measures are met, if applicable.

24 **“SEC. 587F. REGULATORY PATHWAY DESIGNATION.**

25 “(a) PATHWAY DETERMINATIONS.—

1 “(1) IN GENERAL.—After considering available
2 evidence with respect to an in vitro clinical test or
3 category of in vitro clinical tests with the same in-
4 tended use, including the identification, establish-
5 ment, and implementation of mitigating measures
6 under section 587E, as appropriate, the Secretary
7 may, upon the initiative of the Secretary or upon re-
8 quest of a developer, determine that—

9 “(A) such in vitro clinical test is high-risk
10 and subject to premarket review under section
11 587B;

12 “(B) such in vitro clinical tests, including
13 a first-of-a-kind test, is moderate-risk and sub-
14 ject to abbreviated premarket review under sec-
15 tion 587B(b) or technology certification under
16 section 587D(a)(1); or

17 “(C) such in vitro clinical test, including a
18 first-of-a-kind test is low-risk or otherwise ex-
19 empt from premarket review under section
20 587B.

21 “(2) REQUESTS.—

22 “(A) SUBMISSIONS BY DEVELOPERS.—

23 “(i) ABBREVIATED PREMARKET RE-
24 VIEW; TECHNOLOGY CERTIFICATION.—A
25 developer submitting a request that the

1 Secretary make a determination as de-
2 scribed in paragraph (1)(B) shall submit
3 information to support that the in vitro
4 clinical test is moderate-risk or propose
5 mitigating measures, if applicable, that
6 would support such a determination.

7 “(ii) LOW-RISK; EXEMPT FROM PRE-
8 MARKET REVIEW.—A developer submitting
9 a request that the Secretary make a deter-
10 mination as described in paragraph (1)(C)
11 shall submit information that the in vitro
12 clinical test is low-risk, or otherwise appro-
13 priate for exemption from premarket re-
14 view under section 587B and propose miti-
15 gating measures, if applicable, that would
16 support such a determination.

17 “(B) RESPONSE BY THE SECRETARY.—
18 Not later than 30 days after receiving a request
19 under clause (i) or (ii) of subparagraph (A), the
20 Secretary shall provide a timely response de-
21 scribing whether or not the Secretary will ini-
22 tiate the process for making a determination
23 under paragraph (1)(B) or (1)(C) as described
24 in paragraph (4).

1 “(3) SUFFICIENCY OF MITIGATING MEAS-
2 URES.—When determining whether mitigating meas-
3 ures for an in vitro clinical test, or category of in
4 vitro clinical tests, are sufficient to make such test
5 moderate-risk or low-risk, the Secretary shall take
6 into account the following:

7 “(A) The degree to which the technology
8 for the intended use of the in vitro clinical test
9 is well-characterized, taking into consideration
10 factors that include one or more of the fol-
11 lowing:

12 “(i) Peer-reviewed literature.

13 “(ii) Practice guidelines.

14 “(iii) Consensus standards.

15 “(iv) Recognized standards of care.

16 “(v) Use of such technology, including
17 historical use.

18 “(vi) Multiple scientific publications
19 by different authors.

20 “(vii) Adoption by the scientific or
21 clinical community.

22 “(viii) Real world evidence.

23 “(B) Whether the criteria for performance
24 of the test are well-established to be sufficient
25 for the intended use.

1 “(C) The clinical circumstances under
2 which the in vitro clinical test is used, including
3 whether the in vitro clinical test is the sole de-
4 termine for the diagnosis or treatment of the
5 targeted disease, and the availability of other
6 tests (such as confirmatory or adjunctive tests)
7 or relevant material standards.

8 “(D) Whether such mitigating measures
9 sufficiently mitigate the risk of harm such that
10 the test or category of tests is moderate-risk or
11 low-risk.

12 “(4) PROCESS.—

13 “(A) IN GENERAL.—For a test that is not
14 first-of-a-kind, any action under paragraph (1)
15 shall be made by publication of a notice of such
16 proposed action on the website of the Food and
17 Drug Administration, the consideration of com-
18 ments to a public docket on such proposal, and
19 publication of a final action on such website
20 within 60 calendar days of the close of the com-
21 ment period posted to such public docket, not-
22 withstanding subchapter II of chapter 5 of title
23 5, United States Code.

1 “(B) PROCESS FOR FIRST-OF-A-KIND
2 TEST.—In the case of an in vitro clinical test
3 that is first-of-a-kind, the process is as follows:

4 “(i) Any determination that the test is
5 subject to premarket approval or abbrevi-
6 ated premarket review under subpara-
7 graph (A) or (B) of paragraph (1) shall be
8 published on the website of the Food and
9 Drug Administration, notwithstanding sub-
10 clause II of chapter 5 of title 5, United
11 States Code, only after the in vitro clinical
12 test is approved under section 587B. Until
13 that time, the determination shall not be
14 binding on other in vitro clinical tests.

15 “(ii) Any determination other than
16 those made under clause (i) shall be made
17 by publication of a notice of final action on
18 the website of the Food and Drug Admin-
19 istration, notwithstanding subchapter II of
20 chapter 5 of title 5, United States Code.

21 “(5) NO EFFECT ON GRANDFATHERING DETER-
22 MINATIONS.—A determination under paragraph (1)
23 shall have no effect on the applicability of section
24 587G to an in vitro clinical tests.

1 “(b) TRANSITION PERIOD.—Upon a decision by the
2 Secretary to change a regulatory pathway designation, or
3 reclassifies an in vitro clinical test, or category of in vitro
4 clinical tests, the Secretary shall provide an appropriate
5 transition period with respect to any new requirements.

6 “(c) APPEALS.—A decision by the Secretary under
7 this section shall be deemed a significant decision subject
8 to appeal under section 587P.

9 “(d) ADVISORY COMMITTEE.—The Secretary may re-
10 quest recommendations from an advisory committee under
11 section 587H pursuant to carrying out this section.

12 “(e) REQUEST FOR INFORMAL FEEDBACK.—Before
13 submitting a premarket application or technology certifi-
14 cation application for an in vitro clinical test—

15 “(1) the developer of the test may submit to the
16 Secretary a written request for a meeting, con-
17 ference, or written feedback to discuss and provide
18 information relating to the regulation of such in
19 vitro clinical test which may include—

20 “(A) the submission process and the type
21 and amount of evidence expected to dem-
22 onstrate the applicable standard;

23 “(B) which regulatory pathway is appro-
24 priate for an in vitro clinical test; and

1 “(C) an investigation plan for an in vitro
2 clinical test, including a clinical protocol; and

3 “(2) upon receipt of such a request, the Sec-
4 retary shall—

5 “(A) if a meeting is requested—

6 “(i) within 60 calendar days after
7 such receipt, or within such time period as
8 may be agreed to by the developer, meet or
9 confer with the developer submitting the
10 request; and

11 “(ii) within 15 calendar days after
12 such meeting or conference, provide to the
13 developer a written record or response de-
14 scribing the issues discussed and conclu-
15 sions reached in the meeting or conference;
16 and

17 “(B) if written feedback is requested, pro-
18 vide feedback to the requestor within 75 days
19 after such receipt.

20 **“SEC. 587G. GRANDFATHERED IN VITRO CLINICAL TESTS.**

21 “(a) IN GENERAL.—Subject to subsection (d), an in
22 vitro clinical test is exempt from the requirements of this
23 subchapter specified in subsection (b) if—

24 “(1) the test was first offered for clinical use,
25 and was not intended solely for investigational use,

1 before the date of enactment of the VALID Act of
2 2022;

3 “(2) the test was developed by a clinical labora-
4 tory for which a certificate was in effect under sec-
5 tion 353 of the Public Health Service Act that meets
6 the requirements for performing tests of high com-
7 plexity;

8 “(3) the test is performed—

9 “(A) in the same clinical laboratory in
10 which the test was developed for which a certifi-
11 cation is still in effect under section 353 of the
12 Public Health Service Act that meets the re-
13 quirements to perform tests of high complexity;

14 “(B) by another clinical laboratory for
15 which a certificate is in effect under section 353
16 of such Act that meets the requirements to per-
17 form tests of high complexity, and that is with-
18 in the same corporate organization and having
19 common ownership by the same parent corpora-
20 tion as the laboratory in which the test was de-
21 veloped; or

22 “(C) in the case of a test that was devel-
23 oped by the Centers for Disease Control and
24 Prevention or another laboratory in a public
25 health laboratory network coordinated or man-

1 aged by the Centers for Disease Control and
2 Prevention, by a clinical laboratory for which a
3 certificate is in effect under section 353 of such
4 Act that meets the requirements to perform
5 tests of high complexity, and that is within a
6 public health laboratory network coordinated or
7 managed by the Centers for Disease Control
8 and Prevention;

9 “(4) the test does not have in effect an ap-
10 proval under section 515, a clearance under section
11 510(k), an authorization under section 513(f)(2), or
12 an exemption under section 520(m), or licensure
13 under section 351 of the Public Health Service Act;

14 “(5) any modification to the test on or after the
15 date of enactment of the VALID Act of 2022 is
16 made by the initial developer, conforms with section
17 587C(a)(6)(A)(ii), and does not meet the criteria in
18 subsection (d)(1);

19 “(6) when used as an investigational in vitro
20 clinical test, such test complies with section 587S, as
21 applicable;

22 “(7) the test is offered with an order from an
23 authorized person as required under section 353 of
24 the Public Health Service Act, and was offered with
25 a prescription required under section 809.30(f) of

1 title 21, Code of Federal Regulations prior to the ef-
2 fective date of this subchapter;

3 “(8) the test is not for use with home specimen
4 collection, unless the specimen is collected with a
5 collection container, receptacle, or kit that—

6 “(A) has been approved, cleared, or au-
7 thorized by the Secretary for home specimen
8 collection and the collection is performed pursu-
9 ant to the approved, cleared, or authorized la-
10 beling, including any indication for use as pre-
11 scription use or over-the-counter use, or

12 “(B) is exempt from premarket review and
13 its use is consistent with applicable limitations
14 on the exemption;

15 “(9) the test is not a specimen receptacle or in-
16 strument;

17 “(10) each test report for the test bears a
18 statement that reads as follows: ‘This in vitro clin-
19 ical test was introduced into commerce prior to the
20 application of the VALID Act and is exempt from
21 FDA premarket review.’; and

22 “(11) the developer of the test—

23 “(A) maintains documentation dem-
24 onstrating that the test meets and continues to

1 meet the criteria set forth in this subsection;
2 and

3 “(B) makes such documentation available
4 to the Secretary upon request.

5 “(b) EXEMPTIONS APPLICABLE TO GRAND-
6 FATHERED TESTS.—An in vitro clinical test that meets
7 the criteria specified in subsection (a) is exempt from pre-
8 market review under 587B, labeling requirements under
9 587L, and test design requirements and quality require-
10 ments under 587K, and may be lawfully offered subject
11 to the other applicable requirements of this Act.

12 “(c) MODIFICATIONS.—In the case of an in vitro clin-
13 ical test that meets the criteria specified in subsection (a),
14 such test continues to qualify for the exemptions described
15 in subsection (b) if the test is modified and the modifica-
16 tion is of a type described in subsection (a)(5), and the
17 person modifying such in vitro clinical test—

18 “(1) documents each such modification and
19 maintains documentation of the basis for such deter-
20 mination;

21 “(2) provides such documentation relating to
22 the change to the Secretary upon request or inspec-
23 tion; and

1 “(3) does not modify the in vitro clinical test
2 such that it no longer meets the criteria under sub-
3 section (a).

4 “(d) REQUEST FOR INFORMATION.—

5 “(1) CRITERIA.—The criteria described in this
6 paragraph are any of the following:

7 “(A) There is a lack of valid scientific evi-
8 dence to support that the in vitro clinical test
9 is analytically valid or clinically valid.

10 “(B) Such in vitro clinical test is being of-
11 fered by its developer with any false or mis-
12 leading analytical or clinical claims.

13 “(C) It is probable that such in vitro clin-
14 ical test will cause serious adverse health con-
15 sequences.

16 “(2) PROCESS.—

17 “(A) WRITTEN REQUEST FOR INFORMA-
18 TION.—The Secretary may issue a written re-
19 quest to a developer identifying specific sci-
20 entific concerns, based on credible information,
21 with an in vitro clinical test, which indicate that
22 one or more of the criteria described in para-
23 graph (1) apply to such in vitro clinical test.
24 Such written request shall include specific infor-
25 mation requests pertaining to such criteria.

1 “(B) DEADLINE FOR SUBMITTING INFOR-
2 MATION.—Not later than 45 days after receiv-
3 ing a request for information under subpara-
4 graph (A)—

5 “(i) the developer of an in vitro clin-
6 ical test—

7 “(I) may seek a teleconference
8 prior to the submission of information
9 under subclause (II) to discuss the
10 Secretary’s request; and

11 “(II) shall submit the informa-
12 tion requested pursuant to subpara-
13 graph (A), and may include in such
14 submission a request for a teleconfer-
15 ence; and

16 “(ii) the Secretary shall—

17 “(I) schedule a teleconference re-
18 quested under clause (i)(I); and

19 “(II) hold a teleconference if re-
20 quested within 10 days of the Sec-
21 retary’s receipt of the information
22 submitted under clause (i)(II).

23 “(C) REVIEW DEADLINE.—Upon receiving
24 a submission under subparagraph (B), the Sec-
25 retary shall—

1 “(i) review the submitted information
2 within 45 calendar days of such receipt,
3 which may include communication with the
4 developer; and

5 “(ii) determine whether the criteria
6 listed in paragraph (1) apply to the in
7 vitro clinical test and communicate such
8 determination to the developer as described
9 in subparagraph (D).

10 “(D) COMMUNICATION AND RESULTS OF
11 DETERMINATION.—The Secretary shall notify
12 the developer, in writing, of the Secretary’s de-
13 termination under subparagraph (C), as follows:

14 “(i) If the Secretary determines that
15 none of the criteria listed in paragraph (1)
16 apply to the in vitro clinical test, such test
17 shall be exempt from relevant requirements
18 of this subchapter, as set forth in sub-
19 section (b), subject to applicable limitation.

20 “(ii) If the Secretary determines that
21 one or more of the criteria listed in sub-
22 paragraph (1) apply to the test but such a
23 determination may be resolved within a
24 reasonable time, and the test has not been
25 previously subject to this subsection on the

1 basis of the same or substantially similar
2 scientific concerns identified in the written
3 request issued under paragraph
4 (d)(2)(A)—

5 “(I) the Secretary shall notify the
6 developer of such a determination and
7 allow the developer to seek a tele-
8 conference to discuss the finding;

9 “(II) the developer shall submit
10 information demonstrating resolution
11 of the determination within 15 days of
12 receiving the notification; and

13 “(III) the Secretary shall make a
14 determination within 30 days of the
15 submission of information as to
16 whether the criteria under paragraph
17 (1) apply to the test.

18 “(iii) If the Secretary determines that
19 none of the criteria listed in paragraph (1)
20 apply to the test, such test shall be exempt
21 from relevant requirements of the sub-
22 chapter as set forth in subsection (b), sub-
23 ject to applicable limitations.

24 “(iv) If the Secretary determines that
25 one or more of the criteria listed in para-

1 graph (1) apply to the in vitro clinical test,
2 such test is not exempt as set forth in this
3 section and shall not be offered unless ap-
4 proved under section 587B, or, upon a de-
5 termination by the Secretary pursuant to
6 section 587F, offered under a technology
7 certification order under section 587D or
8 offered as a low-risk test.

9 “(v) If the Secretary determines that
10 one or more of the criteria listed in para-
11 graph (1) apply to the in vitro clinical test
12 and clause (ii) does not apply, the in vitro
13 clinical test is not exempt as set forth in
14 section and shall not be offered unless ap-
15 proved under section 587B, or upon a de-
16 termination by the Secretary pursuant to
17 section 587F, offered under a technology
18 certification order under section 587D or
19 offered as a low-risk test.

20 **“SEC. 587H. ADVISORY COMMITTEES.**

21 “(a) IN GENERAL.—The Secretary may establish ad-
22 visory committees or use advisory committee panels of ex-
23 perts established before the date of enactment of the
24 VALID Act of 2022 (including a device classification
25 panel under section 513) for the purposes of providing ex-

1 pert scientific advice and making recommendations related
2 to—

3 “(1) the approval of an application for an in
4 vitro clinical test submitted under this subchapter,
5 including for evaluating, as applicable, the analytical
6 validity, clinical validity, and safety of in vitro clin-
7 ical tests;

8 “(2) the potential effectiveness of mitigating
9 measures for a determination of the applicable regu-
10 latory pathway under section 587F(b) or risk eval-
11 uation for an in vitro clinical test or tests;

12 “(3) quality requirements under section 587K
13 or applying such requirements to in vitro clinical
14 tests developed or imported by developers;

15 “(4) appeals under section 587P; or

16 “(5) such other purposes as the Secretary de-
17 termines appropriate.

18 “(b) APPOINTMENTS.—

19 “(1) VOTING MEMBERS.—The Secretary shall
20 appoint to each committee established under sub-
21 section (a), as voting members, individuals who are
22 qualified by training and experience to evaluate in
23 vitro clinical tests referred to the committee for the
24 purposes specified in subsection (a), including indi-
25 viduals with, to the extent feasible, scientific exper-

1 tise in the development of such in vitro clinical tests,
2 laboratory operations, and the use of in vitro clinical
3 tests. The Secretary shall designate one member of
4 each committee to serve as chair.

5 “(2) NONVOTING MEMBERS.—In addition to the
6 individuals appointed pursuant to paragraph (1), the
7 Secretary shall appoint to each committee estab-
8 lished under subsection (a), as nonvoting members—

9 “(A) a representative of consumer inter-
10 ests; and

11 “(B) a representative of interests of in
12 vitro clinical test developers not directly af-
13 fected by the matter to be brought before the
14 committee.

15 “(3) LIMITATION.—No individual who is a reg-
16 ular full-time employee of the United States and en-
17 gaged in the administration of this Act may be a
18 member of any advisory committee established under
19 subsection (a).

20 “(4) EDUCATION AND TRAINING.—The Sec-
21 retary shall, as appropriate, provide education and
22 training to each new committee member before such
23 member participates in a committee’s activities, in-
24 cluding education regarding requirements under this
25 Act and related regulations of the Secretary, and the

1 administrative processes and procedures related to
2 committee meetings.

3 “(5) MEETINGS.—The Secretary shall ensure
4 that scientific advisory committees meet regularly
5 and at appropriate intervals so that any matter to
6 be reviewed by such a committee can be presented
7 to the committee not more than 60 calendar days
8 after the matter is ready for such review. Meetings
9 of the committee may be held using electronic or tel-
10 ephonic communication to convene the meetings.

11 “(6) COMPENSATION.—Members of an advisory
12 committee established under subsection (a), while at-
13 tending meetings or conferences or otherwise en-
14 gaged in the business of the advisory committee—

15 “(A) shall be entitled to receive compensa-
16 tion at rates to be fixed by the Secretary, but
17 not to exceed the daily equivalent of the rate in
18 effect for positions classified above level GS-15
19 of the General Schedule; and

20 “(B) may be allowed travel expenses as au-
21 thorized by section 5703 of title 5, United
22 States Code, for employees serving intermit-
23 tently in the Government service.

1 “(c) GUIDANCE.—The Secretary may issue guidance
2 on the policies and procedures governing advisory commit-
3 tees established under subsection (a).

4 **“SEC. 587I. BREAKTHROUGH IN VITRO CLINICAL TESTS.**

5 “(a) IN GENERAL.—The purpose of this section is
6 to encourage the Secretary, and provide the Secretary with
7 sufficient authority, to apply efficient and flexible ap-
8 proaches to expedite the development of, and prioritize the
9 review of, in vitro clinical tests that represent break-
10 through technologies.

11 “(b) ESTABLISHMENT OF PROGRAM.—The Secretary
12 shall establish a program to expedite the development of,
13 and provide for the priority review of, in vitro clinical
14 tests.

15 “(c) ELIGIBILITY.—The program developed under
16 subsection (b) shall be available for any in vitro clinical
17 test that—

18 “(1) provides or enables more effective treat-
19 ment or diagnosis of life-threatening or irreversibly
20 debilitating human disease or conditions compared
21 to existing approved or cleared in vitro clinical tests,
22 including an in vitro clinical test offered under a
23 technology certification order; and

24 “(2) is a test—

1 “(A) that represents a breakthrough tech-
2 nology;

3 “(B) for which no approved or cleared al-
4 ternative in vitro clinical test exists, including
5 no in vitro clinical test offered under a tech-
6 nology certification order;

7 “(C) that offers a clinically meaningful ad-
8 vantage over existing alternative in vitro clinical
9 tests that are approved or cleared (including in
10 vitro clinical tests offered under a technology
11 certification order), including the potential to
12 reduce or eliminate the need for hospitalization,
13 improve patient quality of life, facilitate pa-
14 tients’ ability to manage their own care (such
15 as through self-directed personal assistance), or
16 establish long-term clinical efficiencies; or

17 “(D) the availability of which is in the best
18 interest of patients or public health.

19 “(d) DESIGNATION.—

20 “(1) REQUEST.—To receive breakthrough des-
21 ignation under this section, an applicant may re-
22 quest that the Secretary designate the in vitro clin-
23 ical test for expedited development and priority re-
24 view. Any such request for designation may be made
25 at any time prior to, or at the time of, the submis-

1 sion of an application under section 587B or 587D,
2 and shall include information demonstrating that the
3 test meets the criteria described in subsection (c).

4 “(2) DETERMINATION.—Not later than 60 cal-
5 endar days after the receipt of a request under para-
6 graph (1), the Secretary shall determine whether the
7 in vitro clinical test that is the subject of the request
8 meets the criteria described in subsection (c). If the
9 Secretary determines that the test meets the criteria,
10 the Secretary shall designate the test for expedited
11 development and priority review.

12 “(3) REVIEW.—Review of a request under para-
13 graph (1) shall be undertaken by a team that is
14 composed of experienced staff and senior managers
15 of the Food and Drug Administration.

16 “(4) WITHDRAWAL.—

17 “(A) IN GENERAL.—The designation of an
18 in vitro clinical test under this subsection is
19 deemed to be withdrawn, and such in vitro clin-
20 ical test shall no longer be eligible for designa-
21 tion under this section, if an application for ap-
22 proval for such test under section 587B or
23 587D is denied. Such test shall be eligible for
24 breakthrough designation upon a new request
25 for such designation.

1 “(B) EXCEPTION.—The Secretary may not
2 withdraw a designation granted under this sub-
3 section based on the subsequent approval or
4 technology certification of another in vitro clin-
5 ical test that—

6 “(i) is designated under this section;

7 or

8 “(ii) was given priority review under
9 section 515B.

10 “(e) ACTIONS.—For purposes of expediting the devel-
11 opment and review of in vitro clinical tests under this sec-
12 tion, the Secretary may take the actions and additional
13 actions set forth in paragraphs (1) and (2), respectively,
14 of section 515B(e) when reviewing such tests. Any ref-
15 erence or authorization in section 515B(e) with respect
16 to a device shall be deemed a reference or authorization
17 with respect to an in vitro clinical test for purposes of this
18 section.

19 “(f) GUIDANCE.—Not later than the date specified
20 for final guidance under section 825 of the VALID Act
21 of 2022, the Secretary shall issue final guidance on the
22 implementation of this section. Such guidance shall—

23 “(1) set forth the process by which a person
24 may seek a designation under subsection (d);

1 “(2) provide a template for request under sub-
2 section (d);

3 “(3) identify the criteria the Secretary will use
4 in evaluating a request for designation; and

5 “(4) identify the criteria and processes the Sec-
6 retary will use to assign a team of staff, including
7 team leaders, to review in vitro clinical tests des-
8 ignated for expedited development and priority re-
9 view, including any training required for such per-
10 sonnel to ensure effective and efficient review.

11 “(g) RULES OF CONSTRUCTION.—Nothing in this
12 section shall be construed to affect—

13 “(1) the criteria and standards for evaluating
14 an application pursuant to section 587B or 587D,
15 including the recognition of valid scientific evidence
16 as described in section 587(20) and consideration
17 and application of the least burdensome means de-
18 scribed under section 587AA(c);

19 “(2) the authority of the Secretary with respect
20 to clinical holds under section 587S;

21 “(3) the authority of the Secretary to act on an
22 application pursuant to section 587B before comple-
23 tion of an establishment inspection, as the Secretary
24 determines appropriate; or

1 “(4) the authority of the Secretary with respect
2 to postmarket surveillance under section 587X.

3 **“SEC. 587J. REGISTRATION AND LISTING.**

4 “(a) REGISTRATION REQUIREMENT.—

5 “(1) IN GENERAL.—Each person described in
6 subsection (b)(1) shall—

7 “(A) during the period beginning on Octo-
8 ber 1 and ending on December 31 of each year,
9 register with the Secretary the name of such
10 person, places of business of such person, all es-
11 tablishments engaged in the activities specified
12 under this paragraph, the establishment reg-
13 istration number of each such establishment,
14 and a point of contact for each such establish-
15 ment, including an electronic point of contact;
16 and

17 “(B) submit an initial registration con-
18 taining the information required under subpara-
19 graph (A) not later than—

20 “(i) the effective date of this section if
21 such establishment is engaged in any activ-
22 ity described in subsection (b)(1) on such
23 effective date, unless the Secretary estab-
24 lishes by guidance a date later than such

1 implementation date for all or a category
2 of such establishments; or

3 “(ii) 30 days prior to engaging in any
4 activity described in subsection (b)(1), if
5 such establishment is not engaged in any
6 activity described in this paragraph on
7 such effective date.

8 “(2) REGISTRATION NUMBERS.—The Secretary
9 may assign a registration number to any person or
10 an establishment registration number to any estab-
11 lishment registered in accordance with this section.
12 Registration information shall be made publicly
13 available by publication on the website maintained
14 by the Food and Drug Administration, in accord-
15 ance with subsection (d).

16 “(3) INSPECTION.—Each person or establish-
17 ment that is required to be registered with the Sec-
18 retary under this section shall be subject to inspec-
19 tion pursuant to section 704.

20 “(b) LISTING INFORMATION FOR IN VITRO CLINICAL
21 TESTS.—

22 “(1) IN GENERAL.—Each person who—

23 “(A) is a developer; and

24 “(B) introduces or proposes to begin the
25 introduction or delivery for introduction into

1 interstate commerce through an exemption
2 under subsection (a)(1), (a)(2), (a)(3), or (g) of
3 section 587C or section 587G or through the
4 filing of an application under section 587B or
5 section 587D,

6 shall submit a listing to the Secretary containing the
7 information described in paragraph (2), (4), or (5),
8 as applicable, in accordance with the applicable
9 schedule described under subsection (c). Such listing
10 shall be prepared in such form and manner as the
11 Secretary may specify in guidance. Listing informa-
12 tion shall be submitted through the comprehensive
13 test information system in accordance with section
14 587T, as appropriate.

15 “(2) SUBMISSIONS.—Each developer submitting
16 a listing under paragraph (1) shall electronically
17 submit to the comprehensive test information system
18 described in section 587T the following information,
19 as applicable, for each in vitro clinical test for which
20 such person is a developer in the form and manner
21 prescribed by the Secretary, taking into account the
22 least burdensome requirements under section
23 587AA(c):

24 “(A) Name of the establishment and its es-
25 tablishment registration number.

1 “(B) Contact information for the official
2 correspondent for the listing.

3 “(C) Name (common name and trade
4 name, if applicable) of the in vitro clinical test
5 and its test listing number (when available).

6 “(D) The certificate number for any lab-
7 oratory certified by the Secretary under section
8 353 of the Public Health Service Act that
9 meets the requirements to perform high-com-
10 plexity testing and that is the developer of the
11 in vitro clinical test, and the certificate number
12 under such section for any laboratory that is
13 performing the test, is within the same cor-
14 porate organization, and has common ownership
15 by the same parent corporation.

16 “(E) Whether the in vitro clinical test is,
17 as applicable, offered as a test approved under
18 section 587B, cleared to be offered under a
19 granted technology certification order, or of-
20 fered as an exempt in vitro clinical test under
21 section 587C of 587G.

22 “(F) Indications for use information under
23 section 587(10).

1 “(G) A brief summary of the analytical
2 and clinical performance of the in vitro clinical
3 test, and as applicable, the lot release criteria.

4 “(H) A brief description of conformance
5 with any applicable mitigating measures, re-
6 strictions, and standards.

7 “(I) Representative labeling for the in vitro
8 clinical test, as appropriate.

9 “(3) TEST LISTING NUMBER.—The Secretary
10 may assign a test listing number to each in vitro
11 clinical test that is the subject of a listing under this
12 section. The process for assigning test listing num-
13 bers may be established through guidance, and may
14 include the recognition of standards, formats, or
15 conventions developed by a third-party organization.

16 “(4) ABBREVIATED LISTING.—A person who is
17 not a developer but is otherwise required to register
18 pursuant to subsection (a) shall submit an abbrev-
19 viated listing to the Secretary containing the infor-
20 mation described in subparagraphs (A) through (C)
21 of paragraph (2), and the name of the developer.
22 The information shall be submitted in accordance
23 with the applicable schedule described under sub-
24 section (c). Such abbreviated listing shall be pre-
25 pared in such form and manner as the Secretary

1 may specify through guidance. Listing information
2 shall be submitted to the comprehensive test infor-
3 mation system in accordance with section 587T, as
4 appropriate.

5 “(5) GRANDFATHERED TESTS.—A developer of-
6 fering a test that is a grandfathered in vitro clinical
7 test under section 587G(a) shall submit listing infor-
8 mation required under subparagraphs (A) through
9 (F) of paragraph (2), and may submit a statement
10 of the performance specifications for such in vitro
11 clinical tests.

12 “(6) EXEMPT TESTS.—A developer of an in
13 vitro clinical test who introduces or proposes to
14 begin the introduction or delivery for introduction
15 into interstate commerce that is otherwise exempt
16 from the requirement to submit listing information
17 pursuant to an exemption under section 587C may
18 submit listing information under this subsection.

19 “(c) TIMELINES FOR SUBMISSION OF LISTING IN-
20 FORMATION.—

21 “(1) IN GENERAL.—The timelines for submis-
22 sion of registration and listing under subsections (a)
23 and (b) are as follows:

24 “(A) For an in vitro clinical test that was
25 listed as a device under section 510(j) prior to

1 the effective date of this section, a person shall
2 maintain a device listing under section 510
3 until such time as the system for submitting
4 the listing information required under sub-
5 section (b) becomes available and thereafter
6 shall submit the listing information not later
7 than the later of 1 year after the system for
8 submitting the listing under this section be-
9 comes available or the effective date of this sec-
10 tion.

11 “(B) For an in vitro clinical test that is
12 subject to grandfathering under section
13 587G(a) a person shall submit the listing infor-
14 mation required under subsection (b)(5) not
15 later than the later of 1 year after the system
16 for submitting the listing under this section be-
17 comes available or the effective date of this sec-
18 tion.

19 “(C) For an in vitro clinical test that is
20 not described in subparagraph (A) or (B), a
21 person shall submit the required listing infor-
22 mation as follows:

23 “(i) For an in vitro clinical test that
24 is not exempt from premarket approval
25 under section 587B, a person shall submit

1 the required listing information, prior to
2 offering the in vitro clinical test and not
3 later than 30 business days after the date
4 of approval of the premarket approval ap-
5 plication.

6 “(ii) For an in vitro clinical test that
7 is exempt from premarket review under
8 section 587C, the required listing informa-
9 tion shall be submitted prior to offering
10 the in vitro clinical test.

11 “(2) UPDATES.—

12 “(A) UPDATES AFTER CHANGES.—Each
13 developer required to submit listing information
14 under this section shall update such informa-
15 tion within 10 business days of any change that
16 causes any previously listed information to be
17 inaccurate or incomplete.

18 “(B) ANNUAL UPDATES.—Each developer
19 required to submit listing information under
20 this section shall update its information annu-
21 ally during the period beginning on October 1
22 and ending on December 31 of each year.

23 “(d) PUBLIC AVAILABILITY OF LISTING INFORMA-
24 TION.—

1 “(1) IN GENERAL.—Listing information sub-
2 mitted pursuant to this section shall be made pub-
3 licly available on the website of the Food and Drug
4 Administration in accordance with paragraph (3).

5 “(2) CONFIDENTIALITY.—Listing information
6 for an in vitro clinical test that is subject to pre-
7 market approval or technology certification shall re-
8 main confidential until such date as the in vitro clin-
9 ical test receives the applicable premarket approval
10 or the developer receives a technology certification
11 order and for subsequent tests introduced under a
12 technology certification order until their introduc-
13 tion.

14 “(3) EXCEPTIONS FROM PUBLIC AVAILABILITY
15 REQUIREMENTS.—The public listing requirements of
16 this subsection shall not apply to any registration
17 and listing information submitted under subsection
18 (a) or (b), if the Secretary determines that such in-
19 formation—

20 “(A) is a trade secret or confidential com-
21 mercial or financial information; or

22 “(B) if posted, would present a risk to na-
23 tional security.

24 “(e) SUBMISSION OF INFORMATION BY ACCREDITED
25 PERSONS.—If agreed upon by the developer, the informa-

1 tion required under this section may be submitted by a
2 person accredited under section 587Q.

3 **“SEC. 587K. TEST DESIGN AND QUALITY REQUIREMENTS.**

4 “(a) APPLICABILITY.—

5 “(1) IN GENERAL.—Each developer and each
6 other person required to register under section
7 587J(b)(1) shall establish and maintain quality re-
8 quirements in accordance with the applicable re-
9 quirements set forth in subsection (b).

10 “(2) CERTIFIED LABORATORY REQUIRE-
11 MENTS.—A developer shall establish and maintain
12 quality requirement under subsection (b)(2) or
13 (b)(3), as applicable, if such developer is a clinical
14 laboratory certified by the Secretary under section
15 353 of the Public Health Service Act that—

16 “(A) is certified to perform high-com-
17 plexity testing;

18 “(B) develops an in vitro clinical test that
19 is for use only—

20 “(i) within the laboratory certified by
21 the Secretary under such section 353 in
22 which such test was developed; or

23 “(ii) within another laboratory cer-
24 tified by the Secretary under such section
25 353 if such laboratory is—

1 “(I) within the same corporate
2 organization and has common owner-
3 ship by the same parent corporation
4 as the laboratory in which the test
5 was developed; or

6 “(II) within a public health lab-
7 oratory network coordinated or man-
8 aged by the Centers for Disease Con-
9 trol and Prevention, if the test is de-
10 veloped by a public health laboratory
11 or the Centers for Disease Control
12 and Prevention; and

13 “(C) does not manufacture, produce, or
14 distribute in vitro clinical tests other than lab-
15 oratory test protocols.

16 “(3) REGULATIONS.—The Secretary shall pro-
17 mulgate quality system regulations implementing
18 this section. In promulgating such regulations under
19 this section, the Secretary shall consider whether,
20 and to what extent, international harmonization is
21 appropriate.

22 “(4) QUALITY SYSTEMS FOR HYBRID DEVEL-
23 OPERS OF BOTH LABORATORY TEST PROTOCOLS AND
24 OTHER IN VITRO CLINICAL TESTS.—An entity that
25 develops both finished products and laboratory test

1 protocols and other in vitro clinical tests shall com-
2 ply with subsection (b)(1) for activities related to the
3 development of any in vitro clinical test that is not
4 a laboratory test protocol and with subsection (b)(2)
5 or (b)(3), as applicable, for activities related to the
6 development of any laboratory test protocol.

7 “(b) QUALITY REQUIREMENTS.—

8 “(1) IN GENERAL.—The quality requirements
9 applicable under this section shall—

10 “(A) avoid duplication of regulations and
11 guidance under section 353 of the Public
12 Health Service Act;

13 “(B) not apply to laboratory operations;
14 and

15 “(C) include the following, as applicable,
16 subject to subparagraphs (A) and (B) and
17 paragraphs (2) and (3)—

18 “(i) management responsibilities;

19 “(ii) quality audits;

20 “(iii) personnel;

21 “(iv) design controls;

22 “(v) document controls;

23 “(vi) purchasing controls;

24 “(vii) identification and traceability;

- 1 “(viii) production and process con-
2 trols;
3 “(ix) acceptance activities;
4 “(x) nonconforming in vitro clinical
5 tests;
6 “(xi) corrective and preventive action;
7 “(xii) labeling and packaging controls;
8 “(xiii) handling, storage, distribution,
9 and installation;
10 “(xiv) complaints and records;
11 “(xv) servicing; and
12 “(xvi) statistical techniques.

13 “(2) EXCEPTION FOR LABORATORY TEST PRO-
14 TOCOLS.—Developers that are developing test proto-
15 cols for use as described in subsection (a)(2)(B)(i)
16 are exempt from the requirements under paragraph
17 (1)(C) except for the requirements described in
18 clauses (iv), (ix), (xi), and (xiv) of such paragraph.

19 “(3) QUALITY REQUIREMENTS FOR CERTAIN
20 LABORATORIES DISTRIBUTING LABORATORY TEST
21 PROTOCOLS WITHIN ORGANIZATIONS OR PUBLIC
22 HEALTH NETWORKS.—Quality requirements applica-
23 ble to the developer who is distributing a laboratory
24 test protocol as described in subsection (a)(2)(B)(ii)
25 shall consist of the following:

1 “(A) Clauses (iv), (ix), (xi), (xiv), (xii) of
2 paragraph (1)(B).

3 “(B) The requirement to maintain records
4 of the laboratories to which the laboratory test
5 protocol is distributed.

6 “(c) REGULATIONS.—In implementing quality re-
7 quirements for test developers that participate in inter-
8 national audit programs under this section, the Secretary
9 shall—

10 “(1) for purposes of facilitating international
11 harmonization, consider whether the developer par-
12 ticipates in an international audit program in which
13 the United States participates and recognizes com-
14 pliance with, or conformance to, such standards rec-
15 ognized by the Secretary; and

16 “(2) ensure a least burdensome approach de-
17 scribed in section 587AA(c) by leveraging, to the ex-
18 tent applicable, the quality assurance requirements
19 applicable to developers certified by the Secretary
20 under section 353 of the Public Health Service Act.

21 **“SEC. 587L. LABELING REQUIREMENTS.**

22 “(a) IN GENERAL.—An in vitro clinical test shall
23 bear or be accompanied by labeling, as applicable, that
24 meets the requirements set forth in subsections (b) and
25 (c), unless such test is exempt under subsection (d) or (e).

1 “(b) LABELS.—

2 “(1) IN GENERAL.—The label of an in vitro
3 clinical test, shall meet the requirements set forth in
4 paragraph (2) if there is an immediate container to
5 which the label is applied.

6 “(2) REGULATIONS.—The label of an in vitro
7 clinical test shall state the name and place of busi-
8 ness of its developer and meet the requirements set
9 forth in regulations promulgated in accordance with
10 this section.

11 “(c) LABELING.—

12 “(1) IN GENERAL.—Labeling of an in vitro clin-
13 ical test, including labeling in the form of a package
14 insert, website, standalone laboratory reference docu-
15 ment, or other similar document shall include—

16 “(A) adequate directions for use and shall
17 meet the requirements set forth in regulations
18 promulgated under this section, except as pro-
19 vided in subsection (d) or (e); and

20 “(B) the information described in para-
21 graph (2), as applicable.

22 “(2) CONTENT.—Labeling of an in vitro clinical
23 test shall include—

24 “(A) the test listing number that was pro-
25 vided to the developer at the time of listing;

1 “(B) information to facilitate reporting an
2 adverse event;

3 “(C) information regarding accessing the
4 performance summary data displayed in the
5 listing database for the test;

6 “(D) the indications for use of the in vitro
7 clinical test; and

8 “(E) any warnings, contraindications, or
9 limitations.

10 “(3) PUBLIC AVAILABILITY OF INFORMATION.—

11 The Secretary shall make all of the information de-
12 scribed in paragraph (2) with respect to each in
13 vitro clinical test available to the public, as applica-
14 ble, in accordance with section 587T, except to the
15 extent that the Secretary determines that such infor-
16 mation—

17 “(A) is trade secret or confidential com-
18 mercial or financial information; or

19 “(B) if posted, could compromise national
20 security.

21 “(4) ADDITIONAL REQUIREMENTS.—Labeling
22 for an in vitro clinical test used for
23 immunoematology testing shall meet the applicable
24 requirements set forth in part 660 of title 21, Code
25 of Federal Regulations (or any successor regula-

1 tions), related to the labeling of blood grouping re-
2 agents, reagent red blood cells, and anti-human
3 globulin.

4 “(d) EXEMPTIONS AND ALTERNATIVE REQUIRE-
5 MENTS.—

6 “(1) IN GENERAL.—

7 “(A) IN GENERAL.—With respect to an in
8 vitro clinical test that meets the criteria of sub-
9 paragraph (B), the ‘state in one place’ regula-
10 tions under section 809.10(b) of title 21, Code
11 of Federal Regulations (or any successor regu-
12 lations) may be satisfied by the laboratory post-
13 ing such information on its website or in mul-
14 tiple documents, if such documents are main-
15 tained and accessible in one place.

16 “(B) APPLICABLE TESTS.—An in vitro
17 clinical test meets the criteria of this subpara-
18 graph if such test is—

19 “(i) developed by a laboratory cer-
20 tified by the Secretary under section 353
21 of the Public Health Service Act that
22 meets the requirements to perform tests of
23 high-complexity; and

24 “(ii) performed in—

1 “(I) the same laboratory in which
2 such test was developed; or

3 “(II) by another laboratory cer-
4 tified by the Secretary under section
5 353 of the Public Health Service Act
6 that—

7 “(aa) meets the require-
8 ments to perform tests of high
9 complexity; and

10 “(bb) is under common own-
11 ership and control as the labora-
12 tory that developed the test.

13 “(2) TEST INSTRUMENT LABELING.—Unless
14 the instrument is the entire test system, the labeling
15 for an instrument is not required to bear the infor-
16 mation indicated in paragraphs (3), (4), (5), (7),
17 (8), (9), (10), (11), (12), and (13) of section
18 809.10(b) of title 21, Code of Federal Regulations
19 (or any successor regulations).

20 “(3) REAGENT LABELING.—For purposes of
21 compliance with subsection (c)(1), the labeling for a
22 reagent intended for use as a replacement in an in
23 vitro clinical test may be limited to that information
24 necessary to identify the reagent adequately and to
25 describe its proper use in the test.

1 “(4) INVESTIGATIONAL USE.—A shipment or
2 other delivery of an in vitro clinical test for inves-
3 tigational use pursuant to section 587S shall be ex-
4 empt from the labeling requirements of subsections
5 (b) and (c)(1) and from any standard promulgated
6 through regulations, except as required under sec-
7 tion 353 of the Public Health Service Act or section
8 587R of this Act.

9 “(5) GENERAL PURPOSE LABORATORY RE-
10 AGENTS.—The labeling of general purpose labora-
11 tory reagents (such as hydrochloric acid) whose uses
12 are generally known by persons trained in their use
13 need not bear the directions for use required by sub-
14 section (c)(1)(A).

15 “(6) OVER-THE-COUNTER TEST SPECIMEN RE-
16 CEPTACLE LABELING.—The labeling for over-the-
17 counter test specimen receptacles for drugs of abuse
18 testing shall bear the name and place of business of
19 the developer included in the registration under sec-
20 tion 587J and any information specified in applica-
21 ble regulations promulgated under this section, in
22 language appropriate for the intended users.

23 “(e) TESTS IN THE STRATEGIC NATIONAL STOCK-
24 PILE.—

1 “(1) IN GENERAL.—The Secretary may grant
2 an exception or alternative to any provision listed in
3 this section, unless explicitly required by a statutory
4 provision outside this subchapter, for specified lots,
5 batches, or other units of an in vitro clinical test, if
6 the Secretary determines that compliance with such
7 labeling requirement could adversely affect the avail-
8 ability of such products that are, or will be, included
9 in the Strategic National Stockpile under section
10 319F–2 of the Public Health Service Act.

11 “(2) REGULATIONS.—The Secretary may issue
12 regulations amending section 809.11 of title 21,
13 Code of Federal Regulations (or any successor regu-
14 lation) to apply in full or in part to in vitro clinical
15 tests and in vitro clinical test developers.

16 “(f) REGULATIONS.—The Secretary shall issue or re-
17 vise regulations related to standardized, general content
18 and format for in vitro clinical test labeling pursuant to
19 this subsection.

20 **“SEC. 587M. ADVERSE EVENT REPORTING.**

21 “(a) IN GENERAL.—Each in vitro clinical test devel-
22 oper shall establish and maintain a system for establishing
23 and maintaining records of adverse events and reporting
24 adverse events in accordance with this section.

1 “(b) SUBMISSION OF INDIVIDUAL REPORTS.—A de-
2 veloper shall submit an individual adverse event not later
3 than 5 calendar days after the developer receives or be-
4 comes aware of an adverse event that reasonably suggests
5 that an in vitro clinical test may—

6 “(1) have caused or contributed to a patient or
7 user death; or

8 “(2) present an imminent threat to public
9 health.

10 “(c) SUBMISSION OF QUARTERLY REPORTS.—As ap-
11 plicable, a developer shall submit quarterly reports that
12 include any in vitro clinical test errors and serious injuries
13 that occurred during the applicable quarter. Such quar-
14 terly reports shall be submitted not later than the end of
15 the quarter following the quarter in which the developer
16 receives or becomes aware of such adverse events.

17 “(d) DEFINITIONS.—For the purposes of this sec-
18 tion—

19 “(1) the term ‘in vitro clinical test error’ means
20 a failure of an in vitro clinical test to meet its per-
21 formance specifications, or to otherwise perform as
22 intended by the developer, including an inaccurate
23 result resulting from such failure; and

24 “(2) the term ‘serious injury’ means—

1 “(A) a significant delay in a diagnosis that
2 results in the absence, delay, or discontinuation
3 of critical medical treatment or that irreversibly
4 or seriously and negatively alters the course of
5 a disease or condition; or

6 “(B) an injury that—

7 “(i) is life threatening;

8 “(ii) results in permanent impairment
9 of a body function or permanent damage
10 to a body structure; or

11 “(iii) necessitates medical or surgical
12 intervention to preclude permanent impair-
13 ment of a body function or permanent
14 damage to a body structure.

15 “(e) REGULATIONS.—The Secretary shall promulgate
16 regulations to implement this section.

17 **“SEC. 587N. CORRECTIONS AND REMOVALS.**

18 “(a) REGULATIONS.—The Secretary shall promulgate
19 regulations, or amend existing regulations, as appropriate,
20 to implement this section.

21 “(b) REPORTS OF CORRECTIONS AND REMOVALS.—

22 “(1) IN GENERAL.—Each in vitro clinical test
23 developer shall report to the Secretary any correc-
24 tion or removal of an in vitro clinical test under-

1 taken by such developer if the correction or removal
2 was undertaken—

3 “(A) to reduce the risk to health posed by
4 the in vitro clinical test; or

5 “(B) to remedy a violation of this Act
6 caused by the in vitro clinical test which may
7 present a risk to health.

8 “(2) EXCEPTION FOR IN VITRO CLINICAL TESTS
9 OFFERED UNDER A TECHNOLOGY CERTIFICATION
10 ORDER.—For any eligible test offered under a tech-
11 nology certification order under section 587D, a cor-
12 rection and removal report for any correction or re-
13 moval of an in vitro clinical test should demonstrate
14 that the issue or issues causing the correction or re-
15 moval do not adversely impact the ability of other in
16 vitro clinical tests offered under the same technology
17 certification order to meet the applicable standard.

18 “(c) TIMING.—A developer shall submit any report
19 required under this subsection to the Secretary within 15
20 business days of initiating such correction or removal.

21 “(d) RECORDKEEPING.—A developer of an in vitro
22 clinical test that undertakes a correction or removal of an
23 in vitro clinical test which is not required to be reported
24 under this subsection shall keep a record of such correc-
25 tion or removal.

1 “(e) RECALL COMMUNICATIONS.—Upon the report-
2 ing of a correction or removal by the developer—

3 “(1) the Secretary shall classify such correction
4 or removal under this section within 45 calendar
5 days; and

6 “(2) not later than 70 calendar days after the
7 developer or other responsible party notifies the Sec-
8 retary that it has completed a recall action, the Sec-
9 retary shall provide the developer or other respon-
10 sible party with a written statement closing the re-
11 call action or stating the reasons the Secretary can-
12 not close the recall at that time.

13 **“SEC. 5870. RESTRICTED IN VITRO CLINICAL TESTS.**

14 “(a) APPLICABILITY.—

15 “(1) IN GENERAL.—For the types of in vitro
16 clinical tests described in paragraph (3), the Sec-
17 retary may require, in issuing an approval of an in
18 vitro clinical test under section 587B, granting a
19 technology certification order under section 587D, or
20 in issuing a determination under section 587F(a), or
21 by issuing a regulation, that such test, or category
22 of tests, be restricted to sale, distribution, or use
23 upon such conditions as the Secretary may prescribe
24 under paragraph (2).

1 “(2) CONDITIONS.— The Secretary may pre-
2 scribe conditions under this section, based on avail-
3 able evidence, with respect to an in vitro clinical test
4 described in paragraph (3), that are determined to
5 be needed due to the potential for harmful effect of
6 such test (including any resulting absence, signifi-
7 cant delay, or discontinuation of appropriate medical
8 treatment), and are necessary to ensure that the test
9 meets the applicable standard.

10 “(3) IN VITRO CLINICAL TESTS SUBJECT TO
11 RESTRICTIONS.—The restrictions or conditions au-
12 thorized under this section may be applied by the
13 Secretary to any high-risk or moderate-risk in vitro
14 clinical test, prescription home-use in vitro clinical
15 test, direct-to-consumer in vitro clinical test, or over-
16 the-counter in vitro clinical test.

17 “(b) LABELING AND ADVERTISING OF A RESTRICTED
18 IN VITRO CLINICAL TEST.—The labeling and advertising
19 of an in vitro clinical test to which restrictions apply under
20 subsection (a) shall bear such appropriate statements of
21 the restrictions as the Secretary may prescribe in an ap-
22 proval under section 587B, an order under section 587D,
23 a determination under section 587F(a), or in regulation,
24 as applicable.

1 “(c) DEVICE RESTRICTIONS.—An in vitro clinical
2 test that was offered as a restricted device prior to the
3 date of enactment of this subchapter—

4 “(1) shall continue to comply with the applica-
5 ble restrictions under section 515 or section 520(e)
6 until this subchapter takes effect; and

7 “(2) except for in vitro clinical tests required to
8 meet the requirements of section 809.30 of title 21,
9 Code of Federal Regulations prior to the effective
10 date of this subchapter specified in section
11 825(a)(1)(A) of the VALID Act of 2022, such re-
12 strictions described in paragraph (1) shall be
13 deemed to be restrictions under this subchapter as
14 of such effective date.

15 **“SEC. 587P. APPEALS.**

16 “(a) SIGNIFICANT DECISION.—

17 “(1) IN GENERAL.—The Secretary shall—

18 “(A) maintain a substantive summary of
19 the scientific and regulatory rationale for any
20 significant decision of the Food and Drug Ad-
21 ministration pursuant to section 587F, regard-
22 ing—

23 “(i) the submission of an application
24 for, or a review of, an in vitro clinical test
25 under section 587B or section 587D;

1 “(ii) an exemption under section
2 587C; or

3 “(iii) any requirements for mitigation
4 measures to an in vitro clinical test or cat-
5 egory of in vitro clinical tests; and

6 “(B) include in such summaries docu-
7 mentation of significant controversies or dif-
8 ferences of opinion and the resolution of such
9 controversies or differences of opinion.

10 “(2) PROVISION OF DOCUMENTATION.—Upon
11 request, the Secretary shall furnish a substantive
12 summary described in paragraph (1) to the person
13 who has made, or is seeking to make, a submission
14 described in such paragraph.

15 “(3) APPLICATION OF LEAST BURDENSOME RE-
16 QUIREMENTS.—The substantive summary required
17 under this subsection shall include a brief statement
18 regarding how the least burdensome requirements
19 were considered and applied consistent with section
20 587AA(c), as applicable.

21 “(b) REVIEW OF SIGNIFICANT DECISIONS.—

22 “(1) REQUEST FOR SUPERVISORY REVIEW OF
23 SIGNIFICANT DECISION.—A developer may request a
24 supervisory review of the significant decision de-
25 scribed in subsection (a)(1). Such review may be

1 conducted at the next supervisory level or higher
2 above the agency official who made the significant
3 decision.

4 “(2) SUBMISSION OF REQUEST.—A developer
5 requesting a supervisory review under paragraph (1)
6 shall submit such request to the Secretary not later
7 than 30 days after the decision for which the review
8 is requested and shall indicate in the request wheth-
9 er such developer seeks an in-person meeting or a
10 teleconference review.

11 “(3) TIMEFRAME.—The Secretary shall sched-
12 ule an in-person or teleconference review, if so re-
13 quested, not later than 30 days after such request
14 is made. The Secretary shall issue a decision to the
15 developer requesting a review under this subsection
16 not later than 45 days after the request is made
17 under paragraph (1), or, in the case of a developer
18 who requests an in-person meeting or teleconference,
19 30 days after such meeting or teleconference.

20 “(c) ADVISORY PANELS.—The process established
21 under subsection (a) shall permit the appellant to request
22 review by an advisory committee established under section
23 587G when there is a dispute involving substantial sci-
24 entific fact. If an advisory panel meeting is held, the Sec-
25 retary shall make a determination under this subsection

1 not later than 45 days after the requested advisory com-
2 mittee meeting has concluded.

3 “(d) **LEAST BURDENSOME REVIEW.**—Any developer
4 who has submitted an application under section 587B or
5 587D may request a supervisory review of a request for
6 additional information during an evaluation of such sub-
7 mission within 60 calendar days of receipt of the addi-
8 tional information request from the Secretary.

9 “(e) **AVAILABILITY OF ALL REMEDIES.**—The proce-
10 dures set forth in this section shall be in addition to, and
11 not in lieu of, other remedies available to the developer.

12 **“SEC. 587Q. ACCREDITED PERSONS.**

13 “(a) **IN GENERAL.**—

14 “(1) **AUTHORIZATION.**—Beginning on the date
15 of enactment of the VALID Act of 2022, the Sec-
16 retary shall accredit persons for any of the following
17 purposes:

18 “(A) Reviewing applications for premarket
19 approval under section 587B and making find-
20 ings with respect to such applications.

21 “(B) Reviewing applications for technology
22 certification under section 587D and making
23 recommendations to the Secretary with respect
24 to such applications.

1 “(C) Conducting inspections as specified in
2 subsection (c) of in vitro clinical test developers
3 and other persons required to register pursuant
4 to section 587J.

5 “(2) PERSONS SUBMITTING APPLICATIONS.—A
6 person submitting an application for premarket ap-
7 proval under section 587B or an application for
8 technology certification under section 587D may
9 submit such application to the Secretary or to a per-
10 son accredited pursuant to subparagraph (A) or (B)
11 of paragraph (1).

12 “(b) ACCREDITED PERSONS APPLICATION REVIEWS,
13 FINDINGS AND RECOMMENDATIONS.—

14 “(1) REQUIREMENTS FOR PREMARKET APPLI-
15 CATION.—

16 “(A) REVIEW AND FINDING REQUIRE-
17 MENTS.—An accredited person receiving an ap-
18 plication for premarket approval under section
19 587B shall either—

20 “(i) provide to the Secretary, together
21 with the application for premarket ap-
22 proval submitted by the applicant, a find-
23 ing that the criteria for approval of the ap-
24 plication under section 587B(e)(2)(A) are
25 met and issue a copy of such finding to the

1 applicant, which finding shall plainly
2 state—

3 “(I) the basis for the accredited
4 person’s finding that the criteria
5 under section 587B(e)(2)(A) are met;
6 and

7 “(II) any proposed restrictions,
8 mitigating measures, or conditions of
9 approval under section 587B(e)(2)(B),
10 as applicable; or

11 “(ii) provide a notification to the ap-
12 plicant that the accredited person cannot
13 find that the criteria for approval of the
14 application under section 587B(e)(2)(A)
15 are met and the reasons for such decision.

16 “(B) REQUESTING MISSING OR CLARI-
17 FYING INFORMATION.—After receipt of an ap-
18 plication from a developer under this section,
19 the Secretary may request missing or clarifying
20 information from the applicant concerning the
21 application, which the developer shall promptly
22 provide.

23 “(C) SECRETARY ACTION ON FINDING
24 THAT APPROVAL CRITERIA ARE MET.—If the
25 accredited person transmits a finding to the

1 Secretary under subparagraph (A)(i), then prior
2 to the date that is 45 calendar days after the
3 transmittal date, the Secretary shall—

4 “(i) approve the application for pre-
5 market approval under section 587B(e)(2)
6 with appropriate restrictions, mitigating
7 measures, or conditions of approval, as ap-
8 plicable; or

9 “(ii) deny approval of the application
10 by issuing a written notice that reflects ap-
11 propriate management input and concur-
12 rence to the accredited person and the ap-
13 plicant detailing the scientific basis for the
14 Secretary’s determination that the criteria
15 for issuance of an approval under section
16 587B(e)(2)(A) have not been met.

17 “(D) EFFECT OF INACTION ON FINDING.—

18 If the Secretary fails to take an action under
19 subparagraph (C) the Secretary shall—

20 “(i) within 45 calendar days after the
21 transmittal date, provide written feedback
22 to the applicant that—

23 “(I) includes all outstanding
24 issues with the application preventing

1 the Secretary from taking an action
2 under subparagraph (B);

3 “(II) reflects appropriate man-
4 agement input and concurrence; and

5 “(III) includes action items for
6 the Secretary, the applicant, or both,
7 as appropriate, with an estimated date
8 of completion for the Secretary and
9 the applicant to complete their respec-
10 tive tasks, as applicable; and

11 “(ii) promptly schedule a meeting or
12 teleconference to discuss the feedback pro-
13 vided under clause (i), unless the Secretary
14 and applicant agree that the outstanding
15 issues are adequately presented through
16 written correspondence and a meeting or
17 teleconference is not necessary.

18 “(2) REQUIREMENTS FOR TECHNOLOGY CER-
19 TIFICATION.—

20 “(A) REVIEW AND RECOMMENDATION RE-
21 QUIREMENTS.—An accredited person receiving
22 an application for technology certification under
23 section 587D shall either—

24 “(i) provide to the Secretary, together
25 with the application for technology certifi-

1 cation submitted by the applicant, a rec-
2 ommendation that the criteria for issuance
3 of a technology certification order under
4 section 587D(d)(3) are met and issue a
5 copy of such recommendation to the appli-
6 cant, which recommendation shall plainly
7 state the basis for the accredited person's
8 recommendation that the criteria under
9 section 587D(d)(3) are met; or

10 “(ii) provide a notification to the ap-
11 plicant that the accredited person cannot
12 recommend that the criteria for issuance of
13 a technology certification order under sec-
14 tion 587D(d)(3) are met and the reasons
15 for such decision.

16 “(B) REQUESTING MISSING OR CLARI-
17 FYING INFORMATION.—After receipt of an ap-
18 plication under this section, the accredited per-
19 son may request missing or clarifying informa-
20 tion from the applicant concerning the applica-
21 tion, which the applicant shall promptly pro-
22 vide.

23 “(C) SECRETARY ACTION ON REC-
24 OMMENDATION FOR ISSUANCE OF A TECH-
25 NOLOGY CERTIFICATION ORDER.—If the accred-

1 ited person transmits a recommendation to the
2 Secretary under clause (i) of subparagraph (A),
3 then prior to the date that is 60 calendar days
4 after the transmittal date the Secretary shall—

5 “(i) issue the technology certification
6 order under section 587D(d)(3), consistent
7 with such recommendation from the ac-
8 credited person; or

9 “(ii) deny approval of the application
10 by issuing a written notice to the accred-
11 ited person and the applicant detailing the
12 scientific basis for a determination by the
13 Secretary that the criteria for issuance of
14 a technology certification order under sec-
15 tion 587D(d)(3) have not been met.

16 “(c) REQUIREMENTS FOR INSPECTIONS.—

17 “(1) IN GENERAL.—When conducting inspec-
18 tion, persons accredited under subsection (a)(1)(B)
19 shall record in writing their specific observations and
20 shall present their observations to the designated
21 representative of the inspected establishment.

22 “(2) INSPECTION REPORT REQUIREMENTS.—
23 Each person accredited under subsection (a)(1)(C)
24 shall prepare and submit to the Secretary an inspec-
25 tion report in a form and manner designated by the

1 Secretary for conducting inspections. Any statement
2 or representation made by an employee or agent of
3 an establishment to a person accredited to conduct
4 inspections under subsection (a)(1)(C) shall be sub-
5 ject to section 1001 of title 18, United States Code.

6 “(3) SAVINGS CLAUSE.—Nothing in this section
7 affects the authority of the Secretary to inspect any
8 in vitro clinical test developer or other person reg-
9 istered under section 587J or recognize inspections
10 conducted by auditing organizations as described
11 under section 704(g)(15).

12 “(4) INSPECTION LIMITATIONS.—The Secretary
13 shall ensure that inspections carried out under this
14 section are not duplicative of inspections carried out
15 under section 353 of the Public Health Service Act.
16 Inspections under this section shall be limited to the
17 data and information necessary—

18 “(A) for routine surveillance activities of
19 facilities associated with an approved applica-
20 tion under section 587B or issuance of a tech-
21 nology certification order under section 587D;
22 or

23 “(B) to meet the requirements for pre-
24 market approval under section 587B or

1 issuance of a technology certification order
2 under section 587D, as applicable.

3 “(d) ACCREDITATION.—

4 “(1) ACCREDITATION PROGRAM.—The Sec-
5 retary may provide for accreditation under this sec-
6 tion through programs administered by the Food
7 and Drug Administration, by other non-Federal gov-
8 ernment agencies, or by qualified nongovernmental
9 organizations. A person may be accredited for the
10 review of applications submitted under sections
11 587B as described in subsection (a)(1)(A), for the
12 review of applications submitted under section 587D
13 as described in subsection (a)(1)(B), and to conduct
14 inspection activities under subsection (a)(1)(C), or
15 for a subset of such reviews or activities.

16 “(2) ELIGIBLE PERSONS.—

17 “(A) MINIMUM QUALIFICATIONS.—An ac-
18 credited person, at a minimum, shall—

19 “(i) not be an employee of the Federal
20 Government;

21 “(ii) not engage in the activities of a
22 developer, as defined in section 587(7);

23 “(iii) not be a person required to reg-
24 ister under section 587J, unless such per-
25 son has established sufficient processes

1 and protocols to separate activities to de-
2 velop in vitro clinical tests and the activi-
3 ties for which such person would be ac-
4 credited under subsection (a) and discloses
5 applicable information under this section;

6 “(iv) not be owned or controlled by,
7 and shall have no organizational, material,
8 or financial affiliation with, an in vitro
9 clinical test developer or other person re-
10 quired to register under section 587J;

11 “(v) be a legally constituted entity
12 permitted to conduct the activities for
13 which it seeks accreditation;

14 “(vi) ensure that the operations of
15 such person are in accordance with gen-
16 erally accepted professional and ethical
17 business practices; and

18 “(vii) include in its request for accred-
19 itation a commitment to, at the time of ac-
20 creditation and at any time it is per-
21 forming activities pursuant to this sec-
22 tion—

23 “(I) certify that the information
24 reported to the Secretary accurately
25 reflects the data or protocol reviewed,

1 and the documented inspection find-
2 ings, as applicable;

3 “(II) limit work to that for which
4 competence and capacity are available;

5 “(III) treat information received
6 or learned, records, reports, and rec-
7 ommendations as proprietary informa-
8 tion of the person submitting such in-
9 formation; and

10 “(IV) in conducting the activities
11 for which the person is accredited in
12 respect to a particular in vitro clinical
13 test, protect against the use of any
14 employee or consultant who has a fi-
15 nancial conflict of interest regarding
16 that in vitro clinical test.

17 “(B) WAIVER.—The Secretary may waive
18 any requirements in clauses (i), (ii), (iii), or (iv)
19 of subparagraph (A) upon making a determina-
20 tion that such person has implemented other
21 appropriate controls sufficient to ensure a com-
22 petent and impartial review.

23 “(3) ACCREDITATION PROCESS.—

24 “(A) ACCREDITATION PROCESS GUIDANCE
25 AND REGULATIONS.—Not later than 180 days

1 after the date of enactment of the VALID Act
2 of 2022, the Secretary shall issue draft guid-
3 ance specifying the process for submitting a re-
4 quest for accreditation and reaccreditation
5 under this section, including the form and con-
6 tent of information to be submitted, including
7 the criteria that the Secretary will consider to
8 accredit or deny accreditation and, not later
9 than 1 year after the close of the comment pe-
10 riod for the draft guidance, issue final guid-
11 ance.

12 “(B) RESPONSE TO REQUEST.—The Sec-
13 retary shall respond to a request for accredita-
14 tion or reaccreditation within 60 calendar days
15 of the receipt of the request. The Secretary’s
16 response may be to accredit or reaccredit the
17 person, to deny accreditation, or to request ad-
18 ditional information in support of the request.
19 If the Secretary requests additional informa-
20 tion, the Secretary shall respond within 60 cal-
21 endar days of receipt of such additional infor-
22 mation to accredit or deny the accreditation.

23 “(C) TYPE OF ACCREDITATION.—The ac-
24 creditation or reaccreditation of a person shall
25 specify the particular activity or activities under

1 subsection (a) for which such person is accred-
2 ited, and shall include any limitation to certain
3 eligible in vitro clinical tests.

4 “(D) PUBLIC LIST.—The Secretary shall
5 publish on the website of the Food and Drug
6 Administration a list of persons who are accred-
7 ited under this section. Such list shall be up-
8 dated on at least a monthly basis. The list shall
9 specify the particular activity or activities under
10 this section for which the person is accredited.

11 “(E) AUDIT.—The Secretary may audit
12 the performance of persons accredited under
13 this section for purposes of ensuring that such
14 persons continue to meet the published criteria
15 for accreditation, and may modify the scope or
16 particular activities for which a person is ac-
17 credited if the Secretary determines that such
18 person fails to meet one or more criteria for ac-
19 creditation.

20 “(F) SUSPENSION OR WITHDRAWAL.—The
21 Secretary may suspend or withdraw accredita-
22 tion of any person accredited under this section,
23 after providing notice and an opportunity for an
24 informal hearing, when such person is substan-
25 tially not in compliance with the requirements

1 of this section or the published criteria for ac-
2 creditation, or poses a threat to public health,
3 or fails to act in a manner that is consistent
4 with the purposes of this section.

5 “(G) REACCREDITATION.—Accredited per-
6 sons may be initially accredited for up to 3
7 years. After expiration of such initial period,
8 persons may be reaccredited for unlimited addi-
9 tional 5-year periods, as determined by the Sec-
10 retary.

11 “(e) COMPENSATION OF ACCREDITED PERSONS.—
12 Compensation of an accredited person shall be determined
13 by agreement between the accredited person and the per-
14 son who engages the services of the accredited person, and
15 shall be paid by the person who engages such services.

16 “(f) INTERNATIONAL HARMONIZATION.—Notwith-
17 standing any other provision of this section, to facilitate
18 international harmonization the Secretary may recognize
19 persons accredited or recognized by governments, who
20 have also entered into information sharing agreements, in-
21 cluding confidentiality commitments, with the Commis-
22 sioner of Food and Drugs.

23 “(g) INFORMATION SHARING AGREEMENTS.—An ac-
24 credited person may enter into an agreement with a test
25 developer to provide information to the comprehensive test

1 information system under section 587T, including any re-
2 quirements under section 587J.

3 “(h) REPORTS.—Not later than 2 years after the ef-
4 fective date of the VALID Act of 2022, and annually
5 thereafter for the next 4 years, the Secretary shall post
6 on the website of the Food and Drug Administration, a
7 report describing the Secretary’s performance in imple-
8 menting this section, including the Secretary’s progress in
9 minimizing duplicative reviews of applications for which
10 an accredited person finds the criteria for approval are
11 met. Such reports shall include, for each period—

12 “(1) with regard to premarket approval applica-
13 tions—

14 “(A) the total number of findings trans-
15 mitted to the Secretary under subsection
16 (b)(1)(A)(i);

17 “(B) the total number of determinations
18 made by the Secretary under subsection
19 (b)(1)(B)(i) within 30 calendar days of the
20 transmittal date to approve an application;

21 “(C) the total number of determinations
22 made by the Secretary under subsection
23 (b)(1)(B)(ii) within 30 calendar days of the
24 transmittal date to deny approval of an applica-
25 tion; and

1 “(D) the total number of applications that
2 were approved and the total number of applica-
3 tions that were denied approval, after the Sec-
4 retary failed to make a determination within 30
5 calendar days of the transmittal date under
6 subsection (b)(1)(B); and

7 “(2) with regard to applications for technology
8 certification—

9 “(A) the total number of recommendations
10 transmitted to the Secretary under subsection
11 (b)(2)(A)(i);

12 “(B) the total number of determinations
13 made by the Secretary under subsection
14 (b)(2)(B)(i) to issue a technology certification
15 order, including determinations made within 30
16 days of the transmittal date;

17 “(C) the total number of determinations
18 made by the Secretary under subsection
19 (b)(2)(B)(ii) to deny the application for tech-
20 nology certification, including determinations
21 made within 30 calendar days of the trans-
22 mittal date; and

23 “(D) the total number of technology cer-
24 tification orders issued, and the total number of
25 applications for technology certification that

1 were denied, including applications denied after
2 the Secretary failed to make a determination
3 within 30 calendar days of the transmittal date
4 under subsection (b)(2)(B).

5 **“SEC. 587R. RECOGNIZED STANDARDS.**

6 “(a) IN GENERAL.—The Secretary may recognize all
7 or part of appropriate standards established by nationally
8 or internationally recognized standards development orga-
9 nizations for which a person may submit a declaration of
10 conformity in order to meet a requirement under this sub-
11 chapter to which that standard is applicable. Standards
12 for in vitro diagnostic devices previously recognized under
13 section 514(c) shall be considered recognized standards
14 under this section. Recognized and proposed standards
15 shall be accessible to the public at no charge. The applica-
16 tion of any such consensus standard shall only apply pro-
17 spectively. The Secretary shall issue regulations estab-
18 lishing the criteria and process, for such recognition and
19 adoption.

20 “(b) AMENDMENT PROCESS.—The procedures estab-
21 lished in this section or in regulation or guidance issued
22 under this section shall apply to amendment of an existing
23 standard.

1 **“SEC. 587S. INVESTIGATIONAL USE.**

2 “(a) IN GENERAL.—Subject to the conditions pre-
3 scribed in subsections (c), (d), (e), (f), and (g), an in vitro
4 clinical test for investigational use shall be exempt from
5 the requirements of this subchapter, other than sections
6 587A, 587P, 587T, and 587V. The Secretary may amend
7 parts 50, 54, and 56 of title 21 of the Code of Federal
8 Regulations to apply to in vitro clinical tests to permit
9 the investigational use of such tests by experts qualified
10 by scientific training and experience.

11 “(b) REGULATIONS.—

12 “(1) IN GENERAL.—Not later than 2 years
13 after the date of enactment of the VALID Act of
14 2022, the Secretary shall promulgate regulations, or
15 amend existing regulations, to implement this sec-
16 tion.

17 “(2) VARIATION.—The requirements in the reg-
18 ulations promulgated under this section shall take
19 into account variations based on—

20 “(A) the scope and duration of clinical
21 testing to be conducted under investigation that
22 is the subject of such application;

23 “(B) the number of human subjects that
24 are to be involved in such testing;

25 “(C) the need to permit changes to be
26 made to the in vitro clinical test involved during

1 testing conducted in accordance with a plan re-
2 quired under subsection (c)(6); or

3 “(D) whether the clinical testing of such in
4 vitro clinical test is for the purpose of devel-
5 oping data to obtain approval to offer such test.

6 “(c) APPLICATION FOR INVESTIGATIONAL USE.—

7 The following shall apply with respect to in vitro clinical
8 tests for investigational use:

9 “(1) SIGNIFICANT RISK AND OTHER STUD-
10 IES.—In the case of an in vitro clinical test the in-
11 vestigational use of which poses a significant risk to
12 the human subject or involves an exception from in-
13 formed consent for emergency research, a sponsor of
14 an investigation of such a test seeking an investiga-
15 tional use exemption shall submit to the Secretary
16 an investigational use application with respect to the
17 in vitro clinical test in accordance with paragraphs
18 (3) and (4).

19 “(2) NON-SIGNIFICANT RISK STUDIES.—In the
20 case of an in vitro clinical test, the investigational
21 use of which is not described in paragraph (1)—

22 “(A) the sponsor of such investigation
23 shall—

24 “(i) ensure such investigation is con-
25 ducted in compliance with an investiga-

1 tional plan approved by an institutional re-
2 view committee and the labeling of the in
3 vitro clinical test involved clearly and con-
4 spicuously states, ‘For investigational use
5 only’, as specified in paragraph (4)(A)(ii);

6 “(ii) ensure each investigator obtains
7 informed consent as required under part
8 50, 54, and 56 of title 21, Code of Federal
9 Regulations (or any successor regulations),
10 subject to the exceptions set forth in para-
11 graph (6)(C);

12 “(iii) establish and maintain records
13 with respect to all requirements in this
14 subparagraph;

15 “(iv) maintain records and make re-
16 ports as required by the Secretary pursu-
17 ant to regulations issued under subsection
18 (b); and

19 “(v) ensure that investigators monitor
20 investigations, maintain records and make
21 reports as required by the Secretary pursu-
22 ant to regulations issued under subsection
23 (b); and

24 “(B) the sponsor may rely on any excep-
25 tion or exemption described in paragraph (4) or

1 as established by the Secretary in regulations
2 issued under subsection (b).

3 “(3) APPLICATION.—An investigational use ap-
4 plication shall be submitted in such time and man-
5 ner and contain such information as the Secretary
6 may require in regulation, and shall include an in-
7 vestigational plan for proposed clinical testing and
8 assurances that the sponsor submitting the applica-
9 tion will—

10 “(A) establish and maintain records rel-
11 evant to the investigation of such in vitro clin-
12 ical test; and

13 “(B) submit to the Secretary annual re-
14 ports of data obtained as a result of the inves-
15 tigational use of the in vitro clinical test during
16 the period covered by the exemption that the
17 Secretary reasonably determines will enable the
18 Secretary—

19 “(i) to ensure compliance with the
20 conditions for the exemption specified in
21 paragraph (4);

22 “(ii) to review the progress of the in-
23 vestigation involved; and

24 “(iii) to evaluate the ability to meet
25 the applicable standard.

1 “(4) CONDITIONS FOR EXEMPTION.—

2 “(A) IN GENERAL.—An application for an
3 investigational use exemption with respect to a
4 significant risk study shall be granted if each of
5 the following conditions is met:

6 “(i) The risks to the subjects of the in
7 vitro clinical test are outweighed by the an-
8 ticipated benefits of the test to the subjects
9 and the importance of the knowledge to be
10 gained, and adequate assurance of in-
11 formed consent is provided in accordance
12 with paragraphs (6)(B) and (6)(C).

13 “(ii) The proposed labeling for the in
14 vitro clinical test involved clearly and con-
15 spicuously states ‘For investigational use
16 only’.

17 “(iii) Such other requirements the
18 Secretary determines—

19 “(I) are necessary for the protec-
20 tion of the public health and safety;
21 and

22 “(II) do not unduly delay inves-
23 tigation.

24 “(B) CERTAIN SIGNIFICANT RISK STUDIES
25 OF IN VITRO CLINICAL TESTS FOR AN UNMET

1 NEED.—The Secretary shall not impose a limit
2 on the sample size for a significant risk study
3 of an in vitro clinical test that has received
4 breakthrough designation under section 587I.

5 “(5) COORDINATION WITH INVESTIGATIONAL
6 NEW DRUG APPLICATIONS.—Any requirement for
7 the submission of a report to the Secretary pursuant
8 to an application for an investigational new drug ex-
9 emption involving an in vitro clinical test shall su-
10 persede the reporting requirement under paragraph
11 (3)(B), but only to the extent the requirement with
12 respect to the application for exemption with respect
13 to the drug is duplicative of the reporting require-
14 ment under such paragraph.

15 “(6) INVESTIGATIONAL PLAN, PROCEDURES,
16 AND CONDITIONS.—With respect to an investiga-
17 tional plan submitted under paragraph (3), the
18 sponsor submitting such plan shall—

19 “(A) promptly notify the Secretary of the
20 approval or the suspension or termination of
21 the approval of such plan by an institutional re-
22 view committee;

23 “(B) in the case of an in vitro clinical test
24 made available to investigators for clinical test-
25 ing, obtain agreements from each investigator

1 that any testing of the in vitro clinical test in-
2 volving human subjects will be under such in-
3 vestigator’s supervision and in accordance with
4 paragraph (C) and submit such agreements to
5 the Secretary that ensure—

6 “(i) all investigators will comply with
7 this section, regulations promulgated or re-
8 vised under this section, and applicable
9 human subjects regulations; and

10 “(ii) the investigator will ensure
11 that—

12 “(I) informed consent is obtained
13 as required under part 50 of title 21,
14 Code of Federal Regulations (or any
15 successor regulations), amended to
16 apply to in vitro clinical tests; and

17 “(II) the requirements for insti-
18 tutional review board under part 56 of
19 title 21 of the Code of Federal Regu-
20 lations (or successor regulations),
21 amended to apply to in vitro clinical
22 tests, are met; and

23 “(C) ensure that informed consent will be
24 obtained from each human subject (or the rep-
25 resentative of such subject) of proposed clinical

1 testing involving such in vitro clinical test, ex-
2 cept where, subject to such other conditions as
3 the Secretary may prescribe—

4 “(i) the proposed clinical testing poses
5 no more than minimal risk to the human
6 subject and includes appropriate safe-
7 guards to protect the rights, safety, and
8 welfare of the human subject; or

9 “(ii) the investigator conducting or
10 supervising the clinical testing determines
11 in writing that there exists a life-threat-
12 ening situation involving the human sub-
13 ject of such testing which necessitates the
14 use of such in vitro clinical test and it is
15 not feasible to obtain informed consent
16 from the subject and there is not sufficient
17 time to obtain such consent from a rep-
18 resentative of such subject.

19 “(7) CONCURRED BY LICENSED PHYSICIAN.—
20 The determination required by paragraph (6)(C)(ii)
21 shall be concurred in writing by a licensed physician
22 who is not involved in the testing of the human sub-
23 ject with respect to which such determination is
24 made unless immediate use of the in vitro clinical
25 test is required to save the life of the human subject

1 of such testing and there is not sufficient time to ob-
2 tain such concurrence.

3 “(8) SIGNIFICANT RISK.—For purposes of this
4 subsection, the term ‘significant risk’ means, with
5 respect to an in vitro clinical test, that the use of
6 such in vitro clinical test—

7 “(A) is of substantial importance in per-
8 forming an activity or activities described in
9 section 201(ss)(1) for, a serious or life-threat-
10 ening disease or condition without confirmation
11 of the diagnosis by a medically established diag-
12 nostic product or procedure;

13 “(B) requires an invasive sampling proce-
14 dure that presents a significant risk to the
15 human subject, provided that routine
16 venipuncture shall not be considered an invasive
17 sampling procedure; or

18 “(C) otherwise presents a potential for se-
19 rious risk to the health of a human subject.

20 “(d) REVIEW OF APPLICATIONS.—

21 “(1) IN GENERAL.—The Secretary may issue
22 an order approving an investigation as proposed, ap-
23 proving it with conditions or modifications, or dis-
24 approving it.

1 “(2) FAILURE TO ACT.—Unless the Secretary,
2 not later than 30 calendar days after the date of the
3 submission of an application for an investigational
4 use exemption that meets the requirements of sub-
5 section (c), issues an order under paragraph (1) and
6 notifies the sponsor submitting the application, the
7 application shall be treated as approved as of such
8 date without further action by the Secretary.

9 “(3) DENIAL.—The Secretary may deny an in-
10 vestigational use application submitted under this
11 subsection if the Secretary determines that the in-
12 vestigation with respect to which the application is
13 submitted does not conform to the requirements of
14 subsection (c). A notification of such denial sub-
15 mitted to the sponsor with respect to such a request
16 shall contain the order of disapproval and a complete
17 statement of the reasons for the Secretary’s denial
18 of the application.

19 “(e) WITHDRAWAL OF EXEMPTION.—

20 “(1) IN GENERAL.—The Secretary may, by ad-
21 ministrative order, withdraw an exemption approved
22 under this section with respect to an in vitro clinical
23 test, including an exemption treated as approved
24 based on the Secretary’s failure to act pursuant to
25 subsection (d)(2), if the Secretary determines that

1 an investigation conducted under such an exemption
2 does not meet the applicable conditions under sub-
3 section (c)(3) for such exemption.

4 “(2) OPPORTUNITY TO BE HEARD.—

5 “(A) IN GENERAL.—Subject to subpara-
6 graph (B), an order withdrawing an investiga-
7 tional use exemption granted under this section
8 may be issued only after the Secretary provides
9 the sponsor of the in vitro clinical test with an
10 opportunity for an informal hearing.

11 “(B) EXCEPTION.—An order referred to in
12 subparagraph (A) with respect to an investiga-
13 tional use exemption granted under this section
14 may be issued on a preliminary basis before the
15 provision of an opportunity for an informal
16 hearing if the Secretary determines that the
17 continuation of testing under the exemption will
18 result in an unreasonable risk to the public
19 health. The Secretary will provide an oppor-
20 tunity for an informal hearing promptly fol-
21 lowing any preliminary action under this sub-
22 paragraph.

23 “(f) CHANGES.—

24 “(1) IN GENERAL.—The regulations promul-
25 gated under subsection (b) shall provide, with re-

1 spect to an in vitro clinical test for which an exemp-
2 tion under this subsection is in effect, procedures
3 and conditions under which changes are allowed
4 without the additional approval of an application for
5 an exemption or submission of a supplement to such
6 an application. Such regulations shall provide that
7 such a change may be made if—

8 “(A) the sponsor determines, on the basis
9 of credible information (as defined in regula-
10 tions) that the change meets the conditions
11 specified in paragraph (2); and

12 “(B) the sponsor submits to the Secretary,
13 not later than 5 calendar days after making the
14 change, a notice of the change.

15 “(2) CONDITIONS.—The conditions specified in
16 this paragraph are that—

17 “(A) in the case of developmental changes
18 to an in vitro clinical test, including manufac-
19 turing changes, the changes—

20 “(i) do not constitute a significant
21 change in design or in basic principles of
22 operation;

23 “(ii) do not affect the rights, safety,
24 or welfare of the human subjects involved
25 in the investigation; and

1 “(iii) are made in response to infor-
2 mation gathered during the course of an
3 investigation; and

4 “(B) in the case of changes to clinical pro-
5 tocols applicable to the test, the changes do not
6 affect—

7 “(i) the validity of data or information
8 resulting from the completion of an ap-
9 proved clinical protocol, or the relationship
10 of likely patient risk to benefit relied upon
11 to approve a product;

12 “(ii) the scientific soundness of a plan
13 submitted under subsection (c)(3); or

14 “(iii) the rights, safety, or welfare of
15 the human subjects involved in the inves-
16 tigation.

17 “(g) CLINICAL HOLD.—

18 “(1) IN GENERAL.—At any time, the Secretary
19 may impose a clinical hold with respect to an inves-
20 tigation of an in vitro clinical test if the Secretary
21 makes a written determination described in para-
22 graph (2). The Secretary shall, in imposing such
23 clinical hold, specify the basis for the clinical hold,
24 including the specific information available to the
25 Secretary which served as the basis for such clinical

1 hold, and confirm such determination in writing.
2 The applicant may immediately appeal any such de-
3 termination pursuant to section 587P.

4 “(2) DETERMINATION.—

5 “(A) IN GENERAL.—For purposes of para-
6 graph (1), a determination described in this
7 subparagraph with respect to a clinical hold is
8 a determination that, based on credible evi-
9 dence, the in vitro clinical test involved rep-
10 represents an unreasonable risk to the safety of
11 the persons who are the subjects of the clinical
12 investigation, taking into account the qualifica-
13 tions of the clinical investigators, information
14 about the in vitro clinical test, the design of the
15 clinical investigation, the condition for which
16 the in vitro clinical test is to be investigated,
17 and the health status of the subjects involved.

18 “(B) REMOVAL OF CLINICAL HOLD.—Any
19 written request to the Secretary from the spon-
20 sor of an investigation that a clinical hold be re-
21 moved shall receive a decision, in writing and
22 specifying the reasons therefor, within 30 days
23 after receipt of such request. Any such request
24 shall include sufficient information to support
25 the removal of such clinical hold.

1 **“SEC. 587T. COMPREHENSIVE TEST INFORMATION SYSTEM.**

2 “(a) ESTABLISHMENT.—Not later than 2 years after
3 the date of enactment of the VALID Act of 2022, the Sec-
4 retary shall make available a comprehensive test informa-
5 tion system for in vitro clinical tests that is designed to—

6 “(1) provide a transparent interface on the
7 website of the Food and Drug Administration for
8 stakeholders, to the extent permitted by applicable
9 law, which may include access to the—

10 “(A) regulatory pathway designation infor-
11 mation for each in vitro clinical test or tests
12 with the same indications for use;

13 “(B) registration and listing information
14 provided by developers under section 587J, in-
15 cluding the use of a link for labels;

16 “(C) adverse event reports submitted
17 under section 587M, as appropriate;

18 “(D) reports of corrections and removals
19 submitted under section 587N; and

20 “(E) other information pertaining to an in
21 vitro clinical test or tests with the same indica-
22 tions for use, as the Secretary determines ap-
23 propriate; and

24 “(2) provide a secure portal for electronic sub-
25 mission, including applications and other in vitro
26 clinical test submissions, registration and listing in-

1 formation, and adverse event reports, which provides
2 protections from unauthorized disclosure of informa-
3 tion, including of—

4 “(A) trade secret or confidential commer-
5 cial or financial information; and

6 “(B) information that could compromise
7 national security.

8 “(b) **SUBMISSION FUNCTION.**—The comprehensive
9 test information system shall serve as the electronic sub-
10 mission service for test developers submitting information
11 for applications under sections 587B and 587D.

12 **“SEC. 587U. PREEMPTION.**

13 “(a) **IN GENERAL.**—Except as provided in subsection
14 (b), no State, Tribal, or local government (or political sub-
15 division thereof) may establish or continue in effect any
16 requirement—

17 “(1) that is different from, or in addition to,
18 any requirement applicable to an in vitro clinical test
19 under this Act; or

20 “(2) with respect to the analytical validity, clin-
21 ical validity, or safety for individuals who come into
22 contact with such an in vitro clinical test.

23 “(b) **EXCEPTIONS.**—Subsection (a) shall not be con-
24 strued to affect the authority of a State, Tribal, or local
25 government to do any of the following:

1 “(1) To license laboratory personnel, health
2 care practitioners, or health care facilities or to reg-
3 ulate any aspect of a health care practitioner-patient
4 relationship.

5 “(2) To enforce laws of general applicability,
6 such as zoning laws, environmental laws, labor laws,
7 and general business laws.

8 “(3) To authorize laboratories to develop and
9 perform an in vitro clinical test, pursuant to a law
10 enacted by a State prior to January 1, 2022, as long
11 as such law does not impose requirements that are
12 different from any requirement applicable to an in
13 vitro clinical test under this Act. If a State has en-
14 acted such a law, the Secretary shall exempt such
15 test for laboratories in that State from compliance
16 with this subchapter.

17 “(c) CLARIFICATION.—Nothing in this section shall
18 be construed to—

19 “(1) modify any action for damages or the li-
20 ability of any person under the law of any State; or

21 “(2) shift liability to health care practitioners
22 or other users.

23 **“SEC. 587V. ADULTERATION.**

24 “An in vitro clinical test shall be deemed to be adul-
25 terated:

1 “(1) If it consists in whole or in part of any
2 filthy, putrid, or decomposed substance.

3 “(2) If it has been developed, prepared, packed,
4 or held under insanitary conditions whereby it may
5 have been contaminated with filth, or whereby it
6 may have been rendered injurious to health.

7 “(3) If its container or package is composed, in
8 whole or in part, of any poisonous or deleterious
9 substance which may render the contents injurious
10 to health.

11 “(4) If it bears or contains, for purposes of
12 coloring only, a color additive which is unsafe within
13 the meaning of section 721(a).

14 “(5) If its analytical or clinical validity, as ap-
15 plicable, or with respect to a specimen receptacle, its
16 safety, falls below that which it purports or is rep-
17 resented to possess.

18 “(6) If it is required to be, declared to be, pur-
19 ports to be, or is represented as being, in conformity
20 with any performance standard established or recog-
21 nized under section 587R and is not in conformity
22 with such standard.

23 “(7) If it is required to be in compliance with
24 mitigating measures established under section 587E

1 and is not in conformity with such mitigating meas-
2 ures.

3 “(8) If it fails to have in effect an approved
4 premarket application under section 587B, unless
5 such in vitro clinical test is in compliance with the
6 requirements for—

7 “(A) offering without an approved pre-
8 market application under section 587D(b)(1);

9 “(B) an exemption from premarket ap-
10 proval under section 587C or 587G; or

11 “(C) investigational use pursuant to sec-
12 tion 587S.

13 “(9) If it is not in conformity with any condi-
14 tion established under section 587B or 587D.

15 “(10) If it purports to be an in vitro clinical
16 test subject to an exemption under section 587C and
17 it fails to meet or maintain any criteria, condition,
18 or requirement of such exemption.

19 “(11) If it has been granted an exemption
20 under section 587S for investigational use, and the
21 person granted such exemption or any investigator
22 who uses such in vitro clinical test under such ex-
23 emption fails to comply with a requirement pre-
24 scribed by or under such section.

1 “(12) If it fails to meet the quality require-
2 ments prescribed in or established under section
3 587K (as applicable), or the methods used in, or fa-
4 cilities or controls used for, its development, pack-
5 aging, storage, or installation are not in conformity
6 with applicable requirements established under such
7 section.

8 “(13) If it has been developed, processed, pack-
9 aged, or held in any establishment, factory, or ware-
10 house and the owner, operator or agent of such es-
11 tablishment, factory, or warehouse delays, denies, or
12 limits an inspection, or refuses to permit entry or in-
13 spection.

14 “(14) If it is not in compliance with any restric-
15 tion required under section 587O.

16 **“SEC. 587W. MISBRANDING.**

17 “An in vitro clinical test shall be deemed to be mis-
18 branded:

19 “(1) If its labeling is false or misleading in any
20 particular.

21 “(2) If in a package form unless it bears a label
22 containing—

23 “(A) the name and place of business of the
24 test developer, packager, or distributor; and

1 “(B) an accurate statement of the quantity
2 of contents in terms of weight, measure, or nu-
3 merical count with respect to small packages,
4 unless an exemption is granted by the Secretary
5 by the issuance of guidance.

6 “(3) If any word, statement, or other informa-
7 tion required by or under authority of this Act to
8 appear on the label or labeling, including a test re-
9 port, is not prominently placed thereon with such
10 conspicuousness (as compared with other words,
11 statements, designs, or devices, in the labeling) and
12 in such terms as to render it likely to be read and
13 understood by the ordinary individual under cus-
14 tomary conditions of purchase and use.

15 “(4) Unless its labeling bears adequate direc-
16 tions for use and such adequate warnings as are
17 necessary for the protection of users of the in vitro
18 clinical test and recipients of the results of such in
19 vitro clinical test, including patients, consumers, do-
20 nors, and related health care professionals. Required
21 labeling for in vitro clinical tests intended for use in
22 health care facilities, blood establishments, or by a
23 health care professional may be made available solely
24 by electronic means, provided that the labeling com-
25 plies with all applicable requirements of law, and

1 that the test developer, or distributor affords such
2 users the opportunity to request the labeling in
3 paper form, and after such request, promptly pro-
4 vides the requested information without additional
5 cost.

6 “(5) If there is a reasonable probability that it
7 could cause serious or adverse health consequences
8 or death, including through absence, delay, or dis-
9 continuation in diagnosis or treatment, when used in
10 the manner prescribed, recommended, or suggested
11 in the labeling thereof.

12 “(6) If it was developed, sterilized, packaged,
13 repackaged, relabeled, installed, or imported in an
14 establishment not duly registered under section
15 587J or it was not included in a listing under sec-
16 tion 587J, in accordance with timely reporting re-
17 quirements under this subchapter.

18 “(7) In the case of any in vitro clinical test sub-
19 ject to restrictions under section 587O, (1) if its ad-
20 vertising is false or misleading in any particular, (2)
21 if it is offered for clinical use, sold, distributed, or
22 used in violation of such restrictions, or (3) unless
23 the test developer or distributor includes in all ad-
24 vertisements and other descriptive printed matter
25 that such person issues or causes to be issued, a

1 brief statement of the indications for use of the in
2 vitro clinical test and relevant warnings, precautions,
3 side effects, and contraindications. This paragraph
4 shall not be applicable to any printed matter that
5 the Secretary determines to be labeling as defined in
6 section 201(m).

7 “(8) If it is subject to a mitigating measure es-
8 tablished under section 587E and does not bear such
9 labeling as may be prescribed in such mitigating
10 measure.

11 “(9) If it is subject to a standard established
12 under section 587R and it does not bear such label-
13 ing as may be prescribed in such standard.

14 “(10) Unless it bears such labeling as may be
15 required by or established under an applicable label-
16 ing requirement under this Act.

17 “(11) If there was a failure to comply with any
18 requirement prescribed in or under section 587D,
19 587J, 587K, 587L, 587M, 587N, 587X, 587Y,
20 587Z, or to provide any report, material, or other in-
21 formation required with respect to in vitro clinical
22 tests under this subchapter.

23 **“SEC. 587X. POSTMARKET SURVEILLANCE.**

24 “(a) IN GENERAL.—

1 “(1) IN GENERAL.—In addition to other appli-
2 cable requirements under this Act, the Secretary
3 may issue an order requiring a developer of a high-
4 risk or moderate-risk in vitro clinical test to conduct
5 postmarket surveillance of such in vitro clinical test,
6 if the failure of the in vitro clinical test is reasonably
7 likely to result in serious adverse health con-
8 sequences or death from use of such in vitro clinical
9 test.

10 “(2) CONSIDERATION.—In determining whether
11 to require a developer to conduct postmarket surveil-
12 lance of an in vitro clinical test, the Secretary shall
13 take into consideration the benefits and risks for the
14 patient and the least burdensome requirements
15 under section 587AA(c).

16 “(b) SURVEILLANCE APPROVAL.—

17 “(1) IN GENERAL.—Each developer required to
18 conduct surveillance of an in vitro clinical test shall
19 submit, within 30 days of receiving an order from
20 the Secretary, a plan for the required surveillance.
21 The Secretary, within 60 days of the receipt of such
22 plan, shall determine if the person designated to
23 conduct the surveillance has the appropriate quali-
24 fications and experience to undertake such surveil-
25 lance and if the plan will result in useful data that

1 can reveal unforeseen adverse events or other infor-
2 mation necessary to protect the health of patients or
3 the public.

4 “(2) **TIMELINE.**—The developer shall com-
5 mence surveillance under this section not later than
6 15 months after the day on which the Secretary or-
7 ders such postmarket surveillance, unless the Sec-
8 retary determines more time is needed to commence
9 surveillance.

10 “(3) **PROSPECTIVE SURVEILLANCE.**—The Sec-
11 retary may order a prospective surveillance period of
12 up to 3 years. Any determination by the Secretary
13 that a longer period is necessary shall be made by
14 mutual agreement between the Secretary and the de-
15 veloper or, if no agreement can be reached, upon the
16 completion of a dispute resolution process pursuant
17 to section 562.

18 **“SEC. 587Y. ELECTRONIC FORMAT FOR SUBMISSIONS.**

19 “(a) **IN GENERAL.**—All submissions to the Food and
20 Drug Administration with respect to an in vitro clinical
21 test, unless otherwise agreed to by the Secretary, shall—

22 “(1) be made electronically; and

23 “(2) with respect to the information required
24 under sections 587B and 587D, utilize the system
25 described in section 587T.

1 “(b) ELECTRONIC FORMAT.—Beginning on such date
2 as the Secretary specifies in final guidance issued under
3 subsection (c), submissions for in vitro clinical tests, in-
4 cluding recommendations submitted by accredited and rec-
5 ognized persons under section 587Q, and any appeals of
6 action taken by the Secretary with respect to such submis-
7 sions, shall be submitted in such electronic format as spec-
8 ified by the Secretary in such guidance.

9 “(c) GUIDANCE.—The Secretary shall issue guidance
10 implementing this section. Such guidance may—

11 “(1) provide standards for the electronic sub-
12 mission required under subsection (a) or the submis-
13 sion in electronic format required under subsection
14 (b);

15 “(2) set forth criteria for waivers of, or exemp-
16 tions from, the requirements of subsection (a) or (b);
17 and

18 “(3) provide any other information for the effi-
19 cient implementation and enforcement of this sec-
20 tion.

21 **“SEC. 587Z. POSTMARKET REMEDIES.**

22 “(a) SAFETY NOTICE.—

23 “(1) IN GENERAL.—If the Secretary determines
24 that an in vitro clinical test presents an unreason-
25 able risk of substantial harm to the public health,

1 and notification under this subsection is necessary to
2 eliminate the unreasonable risk of such harm and no
3 more practicable means is available under the provi-
4 sions of this Act (other than this section) to elimi-
5 nate the risk, the Secretary may issue such order as
6 may be necessary to ensure that adequate safety no-
7 tice is provided in an appropriate form, by the per-
8 sons and means best suited under the circumstances,
9 to all health care professionals who prescribe, order,
10 or use the in vitro clinical test and to any other per-
11 son (including developers, importers, distributors, re-
12 tailers, and users) who should properly receive such
13 notice.

14 “(2) NOTICE TO INDIVIDUALS.—An order
15 under this subsection shall require that the individ-
16 uals subject to the risk with respect to which the
17 order is to be issued be included in the persons to
18 be notified of the risk unless the Secretary deter-
19 mines that notice to such individuals would present
20 a greater danger to the health of such individuals
21 than no such notice. If the Secretary makes such a
22 determination with respect to such individuals, the
23 order shall require the health care professionals who
24 prescribed, ordered, or used the in vitro clinical test
25 provide notification to the individuals for whom the

1 health professionals prescribed, ordered, or used
2 such test, of the risk presented by such in vitro clin-
3 ical test and of any action which may be taken by
4 or on behalf of such individuals to eliminate or re-
5 duce such risk. Before issuing an order under this
6 subsection, the Secretary shall consult with the per-
7 sons required to give notice under the order.

8 “(b) REPAIR, REPLACEMENT, OR REFUND.—

9 “(1) DETERMINATION AFTER AN INFORMAL
10 HEARING.—

11 “(A) IN GENERAL.—If, after affording op-
12 portunity for an informal hearing, the Secretary
13 determines that—

14 “(i) an in vitro clinical test presents
15 an unreasonable risk of substantial harm
16 to the public health;

17 “(ii) there are reasonable grounds to
18 believe that the in vitro clinical test was
19 not properly developed or manufactured
20 considering the state of the art as it ex-
21 isted at the time of its development;

22 “(iii) there are reasonable grounds to
23 believe that the unreasonable risk was not
24 caused by failure of a person other than a
25 developer, importer, distributor, or retailer

1 of the in vitro clinical test to exercise due
2 care in the installation, maintenance, re-
3 pair, or use of the in vitro clinical test; and
4 “(iv) the notice authorized by sub-
5 section (a) would not by itself be sufficient
6 to eliminate the unreasonable risk and ac-
7 tion described in paragraph (2) of this sub-
8 section is necessary to eliminate such risk,
9 the Secretary may order the developer, im-
10 porter, or any distributor of such in vitro clin-
11 ical test, or any combination of such persons, to
12 submit to him within a reasonable time a plan
13 for taking one or more of the actions described
14 in paragraph (2). An order issued under the
15 preceding sentence which is directed to more
16 than one person shall specify which person may
17 decide which action shall be taken under such
18 plan and the person specified shall be the per-
19 son who the Secretary determines bears the
20 principal, ultimate financial responsibility for
21 action taken under the plan unless the Sec-
22 retary cannot determine who bears such respon-
23 sibility or the Secretary determines that the
24 protection of the public health requires that
25 such decision be made by a person (including a

1 health professional or user of the in vitro clin-
2 ical test) other than the person the Secretary
3 determines bears such responsibility.

4 “(B) SECRETARY APPROVAL OF PLAN.—
5 The Secretary shall approve a plan submitted
6 pursuant to an order issued under subpara-
7 graph (A) unless the Secretary determines
8 (after affording opportunity for an informal
9 hearing) that the action or actions to be taken
10 under the plan or the manner in which such ac-
11 tion or actions are to be taken under the plan
12 will not assure that the unreasonable risk with
13 respect to which such order was issued will be
14 eliminated. If the Secretary disapproves a plan,
15 the Secretary shall order a revised plan to be
16 submitted within a reasonable time. If the Sec-
17 retary determines (after affording opportunity
18 for an informal hearing) that the revised plan
19 is unsatisfactory or if no revised plan or no ini-
20 tial plan has been submitted to the Secretary
21 within the prescribed time, the Secretary
22 shall—

23 “(i) prescribe a plan to be carried out
24 by the person or persons to whom the

1 order issued under subparagraph (A) was
2 directed; or

3 “(ii) after affording an opportunity
4 for an informal hearing, by order prescribe
5 a plan to be carried out by a person who
6 is a developer, importer, distributor, or re-
7 tailer of the in vitro clinical test with re-
8 spect to which the order was issued but to
9 whom the order under subparagraph (A)
10 was not directed.

11 “(2) ACTIONS ON A PLAN.—The actions that
12 may be taken under a plan submitted under an
13 order issued under paragraph (1)(A) are as follows:

14 “(A) To repair the in vitro clinical test so
15 that it does not present the unreasonable risk
16 of substantial harm with respect to which the
17 order under paragraph (1)(A) was issued.

18 “(B) To replace the in vitro clinical test
19 with a like or equivalent test which is in con-
20 formity with all applicable requirements of this
21 Act.

22 “(C) To refund the purchase price of the
23 in vitro clinical test (less a reasonable allowance
24 for use if such in vitro clinical test has been in
25 the possession of the user for one year or more

1 at the time of notice ordered under subsection
2 (a), or at the time the user receives actual no-
3 tice of the unreasonable risk with respect to
4 which the order was issued under paragraph
5 (1)(A), whichever occurs first).

6 “(3) NO CHARGE.—No charge shall be made to
7 any person (other than a developer, importer, dis-
8 tributor, or retailer) for using a remedy described in
9 paragraph (2) and provided under an order issued
10 under paragraph (1), and the person subject to the
11 order shall reimburse each person (other than a de-
12 veloper, manufacturer, importer, distributor, or re-
13 tailer) who is entitled to such a remedy for any rea-
14 sonable and foreseeable expenses actually incurred
15 by such person in using such remedy.

16 “(c) REIMBURSEMENT.—An order issued under sub-
17 section (b)(1)(A) with respect to an in vitro clinical test
18 may require any person who is a developer, importer, dis-
19 tributor, or retailer of the in vitro clinical test to reimburse
20 any other person who is a developer, importer, distributor,
21 or retailer of such in vitro clinical test for such other per-
22 son’s expenses actually incurred in connection with car-
23 rying out the order if the Secretary determines such reim-
24 bursement is required for the protection of the public
25 health. Any such requirement shall not affect any rights

1 or obligations under any contract to which the person re-
2 ceiving reimbursement or the person making such reim-
3 bursement is a party.

4 “(d) RECALL AUTHORITY.—

5 “(1) IN GENERAL.—If the Secretary finds that
6 there is a reasonable probability that an in vitro
7 clinical test approved under section 587B or offered
8 under a technology certification order under section
9 587D would cause serious, adverse health con-
10 sequences or death, including by the absence, signifi-
11 cant delay, or discontinuation of appropriate medical
12 treatment, the Secretary shall issue an order requir-
13 ing the appropriate person (including the developers,
14 importers, distributors, or retailers of the in vitro
15 clinical test)—

16 “(A) to immediately cease distribution of
17 such in vitro clinical test; and

18 “(B) to immediately notify health profes-
19 sionals and applicable in vitro clinical test user
20 facilities of the order and to instruct such pro-
21 fessionals and facilities to cease use of such in
22 vitro clinical test.

23 “(2) INFORMAL HEARING.—The order issued
24 under paragraph (1)(A), shall provide the person
25 subject to the order with an opportunity for an in-

1 formal hearing, to be held not later than 10 calendar
2 days after the date of the issuance of the order, on
3 the actions required by the order and on whether the
4 order should be amended to require a recall of such
5 in vitro clinical test. If, after providing an oppor-
6 tunity for such a hearing, the Secretary determines
7 that inadequate grounds exist to support the actions
8 required by the order, the Secretary shall vacate the
9 order.

10 “(3) AMENDED ORDER.—

11 “(A) IN GENERAL.—If, after providing an
12 opportunity for an informal hearing under
13 paragraph (2), the Secretary determines that
14 the order should be amended to include a recall
15 of the in vitro clinical test with respect to which
16 the order was issued, the Secretary shall, except
17 as provided in subparagraph (B), amend the
18 order to require a recall. The Secretary shall
19 specify a timetable in which the recall will occur
20 and shall require periodic reports describing the
21 progress of the recall.

22 “(B) REQUIREMENTS.—An amended order
23 under subparagraph (A)—

24 “(i) shall not include recall of the in
25 vitro clinical test from individuals;

1 “(ii) shall not include recall of an in
2 vitro clinical test from test user facilities if
3 the Secretary determines that the risk of
4 recalling such in vitro clinical test from the
5 facilities presents a greater health risk
6 than the health risk of not recalling the in
7 vitro clinical test from use; and

8 “(iii) shall provide for notice to indi-
9 viduals subject to the risks associated with
10 the use of such in vitro clinical test. In
11 providing the notice required by this
12 clause, the Secretary may use the assist-
13 ance of health professionals who pre-
14 scribed, ordered, or used such an in vitro
15 clinical test for individuals.

16 “(4) CLARIFICATION.—The remedy provided by
17 this subsection shall be in addition to remedies pro-
18 vided by subsections (a), (b), and (c).

19 **“SEC. 587AA. APPLICABILITY.**

20 “(a) IN GENERAL.—An in vitro clinical test shall be
21 subject to the requirements of this subchapter, except as
22 otherwise provided in this subchapter. Laboratory oper-
23 ations shall not be subject to the requirements of this sub-
24 chapter.

1 “(b) INTERSTATE COMMERCE.—Any in vitro clinical
2 test that is offered, including by making available for clin-
3 ical use in the United States is deemed to be an act that
4 constitutes introduction into interstate commerce for pur-
5 poses of enforcing the requirements of this Act.

6 “(c) LEAST BURDENSOME REQUIREMENTS.—

7 “(1) IN GENERAL.—In carrying out this sub-
8 chapter, the Secretary shall consider the least bur-
9 densome means necessary to meet the applicable
10 standard, and other regulatory requirements, as de-
11 termined by the Secretary.

12 “(2) NECESSARY DEFINED.—For purposes of
13 paragraph (1), the term ‘necessary’ means the min-
14 imum required information that would support a de-
15 termination by the Secretary that the application
16 meet the applicable standard or regulatory require-
17 ment, as determined by the Secretary.

18 “(d) SERVICE OF ORDERS.—Orders of the Secretary
19 under this section with respect to applications under sub-
20 section (a) or (b) of section 587B or supplements under
21 subsection (f) of such section shall be served—

22 “(1) in person by any officer or employee of the
23 Department of Health and Human Services des-
24 ignated by the Secretary; or

1 “(2) by mailing the order by registered mail or
2 certified mail or electronic equivalent addressed to
3 the applicant at the last known address in the
4 records of the Secretary.

5 “(e) LABORATORIES AND BLOOD AND TISSUE ES-
6 TABLISHMENTS.—

7 “(1) RELATION TO LABORATORY CERTIFI-
8 CATION PURSUANT TO SECTION 353 OF THE PUBLIC
9 HEALTH SERVICE ACT.—Nothing in this subchapter
10 shall be construed to modify the authority of the
11 Secretary with respect to laboratories or clinical lab-
12 oratories under section 353 of the Public Health
13 Service Act.

14 “(2) AVOIDING DUPLICATION.—In imple-
15 menting this subchapter, the Secretary shall avoid
16 issuing or enforcing regulations or guidance that are
17 duplicative of regulations or guidance under section
18 353 of the Public Health Service Act.

19 “(3) BLOOD AND TISSUE.—Nothing in this sub-
20 chapter shall be construed to modify the authority of
21 the Secretary with respect to laboratories, establish-
22 ments, or other facilities to the extent they are en-
23 gaged in the propagation, manufacture, or prepara-
24 tion, including filling, labeling, packaging, and stor-
25 age, of blood, blood components, human cells, tis-

1 sues, or tissue products pursuant to any require-
2 ments under this Act or section 351 or 361 of the
3 Public Health Service Act.

4 “(f) NOT COMBINATION PRODUCT.—A product con-
5 stituted of a device and an in vitro clinical test is not a
6 combination product and shall be regulated as a device.

7 “(g) PRACTICE OF MEDICINE.—Nothing in this sub-
8 chapter shall be construed to limit or interfere with the
9 authority of a health care practitioner to prescribe or ad-
10 minister any lawfully offered in vitro clinical test for any
11 condition or disease within a legitimate health care practi-
12 tioner-patient relationship pursuant to applicable Federal
13 or State law.

14 “(h) SALE, DISTRIBUTION, LABELING.—Nothing in
15 this section shall be construed to limit the authority of
16 the Secretary to establish or enforce restrictions on the
17 sale, distribution, or labeling of an in vitro clinical test
18 under this Act.

19 “(i) PROMOTION OF UNAPPROVED USES.—Nothing
20 in this section shall be construed to alter any prohibition
21 on the promotion of unapproved uses of legally marketed
22 in vitro clinical tests.

23 **“SEC. 587BB. JUDICIAL REVIEW.**

24 “(a) IN GENERAL.—Not later than 30 days after an
25 order issued pursuant to sections 587B or 587D, any per-

1 son adversely affected by such order may file a petition
2 with the United States Court of Appeals for the District
3 of Columbia or for the circuit wherein such person resides
4 or has a principal place of business for judicial review of
5 such order, in accordance with the procedure set forth in
6 section 517(a).

7 “(b) APPLICATION OF PROVISIONS.—Subsections (a)
8 through (e) of section 517 shall apply with respect to a
9 petition under subsection (a) of this section in the same
10 manner such subsections apply to a petition under section
11 517. Subsection (f) of section 517 shall apply to an order
12 issued under section 587B or 587D.”

13 **SEC. 824. ENFORCEMENT AND OTHER PROVISIONS.**

14 (a) PROHIBITED ACTS.—Section 301 of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C. 331), as
16 amended by section 811, is further amended—

17 (1) in paragraphs (a), (b), (c), (g), (h), (k), (q),
18 (r), and (y), by inserting “in vitro clinical test,”
19 after “device,” each place it appears;

20 (2) in paragraph (g), by inserting after “mis-
21 branded”, “, and the development within any Terri-
22 tory of any in vitro clinical test that is adulterated
23 or misbranded”;

24 (3) in paragraph (y), by inserting “or 587Q”
25 after “section 523” each place it appears;

1 (4) in paragraph (ff), by striking “or device”
2 and inserting “, device, or in vitro clinical test”; and

3 (5) by adding at the end, the following:

4 “(kkk)(1) Forging, counterfeiting, simulating, or
5 falsely representing, or without proper authority using any
6 mark, stamp, tag, label, or other identification upon any
7 in vitro clinical test or container, packaging, or labeling
8 thereof so as to render such in vitro clinical test a counter-
9 feit in vitro clinical test.

10 “(2) Making, selling, disposing of, or keeping in pos-
11 session, control, or custody, or concealing any punch, die,
12 plate, stone, or other thing designed to print, imprint, or
13 reproduce the trademark, trade name, or other identifying
14 mark or imprint of another or any likeness of any of the
15 foregoing upon any in vitro clinical test or container, pack-
16 aging, or labeling thereof so as to render such in vitro
17 clinical test a counterfeit in vitro clinical test.

18 “(3) The doing of any act which causes an in vitro
19 clinical test to be a counterfeit in vitro clinical test, or
20 the sale or dispensing, or the holding for sale or dis-
21 pensing, of a counterfeit in vitro clinical test.

22 “(lll)(1) The introduction or delivery for introduction
23 into interstate commerce of an in vitro clinical test in vio-
24 lation of section 587A(a).

1 “(2) The making of a false, fraudulent, or deceptive
2 statement about an in vitro clinical test that is exempt
3 from premarket review under section 587C.

4 “(3) The failure to maintain complete and accurate
5 documentation for an exemption as required under section
6 587C or the failure to provide labeling required under sec-
7 tion 587L.

8 “(4) With respect to an in vitro clinical test, the sub-
9 mission of any report or listing under this Act that is false
10 or misleading in any material respect.

11 “(5) The failure to comply with a condition of ap-
12 proval, or restriction required under an approved applica-
13 tion under section 587B; the failure to perform a risk
14 analysis required by section 587B; the failure to submit
15 an annual update required under section 587J(c)(2)(B);
16 or the failure to complete postmarket surveillance as re-
17 quired under section 587X.

18 “(6) The failure to comply with applicable require-
19 ments to submit an application or report under section
20 587D(e).

21 “(7) The failure to comply with applicable mitigating
22 measures established under section 587E or to submit,
23 maintain, or make available the documentation required
24 under section 587E(b); or the failure to comply with appli-

1 cable performance standards established under section
2 587R.

3 “(8) The failure to register in accordance with section
4 587J, the failure to provide information required under
5 section 587J(b), or the failure to maintain or submit infor-
6 mation required under section 587J(c).

7 “(9) The failure to comply with requirements under
8 section 587M or 587N, the failure to comply with a re-
9 striction required under section 587O, or the failure to
10 comply with labeling and advertising requirements under
11 section 587O(b).

12 “(10) The failure to comply with the requirements
13 of section 587Q.

14 “(11) The failure to comply with any requirement of
15 section 587S; the failure to furnish any notification, infor-
16 mation, material, or report required under section 587S;
17 or the failure to comply with an order issued under section
18 587S.

19 “(12) The failure to furnish information requested by
20 the Secretary under 587G(d)(2).”.

21 (b) PENALTIES.—Section 303 of the Federal Food,
22 Drug, and Cosmetic Act (21 U.S.C. 333) is amended—

23 (1) in subsection (b)(8), by inserting “or coun-
24 terfeit in vitro clinical test” after “counterfeit drug”;

25 (2) in subsection (c)—

1 (A) by striking “; or (5)” and inserting “;
2 (5)”; and

3 (B) by inserting before the period at the
4 end the following: “; or (6) for having violated
5 section 301(kkk)(2) if such person acted in
6 good faith and had no reason to believe that use
7 of the punch, die, plate, stone, or other thing
8 involved would result in an in vitro clinical test
9 being a counterfeit in vitro clinical test, or for
10 having violated section 301(kkk)(3) if the per-
11 son doing the act or causing it to be done acted
12 in good faith and had no reason to believe that
13 the in vitro clinical test was a counterfeit in
14 vitro clinical test”; and

15 (3) in subsection (f)(1)—

16 (A) in subparagraph (A)—

17 (i) by inserting “or in vitro clinical
18 tests” after “which relates to devices”;

19 (ii) by inserting “or section
20 587Q(a)(1)” after “section 704(g)”; and

21 (iii) by inserting “or in vitro clinical
22 tests, as applicable” before the period at
23 the end of the second sentence; and

1 (B) in subparagraph (B)(i), by striking “or
2 520(f)” and inserting “, 520(f), 587K, or
3 587M,”.

4 (c) SEIZURE.—Section 304 of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 334) is amended—

6 (1) in subsection (a)(2)—

7 (A) by striking “, and (E)” and inserting
8 “, (E)”; and

9 (B) by inserting before the period at the
10 end the following: “, and (F) Any in vitro clin-
11 ical test that is a counterfeit in vitro clinical
12 test, (G) Any container, packaging, or labeling
13 of a counterfeit in vitro clinical test, and (H)
14 Any punch, die, plate, stone, labeling, container,
15 or other thing used or designed for use in mak-
16 ing a counterfeit in vitro clinical test”;

17 (2) in subsection (d)(1), by inserting “in vitro
18 clinical test,” after “device,”; and

19 (3) in subsection (g)—

20 (A) in paragraph (1), by inserting “, in
21 vitro clinical test,” after “device” each place it
22 appears; and

23 (B) in paragraph (2)—

1 (i) in subparagraph (A), by inserting
2 “, in vitro clinical test,” after “device”;
3 and

4 (ii) in subparagraph (B), by inserting
5 “or in vitro clinical test” after “device”
6 each place it appears.

7 (d) DEBARMENT, TEMPORARY DENIAL OF AP-
8 PROVAL, AND SUSPENSION.—Section 306 of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C. 335a) is
10 amended by adding at the end the following:

11 “(n) IN VITRO CLINICAL TESTS; MANDATORY DE-
12 BARMENT REGARDING THIRD-PARTY INSPECTIONS AND
13 REVIEWS.—

14 “(1) IN GENERAL.—If the Secretary finds that
15 a person has been convicted of a felony for a viola-
16 tion of section 301(gg) or 301(kkk)(1), the Sec-
17 retary shall debar such person from being accredited
18 under section 587Q and from carrying out activities
19 under an agreement described in section 803(b).

20 “(2) DEBARMENT PERIOD.—The Secretary
21 shall debar a person under paragraph (1) for the fol-
22 lowing periods:

23 “(A) The period of debarment of a person
24 (other than an individual) shall not be less than
25 1 year or more than 10 years, but if an act

1 leading to a subsequent debarment under such
2 paragraph occurs within 10 years after such
3 person has been debarred under such para-
4 graph, the period of debarment shall be perma-
5 nent.

6 “(B) The debarment of an individual shall
7 be permanent.

8 “(3) TERMINATION OF DEBARMENT; JUDICIAL
9 REVIEW; OTHER MATTERS.—Subsections (c)(3), (d),
10 (e), (i), (j), and (l)(1) apply with respect to a person
11 (other than an individual) or an individual who is
12 debarred under paragraph (1) to the same extent
13 and in the same manner as such subsections apply
14 with respect to a person who is debarred under sub-
15 section (a)(1), or an individual who is debarred
16 under subsection (a)(2), respectively.”.

17 (e) EXPANDED ACCESS TO UNAPPROVED THERAPIES
18 AND DIAGNOSTICS.—Section 561 of the Federal Food,
19 Drug, and Cosmetic Act (21 U.S.C. 360bbb) is amend-
20 ed—

21 (1) in subsections (a) through (d)—

22 (A) by striking “or investigational devices”
23 each place it appears and inserting “, investiga-
24 tional devices, or investigational in vitro clinical
25 tests”; and

1 (B) by striking “or investigational device”
2 each place it appears (other than the second
3 such place in paragraph (3)(A)) of subsection
4 (c) and inserting “, investigational device, or
5 investigational in vitro clinical test”;

6 (2) in subsection (b)(4) by striking “or 520(g)”
7 each place it appears and inserting “, 520(g), or
8 587S”;

9 (3) in subsection (c)—

10 (A) by amending the subsection heading to
11 read: “TREATMENT INVESTIGATIONAL NEW
12 DRUG APPLICATIONS, TREATMENT INVESTIGA-
13 TIONAL DEVICE EXEMPTIONS, AND TREAT-
14 MENT INVESTIGATIONAL IN VITRO CLINICAL
15 TEST EXEMPTIONS.”;

16 (B) in paragraph (3)(A), by striking “or
17 investigational device exemption in effect under
18 section 520(g)” and inserting “, investigational
19 device exemption in effect under section 520(g),
20 or investigational in vitro clinical test exemption
21 under section 587S”;

22 (C) by striking “or treatment investiga-
23 tional device exemption” each place it appears
24 and inserting “, treatment investigational device

1 exemption, or treatment investigational in vitro
2 clinical test exemption”;

3 (D) in paragraph (5), by striking “or
4 520(g)” and inserting “, 520(g), or 587S”;

5 (E) in the matter following paragraph (7)
6 by striking “or 520(g)” each place it appears
7 and inserting “, 520(g), or 587S”;

8 (4) by amending subsection (e) to read as fol-
9 lows:

10 “(e) DEFINITIONS.—In this section, the terms ‘inves-
11 tigational drug’, ‘investigational device’, ‘investigational in
12 vitro clinical test’, ‘treatment investigational new drug ap-
13 plication’, ‘treatment investigational device exemption’,
14 and ‘treatment investigational in vitro clinical test exemp-
15 tion’ shall have the meanings given the terms in regula-
16 tions prescribed by the Secretary.”.

17 (f) OPTIMIZING GLOBAL CLINICAL TRIALS.—Section
18 569A(b) of the Federal Food, Drug, and Cosmetic Act (21
19 U.S.C. 360bbb–8a(b)) is amended—

20 (1) by striking “subsection” each place it ap-
21 pears and inserting “paragraph”; and

22 (2) by inserting “an in vitro clinical test, as de-
23 fined in paragraph (ss) of such section,” before “or
24 a biological product”.

1 (g) PATIENT PARTICIPATION IN MEDICAL PRODUCT
2 DISCUSSION.—The heading of subsection (a) of section
3 569C of the Federal Food, Drug, and Cosmetic Act (21
4 U.S.C. 360bbb–8c) is amended by striking “DRUGS AND
5 DEVICES” and inserting “DRUGS, DEVICES, AND IN
6 VITRO CLINICAL TESTS”.

7 (h) REGULATIONS AND HEARINGS.—Clause (ii) of
8 section 701(h)(1)(C) of the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 371(h)(1)(C)) is amended—

10 (1) by inserting “and in vitro clinical tests”
11 after “devices”; and

12 (2) by moving the margin of such clause 2 ems
13 to the left.

14 (i) RECORDS.—Section 703 of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C. 373) is amended—

16 (1) by inserting “in vitro clinical tests,” after
17 “devices,” each place such term appears; and

18 (2) by inserting “in vitro clinical test,” after
19 “device,” each place such term appears.

20 (j) FACTORY INSPECTION.—Section 704 of the Fed-
21 eral Food, Drug, and Cosmetic Act (21 U.S.C. 374) (other
22 than subsection (g)) is amended—

23 (1) by striking “drugs or devices” each place it
24 appears and inserting “drugs, devices, or in vitro
25 clinical tests”;

1 (2) in subsection (a)(1), in the fourth sentence,
2 by striking “or chapter IX” and inserting “section
3 587S, section 587M, section 587N, or chapter IX”;

4 (3) after making the amendments in para-
5 graphs (1) and (2), by inserting “in vitro clinical
6 tests,” after “devices,” each place it appears;

7 (4) in subsection (a)(2)(B)—

8 (A) by inserting “or in vitro clinical tests”
9 after “prescribe or use devices”; and

10 (B) by inserting “or in vitro clinical tests”
11 after “process devices”;

12 (5) by inserting “in vitro clinical test,” after
13 “device,” each place it appears;

14 (6) in subsection (e), by inserting “, or section
15 587M, 587N, or 587S,” after “section 519 or
16 520(g)”;

17 (7) in subsection (f)(3)—

18 (A) in subparagraph (A), by striking “or”
19 at the end;

20 (B) in subparagraph (B), by striking the
21 period at the end and inserting “; or”; and

22 (C) after subparagraph (B), by inserting
23 the following:

24 “(C) is accredited under section 587Q.”;

25 and

1 (8) by adding at the end the following:

2 “(i) For purposes of this section, the term ‘establish-
3 ment’ includes a laboratory performing an in vitro clinical
4 test.”.

5 (k) PUBLICITY.—Section 705(b) of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 375(b)) is amended
7 by inserting “in vitro clinical tests,” after “devices,”.

8 (l) PRESUMPTION.—Section 709 of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 379a) is amended by
10 inserting “in vitro clinical test,” after “device,”.

11 (m) LISTING AND CERTIFICATION OF COLOR ADDI-
12 TIVES FOR FOODS, DRUGS, AND COSMETICS.—Section
13 721(a) of the Federal Food, Drug, and Cosmetic Act (21
14 U.S.C. 379e(a)) is amended—

15 (1) in the matter preceding paragraph (1), by
16 inserting “or in vitro clinical tests” after “or de-
17 vices”; and

18 (2) in the flush text following paragraph (2)—

19 (A) by inserting “or an in vitro clinical
20 test” after “a device”; and

21 (B) by inserting “or in vitro clinical tests”
22 after “devices”.

23 (n) IMPORTS AND EXPORTS.—Section 801 of the
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381)
25 is amended—

1 (1) in subsection (a)—

2 (A) by inserting “in vitro clinical tests,”
3 after “devices,” each place it appears; and

4 (B) by inserting “in the case of an in vitro
5 clinical test, the test does not conform to the
6 applicable requirements of section 587K, or”
7 after “requirements of section 520(f), or”;

8 (2) in subsection (d)(3)—

9 (A) in subparagraph (A)—

10 (i) in the matter preceding clause (i),
11 by inserting “and no component of an in
12 vitro clinical test or other article of in vitro
13 clinical test that requires further proc-
14 essing,” after “health-related purposes”;

15 (ii) in clause (i), by striking “drug or
16 device” and inserting “drug, device, or in
17 vitro clinical test”; and

18 (iii) in clause (i)(I), by inserting “in
19 vitro clinical test,” after “device,”; and

20 (B) in subparagraph (B), by inserting “in
21 vitro clinical test,” after “device,”;

22 (3) in subsection (e)(1), by inserting “in vitro
23 clinical test,” after “device,”; and

24 (4) in subsection (o)—

1 (A) by inserting “or in vitro clinical test”
2 after “device”; and

3 (B) by inserting “, or under section 587J
4 of each foreign establishment,” after “section
5 510(i) of each establishment”.

6 (o) OFFICE OF INTERNATIONAL RELATIONS.—Sec-
7 tion 803 of the Federal Food, Drug, and Cosmetic Act
8 (21 U.S.C. 383) is amended—

9 (1) in subsection (b)—

10 (A) in the matter preceding paragraph (1),
11 by inserting “and in vitro clinical tests” after
12 “devices”; and

13 (B) in paragraph (1), by striking “, and”
14 and inserting “and quality requirements estab-
15 lished under section 587K; and”; and

16 (2) in subsection (c)—

17 (A) in paragraph (2), by inserting “in vitro
18 clinical tests,” after “devices,”; and

19 (B) in paragraph (4), by inserting “or in
20 vitro clinical tests” after “devices”.

21 (p) RECOGNITION OF FOREIGN GOVERNMENT IN-
22 SPECTIONS.—Section 809(a)(1) of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C. 384e(a)(1)) is amend-
24 ed by inserting “, or of foreign establishments registered
25 under section 587J” after “510(h)”.

1 (q) FOOD AND DRUG ADMINISTRATION.—Section
2 1003(b)(2) of the Federal Food, Drug, and Cosmetic Act
3 (21 U.S.C. 393(b)(2)) is amended—

4 (1) in subparagraph (D), by striking “and” at
5 the end;

6 (2) in subparagraph (E), by striking the semi-
7 colon at the end and inserting “; and”; and

8 (3) by adding at the end the following:

9 “(F) in vitro clinical tests are analytically
10 and clinically valid;”.

11 (r) OFFICE OF WOMEN’S HEALTH.—Section 1011(b)
12 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 399b(b)) is amended—

14 (1) in paragraph (1), by inserting “in vitro clin-
15 ical tests,” after “devices,”; and

16 (2) in paragraph (4), by striking “and device
17 manufacturers” and inserting “device manufactur-
18 ers, and in vitro clinical test developers”.

19 (s) COUNTERMEASURE PROVISIONS OF THE PUBLIC
20 HEALTH SERVICE ACT.—Title III of the Public Health
21 Service Act is amended—

22 (1) in section 319F–1(a)(2)(A) (42 U.S.C.
23 247d–6a(a)(2)(A))—

24 (A) in the matter preceding clause (i)—

1 (i) by striking “or device” and insert-
2 ing “device”; and

3 (ii) by inserting “or an in vitro clin-
4 ical tests (as that term is defined in sec-
5 tion 201(ss) of the Federal Food, Drug,
6 and Cosmetic Act (21 U.S.C. 321(ss)),”
7 after “Act (21 U.S.C. 321(h)),”; and

8 (B) in each of clauses (ii) and (iii), by
9 striking “or device” and inserting “device, or in
10 vitro clinical test”;

11 (2) in section 319F-2(c)(1)(B) (42 U.S.C.
12 247d-6b(c)(1)(B))—

13 (A) by striking “or device” and inserting
14 “device”; and

15 (B) by inserting “, or an in vitro clinical
16 test (as that term is defined in section 201(ss)
17 of the Federal Food, Drug, and Cosmetic Act
18 (21 U.S.C. 321(ss)))” after “Act (21 U.S.C.
19 321(h)),”; and

20 (3) in section 319F-3(i)(7) (42 U.S.C. 247d-
21 6d(i)(7))—

22 (A) in the matter preceding subparagraph
23 (A)—

24 (i) by striking “or device” and insert-
25 ing “device”; and

1 (ii) by inserting “or an in vitro clin-
2 ical tests (as that term is defined in sec-
3 tion 201(ss) of the Federal Food, Drug,
4 and Cosmetic Act (21 U.S.C. 321(ss)),”
5 after “Act (21 U.S.C. 321(h))”;

6 (B) in subparagraph (A)—

7 (i) by moving the margin of clause
8 (iii) 2 ems to the left; and

9 (ii) in clause (iii), by striking “or de-
10 vice” and inserting “device, or in vitro clin-
11 ical test”; and

12 (C) in subparagraph (B)—

13 (i) in clause (i), by inserting “or of-
14 fered under a technology certification
15 order” after “approved or cleared”; and

16 (ii) in clause (ii), by striking “or
17 520(g)” and inserting “, 520(g), or 587S”.

18 **SEC. 825. TRANSITION.**

19 (a) IMPLEMENTATION.—

20 (1) EFFECTIVE DATE.—

21 (A) IN GENERAL.—Except as otherwise
22 provided in this section, the amendments made
23 by this Act shall take effect on October 1, 2027
24 (in this section and in subchapter J of chapter
25 V of the Federal Food, Drug, and Cosmetic

1 Act, as added by this Act, referred to in this
2 section as the “effective date of this Act”).

3 (B) EXCEPTIONS.—

4 (i) IN GENERAL.—The Secretary of
5 Health and Human Services (in this sec-
6 tion referred to as the “Secretary”) may
7 take the actions described in paragraph
8 (2), and may expend such funds as the
9 Secretary determines necessary to ensure
10 an orderly transition, including prior to the
11 effect date of this Act.

12 (ii) IMPLEMENTATION OF CERTAIN
13 PROVISIONS.—The Secretary may imple-
14 ment sections 587J and 587U of the Fed-
15 eral Food, Drug, and Cosmetic Act (as
16 added by section 823) beginning on Octo-
17 ber 1, 2024, and such sections may take
18 effect not earlier than October 1, 2027, to
19 the extent and for the purposes indicated
20 in such sections. In the case of a developer
21 who, between October 1, 2024, and the ef-
22 fective date of this Act, registers under
23 such section 587J with respect to an arti-
24 cle that is an in vitro clinical test, such de-
25 veloper shall not be required to register

1 with respect to such article under section
2 510 of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 360).

4 (2) ACTIONS.—The Secretary—

5 (A) shall—

6 (i) within 1 year of the date of enact-
7 ment of this Act, hold the public meetings
8 described in section 587D(i) of the Federal
9 Food, Drug, and Cosmetic Act (as added
10 by section 823);

11 (ii) within 3 years of the date of en-
12 actment of this Act, promulgate final regu-
13 lations required under the amendments
14 made by this Act; and

15 (iii) within 30 months of the date of
16 enactment of this Act, issue final guidance
17 on applicability requirements under
18 amendments made by this Act; and

19 (B) may take additional actions after the
20 date of enactment that the Secretary deter-
21 mines necessary to ensure an orderly transition,
22 including—

23 (i) establishment of mitigating meas-
24 ures for an in vitro clinical test or category
25 of in vitro clinical tests, which may not

1 take effect until after the effective date de-
2 scribed in paragraph (1)(A); and

3 (ii) establishment of the comprehen-
4 sive test information system under section
5 587T of the Federal Food, Drug, and Cos-
6 metic Act, as added by section 823.

7 (3) APPLICABILITY OF GUIDANCE AND REGULA-
8 TIONS.—Notwithstanding the date on which guid-
9 ance or regulations are issued under paragraph (2)
10 and section 587K of the Federal Food, Drug, and
11 Cosmetic Act, as added by section 823, no guidance
12 or regulations issued pursuant to the amendments
13 made by this Act shall be implemented or take effect
14 until the effective date of this Act, except as other-
15 wise specified in this Act (including the amendments
16 made by this Act).

17 (b) APPLICATION OF AUTHORITIES TO IN VITRO
18 CLINICAL TESTS UNDER REVIEW ON THE EFFECTIVE
19 DATE OF THIS ACT.—For any in vitro clinical test for
20 which a submission for approval under section 515 of the
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e),
22 clearance under section 510(k) of such Act (21 U.S.C.
23 360(k)), authorization under section 513(f)(2) of such Act
24 (21 U.S.C. 360c(f)(2)), or licensure under section 351 of
25 the Public Health Service Act (42 U.S.C. 262) is pending

1 on the effective date of this Act, including transitional in
2 vitro clinical tests as described in subsection (c), the Sec-
3 retary may review and take action on such submission
4 after the effective date of this Act according to the statu-
5 tory provision under which such submission was sub-
6 mitted.

7 (c) APPLICATION OF AUTHORITIES TO TRANSI-
8 TIONAL IN VITRO CLINICAL TESTS.—

9 (1) DEFINITION.—For purposes of this section,
10 the term “transitional in vitro clinical test” means
11 an in vitro clinical test that—

12 (A) is first offered for clinical use during
13 the period beginning on the date of enactment
14 of this Act and ending on the effective date of
15 this Act;

16 (B) is developed by a clinical laboratory
17 certified by the Secretary under section 353 of
18 the Public Health Service Act (42 U.S.C. 263a)
19 that meets the requirements for performing
20 high-complexity testing and performed—

21 (i) in the same clinical laboratory in
22 which the test was developed and for which
23 a certification is still in effect under such
24 section 353 that meets the requirements to
25 perform tests of high complexity;

1 (ii) by another laboratory for which a
2 certificate is in effect under such section
3 353 that meets the requirements to per-
4 form tests of high complexity, is within the
5 same corporate organization, and has com-
6 mon ownership by the same parent cor-
7 poration as the laboratory in which the
8 test was developed; or

9 (iii) in the case of a test that was de-
10 veloped by the Centers for Disease Control
11 and Prevention or another laboratory in a
12 public health laboratory network coordi-
13 nated or managed by the Centers for Dis-
14 ease Control and Prevention, by a clinical
15 laboratory for which a certificate is in ef-
16 fect under such section 353 that meets the
17 requirements to perform tests of high com-
18 plexity, and that is within a public health
19 laboratory network coordinated or man-
20 aged by the Centers for Disease Control
21 and Prevention; and

22 (C) when first offered, is not approved
23 under section 515 of the Federal Food, Drug,
24 and Cosmetic Act, cleared under section 510(k)
25 of such Act, authorized under section 513(f)(2)

1 of such Act, subject to a humanitarian device
2 exemption under section 520(m) of such Act
3 (21 U.S.C. 360j(m)), subject to an exemption
4 for investigation use under section 520(g) of
5 such Act (21 U.S.C. 360j(g)), authorized under
6 section 564 of such Act (21 U.S.C. 360bbb-3),
7 or licensed under section 351 of the Public
8 Health Service Act (42 U.S.C. 262).

9 (2) PREMARKET REVIEW OR TECHNOLOGY CER-
10 TIFICATION.—A transitional in vitro clinical test
11 that is the subject of an application for premarket
12 review under section 587B of the Federal Food,
13 Drug, and Cosmetic Act or technology certification
14 application under section 587D of such Act, as
15 added by this Act, may continue to be offered, sold,
16 or distributed without marketing authorization until
17 completion of the Secretary's review of the pre-
18 market application or technology certification appli-
19 cation, if such application is submitted no later than
20 90 days after the effective date of this Act.

21 (3) TESTS APPROVED BY NEW YORK STATE.—
22 Notwithstanding paragraph (2), a transitional in
23 vitro clinical test that has been approved by the New
24 York State Department of Health may continue to

1 be offered, sold, or distributed after the effective
2 date if—

3 (A) starting on the effective date of this
4 Act, the in vitro clinical test complies with the
5 requirements of subchapter J of the Federal
6 Food, Drug, and Cosmetic Act, as added by
7 this Act, except for section 587B of the Federal
8 Food, Drug, and Cosmetic Act, as added by
9 section 823, and design control provisions of
10 section 587K of such Act;

11 (B) each test report template for the test
12 bears a statement of adequate prominence that
13 reads as follows: “This in vitro clinical test was
14 developed and first introduced prior to the ef-
15 fective date of the VALID Act of 2022. This
16 test was approved by the New York State De-
17 partment of Health, but the test has not been
18 reviewed by the Food and Drug Administra-
19 tion.”;

20 (C) a premarket application under section
21 587B of the Federal Food, Drug, and Cosmetic
22 Act, as added by section 823, or technology cer-
23 tification application under section 587D of
24 such Act, as added by section 823, is submitted
25 no later than—

1 (i) 5 years after the effective date of
2 this Act, if the in vitro clinical test is ap-
3 proved by the New York State Department
4 of Health as a genetic testing molecular
5 test, a microbiology molecular test, an on-
6 cology molecular test, or any other type of
7 molecular test; or

8 (ii) 2 years after the effective date of
9 this Act, if the in vitro clinical test is ap-
10 proved by the New York State Department
11 of Health as a type of test not described
12 in clause (i); and

13 (D) a test in compliance with this para-
14 graph may continue to be offered, sold, or dis-
15 tributed until the completion of the Secretary's
16 review of the premarket application or tech-
17 nology certification application described in sub-
18 paragraph (C).

19 (d) CONVERSION.—

20 (1) DEEMED PREMARKET APPROVAL.—Begin-
21 ning on the effective date of this Act—

22 (A) any in vitro clinical test with a pre-
23 market approval under section 515 of the Fed-
24 eral Food, Drug, and Cosmetic Act (21 U.S.C.
25 360e) or a licensure under section 351 of the

1 Public Health Service Act (42 U.S.C. 262) is
2 deemed to be approved pursuant to an applica-
3 tion under section 587B(a) of the Federal
4 Food, Drug, and Cosmetic Act, as added by
5 this Act; and

6 (B) any in vitro clinical test (as so defined)
7 that was cleared under section 510(k) of the
8 Federal Food, Drug, and Cosmetic Act (21
9 U.S.C. 360(k)) or authorized under section
10 513(f)(2) of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 360c(f)(2)) is deemed to
12 be approved pursuant to an application under
13 section 587B(b) of the Federal Food, Drug,
14 and Cosmetic Act, as added by this Act.

15 (2) DEEMED INVESTIGATIONAL USE EXEMP-
16 TION.—Any in vitro clinical test that has an inves-
17 tigational device exemption in effect under section
18 520(g) of the Federal Food, Drug, and Cosmetic Act
19 (21 U.S.C. 360j(g)) is deemed to have an investiga-
20 tional use exemption in effect under section 587S of
21 such Act, as added by this Act, beginning on the ef-
22 fective date of this Act.

23 (3) DEEMED HUMANITARIAN DEVICE EXEMP-
24 TION.—Any in vitro clinical test that has an ap-
25 proved humanitarian device exemption under section

1 520(m) of such Act is deemed to have a humani-
2 tarian test exemption under section 587A(g) of such
3 Act, as added by this Act, beginning on the effective
4 date of this Act.

5 (4) DEEMED DESIGNATED BREAKTHROUGH.—
6 Any in vitro clinical test that has received a break-
7 through device designation under section
8 515B(e)(1)(D) of such Act (21 U.S.C. 360e-
9 3(e)(1)(D)) is deemed to have a breakthrough in
10 vitro clinical test designation under section 587C of
11 such Act, as added by this Act, beginning on the ef-
12 fective date of this Act.

13 (5) DEEMED REQUEST FOR INFORMAL FEED-
14 BACK.—With regard to any in vitro clinical test that
15 is the subject of a pre-submission request described
16 in the guidance, “Requests for Feedback and Meet-
17 ings for Medical Device Submissions: The Q-Submis-
18 sion Program”, issued by the Food and Drug Ad-
19 ministration on January 6, 2021, such request is
20 deemed to constitute a request for informal feedback
21 under section 587F of the Federal Food, Drug, and
22 Cosmetic Act, as added by section 823, beginning on
23 the effective date of this Act.

24 (e) PREVIOUSLY CLASSIFIED DEVICES.—Notwith-
25 standing section 587 of the Federal Food, Drug, and Cos-

1 metric Act, as added by section 823, for purposes of sub-
2 chapter J of chapter V of such Act, as added by section
3 823, the following apply:

4 (1) In the case of an in vitro clinical test type
5 that has been classified by the Secretary as a class
6 I device pursuant to section 513 of such Act (21
7 U.S.C. 360c), such in vitro clinical test shall be low-
8 risk, unless the in vitro clinical test is a test de-
9 scribed in section 510(l) of such Act or the test is
10 redesignated by the Secretary pursuant to section
11 587F of such Act.

12 (2) In the case of an in vitro clinical test type
13 that has been classified by the Secretary as a class
14 II device pursuant to section 513 of such Act (21
15 U.S.C. 360c), such in vitro clinical test shall be
16 moderate-risk, unless inaccurate results from the
17 test would be immediately life threatening or the test
18 is redesignated by the Secretary pursuant to section
19 587F of such Act.

20 (3) In the case of an in vitro clinical test type
21 that has been classified by the Secretary as a class
22 III device pursuant to section 513 of such Act (21
23 U.S.C. 360c) or an in vitro clinical test licensed pur-
24 suant to section 351 of the Public Health Service
25 Act (42 U.S.C. 262), such in vitro clinical test shall

1 be high-risk, unless redesignated by the Secretary
2 pursuant to section 587F of the Federal Food,
3 Drug, and Cosmetic Act.

4 **SEC. 826. EMERGENCY USE AUTHORIZATION.**

5 (a) IN GENERAL.—Section 564 of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) is amend-
7 ed—

8 (1) by inserting “or developer” after “manufac-
9 turer”, each place such term appears;

10 (2) in subsection (a)—

11 (A) in paragraphs (1) and (4)(C), by in-
12 serting “in vitro clinical test,” before “or bio-
13 logical product” each place such term appears;

14 (B) in paragraph (2)(A), by striking “or
15 515” and inserting “515, or 587B”; and

16 (C) by adding at the end the following:

17 “(F) The terms ‘develop’ and ‘developer’,
18 with respect to an in vitro clinical test, have the
19 meanings given such terms in section 587.”;

20 (3) in subsection (b), by inserting “or devel-
21 oper” after “manufacturer” each place such term
22 appears;

23 (4) in subsection (e)—

24 (A) by inserting “or developers” after
25 “manufacturers” each place such term appears;

1 (B) in paragraph (2)(B)(ii), by inserting
2 “or develop” after “not manufacture”;

3 (C) in paragraph (3)—

4 (i) in subparagraph (A), by striking
5 “or 520(f)(1)” and inserting “, 520(f)(1),
6 or 587V”;

7 (ii) in subparagraph (B), by striking
8 “and” at the end;

9 (iii) in subparagraph (C), by striking
10 the period and inserting “ or 587O; and”;
11 and

12 (iv) by adding at the end the fol-
13 lowing:

14 “(D) quality requirements (with respect to
15 in vitro clinical tests) under section 587K.”;
16 and

17 (D) in paragraph (4)—

18 (i) in subparagraph (A), by striking “;
19 or” and inserting a semicolon;

20 (ii) in subparagraph (B), by striking
21 the period and inserting “; or”; and

22 (iii) by adding at the end the fol-
23 lowing:

1 “(C) with respect to in vitro clinical tests,
2 requirements applicable to restricted in vitro
3 clinical tests pursuant to section 587O.”;

4 (5) in subsection (k), by striking “or 520(g)”
5 and inserting “520(g), or 587S”; and

6 (6) in subsection (m)—

7 (A) in the subsection heading, by striking
8 “LABORATORY TESTS ASSOCIATED WITH DE-
9 VICES” inserting “IN VITRO CLINICAL TESTS”
10 after “DEVICES”; and

11 (B) in paragraph (1)—

12 (i) by striking “to a device” and in-
13 serting “to an in vitro clinical test”; and

14 (ii) by striking “such device” and in-
15 serting “such in vitro clinical test”.

16 (b) EMERGENCY USE OF MEDICAL PRODUCTS.—Sec-
17 tion 564A of the Federal Food, Drug, and Cosmetic Act
18 (21 U.S.C. 360bbb–3a) is amended—

19 (1) in subsection (a)—

20 (A) in paragraph (2), by inserting “in vitro
21 clinical test,” after “device,”; and

22 (B) by adding at the end the following:

23 “(3) DEVELOPER.—The term ‘developer’, with
24 respect to an in vitro clinical test, has the meaning
25 given such term in section 587.”;

1 (2) by inserting “or developer” after “manufac-
2 turer” each place it appears; and

3 (3) in subsection (c)(1)—

4 (A) by inserting “or quality requirements”
5 after “good manufacturing practice require-
6 ments”; and

7 (B) by striking “or 520(f)(1)” and insert-
8 ing “, 520(f)(1), or 587K”.

9 (c) PRODUCTS HELD FOR EMERGENCY USE.—Sec-
10 tion 564B(2) of the Federal Food, Drug, and Cosmetic
11 Act (21 U.S.C. 360bbb–3b(2)) is amended—

12 (1) in subparagraph (A), by striking “or 515”
13 and inserting “515, or 587B”; and

14 (2) in subparagraph (B), by striking “or 520”
15 and inserting 520, or 587S.

16 **SEC. 827. ANTIMICROBIAL SUSCEPTIBILITY TESTS.**

17 Section 511A of the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 360a–2) is amended—

19 (1) in subsection (a)(1)(C)—

20 (A) by striking “clear under section
21 510(k), classify under section 513(f)(2), or ap-
22 prove under section 515” and inserting “ap-
23 prove under section 587B, exempt from pre-
24 market review under section 587C, or grant a

1 technology certification order under section
2 587D”; and

3 (B) by striking “testing devices” and in-
4 serting “in vitro clinical tests”;

5 (2) in subsection (c)(5)—

6 (A) by striking “drug or device” and in-
7 serting “drug, device, or in vitro clinical test”;

8 and

9 (B) by striking “the drug or the device”
10 and inserting “the drug, device, or in vitro clin-
11 ical test”;

12 (3) in subsection (e)—

13 (A) in the heading, by striking “TESTING
14 DEVICES” and inserting “IN VITRO CLINICAL
15 TESTS”;

16 (B) in paragraph (1)—

17 (i) by striking “510, 513, and 515,”
18 and inserting “587B, and 587D”;

19 (ii) by striking “antimicrobial suscep-
20 tibility testing device” and inserting “anti-
21 microbial susceptibility in vitro clinical
22 test”; and

23 (iii) by striking “such device” and in-
24 serting “such in vitro clinical test”; and

25 (C) in paragraph (2)—

1 (i) in the heading, by striking “TEST-
2 ING DEVICES” and inserting “IN VITRO
3 CLINICAL TESTS”;

4 (ii) in subparagraphs (A) and (B)
5 (other than clause (iii) of such subpara-
6 graph (B)), by striking “device” each place
7 it appears and inserting “in vitro clinical
8 test”;

9 (iii) in subparagraph (B)(iii), by strik-
10 ing “a device” and inserting “an in vitro
11 clinical test”; and

12 (iv) by amending subparagraph (C) to
13 read as follows:

14 “(C) The antimicrobial susceptibility in
15 vitro clinical test meets all other requirements
16 to be approved under section 587B, to be ex-
17 empted from premarket review under section
18 587C, or to be offered under a technology cer-
19 tification order under section 587D.”;

20 (4) in subsection (f), by amending paragraph
21 (1) to read as follows:

22 “(1) The term ‘antimicrobial susceptibility in
23 vitro clinical test’ means an in vitro clinical test that
24 utilizes susceptibility test interpretive criteria to de-

1 termine and report the in vitro susceptibility of cer-
2 tain microorganisms to a drug (or drugs).”; and

3 (5) in subsection (g)(2)—

4 (A) by amending the matter preceding sub-
5 paragraph (A) to read as follows:

6 “(2) with respect to approving an application
7 under section 587B or granting a technology certifi-
8 cation order under section 587D—”; and

9 (B) in subparagraph (A)—

10 (i) by striking “device” and inserting
11 “in vitro clinical test”; and

12 (ii) by striking “antimicrobial suscep-
13 tibility testing device” and inserting “anti-
14 microbial susceptibility in vitro clinical
15 test”.

16 **SEC. 828. COMBINATION PRODUCTS.**

17 (a) IN GENERAL.—Section 503(g) of the Federal
18 Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)) is
19 amended—

20 (1) in paragraph (1)—

21 (A) in subparagraph (A), by striking “or
22 biological product” and inserting “in vitro clin-
23 ical test, or biological product (except for a
24 product constituted of a device and an in vitro
25 clinical test)”; and

1 (B) in subparagraph (B), by adding at the
2 end the following: “For purposes of this Act, a
3 product that constitutes a combination of a de-
4 vice and an in vitro clinical test is not a com-
5 bination product within the meaning of this
6 subsection.”; and

7 (C) in subparagraph (D)(ii)—

8 (i) by inserting “or in vitro clinical
9 test” after “device”; and

10 (ii) by inserting “and in vitro clinical
11 tests” before “shall”;

12 (2) in paragraph (3), by striking “safety and
13 effectiveness or substantial equivalence” and insert-
14 ing “safety and effectiveness, substantial equiva-
15 lence, or analytical validity and clinical validity” be-
16 fore “for the approved constituent part”;

17 (3) in paragraph (4)—

18 (A) in subparagraph (A), by striking “or
19 513(f)(2) (submitted in accordance with para-
20 graph (5))” and inserting “513(f)(2) (sub-
21 mitted in accordance with paragraph (5)),
22 587B, or 587D, or an exempt test under sec-
23 tion 587C, as applicable”; and

24 (B) in subparagraph (B), by inserting “,
25 587B, or 587D” after “section 515”;

1 (4) in paragraph (5)(A), by striking “or
2 510(k)” and inserting “, 510(k), 587B, or 587D”;

3 (5) in paragraph (7), by striking “or substan-
4 tial equivalence” and inserting “, substantial equiva-
5 lence, or analytical validity and clinical validity”;

6 (6) in paragraph (8), by adding at the end the
7 following:

8 “(I) This paragraph shall not apply to a
9 product constituted of a device and an in vitro
10 clinical test.”; and

11 (7) in paragraph (9)—

12 (A) in subparagraph (C)(i), by striking “or
13 520(g)” and inserting “520(g), 587B, or
14 587D”; and

15 (B) in subparagraph (D), by striking “or
16 520” and inserting “520, 587B, or 587D”.

17 (b) CLASSIFICATION OF PRODUCTS.—Section 563 of
18 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
19 360bbb–2) is amended by adding at the end the following:

20 “(d) EXEMPTION.—This section shall not apply to a
21 product constituted of a device and an in vitro clinical
22 test.”.

23 **SEC. 829. RESOURCES.**

24 (a) FINDINGS.—Congress finds that the fees author-
25 ized by this section will be dedicated to meeting the goals

1 identified in the letters from the Secretary of Health and
2 Human Services to the Committee on Health, Education,
3 Labor, and Pensions of the Senate and the Committee on
4 Energy and Commerce of the House of Representatives,
5 as set forth in the Congressional Record.

6 (b) ESTABLISHMENT OF USER FEE PROGRAM.—

7 (1) DEVELOPMENT OF USER FEES FOR IN
8 VITRO CLINICAL TESTS.—

9 (A) IN GENERAL.—Beginning not later
10 than October 1, 2025, the Secretary of Health
11 and Human Services (in this section referred to
12 as the “Secretary”) shall develop recommenda-
13 tions to present to Congress with respect to the
14 goals, and plans for meeting the goals, for the
15 process for the review of in vitro clinical test
16 submissions and applications under subchapter
17 J of chapter V of the Federal Food, Drug, and
18 Cosmetic Act, as added by this Act, for the first
19 5 fiscal years after fiscal year 2027 and for the
20 authorization of the In Vitro Clinical Test User
21 Fee Program, as described in this section, for
22 such fiscal years. In developing such rec-
23 ommendations, the Secretary shall consult
24 with—

1 (i) the Committee on Health, Edu-
2 cation, Labor, and Pensions of the Senate;

3 (ii) the Committee on Energy and
4 Commerce of the House of Representa-
5 tives;

6 (iii) scientific and academic experts;

7 (iv) health care professionals;

8 (v) representatives of patient and con-
9 sumer advocacy groups; and

10 (vi) the regulated industry.

11 (B) PRIOR PUBLIC INPUT.—Prior to begin-
12 ning negotiations with the regulated industry
13 on the authorization of the In Vitro Clinical
14 Test User Fee Program, as described in this
15 section, the Secretary shall—

16 (i) publish a notice in the Federal
17 Register requesting public input on the au-
18 thorization of user fees;

19 (ii) hold a public meeting at which the
20 public may present its views on the author-
21 ization, including specific suggestions for
22 the recommendations submitted under sub-
23 paragraph (E);

24 (iii) provide a period of 30 days after
25 the public meeting to obtain written com-

1 ments from the public suggesting changes
2 to the authorization of the In Vitro Clin-
3 ical Test User Fee Program, as described
4 in this section; and

5 (iv) publish any comments received
6 under clause (iii) on the website of the
7 Food and Drug Administration.

8 (C) PERIODIC CONSULTATION.—Not less
9 frequently than once every month during nego-
10 tiations with the regulated industry, the Sec-
11 retary shall hold discussions with representa-
12 tives of patient and consumer advocacy groups
13 to continue discussions of the authorization of
14 the In Vitro Clinical Test User Fee Program
15 and to solicit suggestions to be included in the
16 recommendations transmitted to Congress
17 under subparagraph (E).

18 (D) PUBLIC REVIEW OF RECOMMENDA-
19 TIONS.—After negotiations with the regulated
20 industry, the Secretary shall—

21 (i) present the recommendations de-
22 veloped under subparagraph (A) to the
23 Committee on Health, Education, Labor,
24 and Pensions of the Senate and the Com-

1 mittee on Energy and Commerce of the
2 House of Representatives;

3 (ii) publish such recommendations in
4 the Federal Register;

5 (iii) provide for a period of 30 days
6 for the public to provide written comments
7 on such recommendations;

8 (iv) hold a meeting at which the pub-
9 lic may present its views on such rec-
10 ommendations; and

11 (v) after consideration of such public
12 views and comments, revise such rec-
13 ommendations as necessary.

14 (E) TRANSMITTAL OF RECOMMENDA-
15 TIONS.—

16 (i) IN GENERAL.—Not later than Jan-
17 uary 15, 2027, the Secretary shall trans-
18 mit to Congress the revised recommenda-
19 tions under subparagraph (A), a summary
20 of the views and comments received under
21 such subparagraph, and any changes made
22 to the recommendations in response to
23 such views and comments.

1 (ii) RECOMMENDATION REQUIRE-
2 MENTS.—The recommendations trans-
3 mitted under this subparagraph shall—

4 (I) include the number of full-
5 time equivalent employees per fiscal
6 year that are agreed to be hired to
7 carry out the goals included in such
8 recommendations for each year of the
9 5-year period;

10 (II) provide that the amount of
11 operating reserve balance in the user
12 fee program established under this
13 section is not more than the equiva-
14 lent of 10 weeks of operating reserve;

15 (III) require the development of
16 a strategic plan for any surplus within
17 the operating reserve account above
18 the 10-week operating reserve within
19 2 years of the establishment of the
20 program;

21 (IV) include an operating reserve
22 adjustment such that, if the Secretary
23 has an operating reserve balance in
24 excess of 10 weeks of such operating
25 reserves, the Secretary shall decrease

1 such fee revenue and fees to provide
2 for not more than 10 weeks of such
3 operating reserves;

4 (V) if an adjustment is made as
5 described in subclause (IV), provide
6 the rationale for the amount of the
7 decrease in fee revenue and fees shall
8 be contained in the Federal Register;
9 and

10 (VI) provide that the fees as-
11 sessed and collected for the full-time
12 equivalent employees at the Center for
13 Devices and Radiological Health, with
14 respect to which the majority of time
15 reporting data indicates are dedicated
16 to the process for the review of in
17 vitro clinical test submissions and ap-
18 plications under paragraph (5), are
19 not supported by the funds authorized
20 to be collected and assessed under sec-
21 tion 738 of the Federal Food, Drug,
22 and Cosmetic Act (21 U.S.C. 379j).

23 (F) PUBLICATION OF RECOMMENDA-
24 TIONS.—The Secretary shall publish on the
25 website of the Food and Drug Administration

1 the revised recommendations under subpara-
2 graph (A), a summary of the views and com-
3 ments received under subparagraphs (B)
4 through (D), and any changes made to the rec-
5 ommendations originally proposed by the Sec-
6 retary in response to such views and comments.

7 (G) MINUTES OF NEGOTIATION MEET-
8 INGS.—

9 (i) PUBLIC AVAILABILITY.—The Sec-
10 retary shall make publicly available, on the
11 website of the Food and Drug Administra-
12 tion, minutes of all negotiation meetings
13 conducted under this subsection between
14 the Food and Drug Administration and the
15 regulated industry not later than 30 days
16 after such meeting.

17 (ii) CONTENT.—The minutes de-
18 scribed under clause (i) shall summarize
19 any substantive proposal made by any
20 party to the negotiations, any significant
21 controversies or differences of opinion dur-
22 ing the negotiations, and the resolution of
23 any such controversy or difference of opin-
24 ion.

1 (2) ESTABLISHMENT OF USER FEE PRO-
2 GRAM.—Effective on October 1, 2027, provided that
3 the Secretary transmits the recommendations under
4 paragraph (1)(E), the Secretary is authorized to col-
5 lect user fees relating to the review of in vitro clin-
6 ical test submissions and applications submitted
7 under subchapter J of chapter V of the Federal
8 Food, Drug, and Cosmetic Act, as added by this
9 Act. Fees under such program shall be assessed and
10 collected only if the requirements under paragraph
11 (4) are met.

12 (3) AUDIT.—

13 (A) IN GENERAL.—On the date that is 2
14 years after first receiving a user fee applicable
15 to submission of an in vitro clinical test applica-
16 tion submitted under subchapter J of chapter V
17 of the Federal Food, Drug, and Cosmetic Act,
18 as added by this Act, and on a biennial basis
19 thereafter, the Secretary shall perform an audit
20 of the costs of reviewing such applications
21 under such subchapter J. Such an audit shall
22 compare the costs of reviewing such applica-
23 tions under such subchapter J to the amount of
24 the user fee applicable to such applications.

1 (B) ALTERATION OF USER FEE.—If the
2 audit performed under subparagraph (A) indi-
3 cates that the user fees applicable to applica-
4 tions submitted under such subchapter J exceed
5 49 percent of the costs of reviewing such appli-
6 cations, the Secretary shall alter the user fees
7 applicable to applications submitted under such
8 subchapter J such that the user fees do not ex-
9 ceed such percentage.

10 (C) ACCOUNTING STANDARDS.—The Sec-
11 retary shall perform an audit under subpara-
12 graph (A) in conformance with the accounting
13 principles, standards, and requirements pre-
14 scribed by the Comptroller General of the
15 United States under section 3511 of title 31,
16 United States Code, to ensure the validity of
17 any potential variability.

18 (4) CONDITIONS.—The user fee program de-
19 scribed in this subsection shall take effect only if the
20 Food and Drug Administration issues draft guidance
21 related to the review requirements for in vitro diag-
22 nostic tests that would be subject to premarket re-
23 view under section 587B of the Federal Food, Drug,
24 and Cosmetic Act, as added by section 823, the re-
25 view requirements for test categories eligible for

1 technology certification under section 587D of such
2 Act, as added by section 823, and the parameters
3 for the test categories that would be exempt from
4 any review under subchapter J of chapter V of such
5 Act.

6 (5) USER FEE PROGRAM DEFINITIONS AND RE-
7 SOURCE REQUIREMENTS.—

8 (A) IN GENERAL.—The term “process for
9 the review of in vitro clinical test submissions
10 and applications” means the following activities
11 of the Secretary with respect to the review of in
12 vitro clinical test premarket and technology cer-
13 tification applications including supplements for
14 such applications:

15 (i) The activities necessary for the re-
16 view of premarket applications, premarket
17 reports, technology certification applica-
18 tions, and supplements to such applica-
19 tions.

20 (ii) Actions related to submissions in
21 connection with in vitro clinical test devel-
22 opment, the issuance of action letters that
23 allow the marketing of in vitro clinical
24 tests or which set forth in detail the spe-
25 cific deficiencies in such applications, re-

1 ports, supplements, or submissions and,
2 where appropriate, the actions necessary to
3 support the development of in vitro clinical
4 tests.

5 (iii) The inspection of manufacturing
6 establishments and other facilities under-
7 taken as part of the Secretary's review of
8 pending premarket applications, technology
9 certifications, and supplements.

10 (iv) Monitoring of research conducted
11 in connection with the review of such appli-
12 cations, supplements, and submissions.

13 (v) Review of in vitro clinical test ap-
14 plications subject to section 351 of the
15 Public Health Service Act (42 U.S.C. 262)
16 and activities conducted in anticipation of
17 the submission of such applications for in-
18 vestigational use under section 587S of the
19 Federal Food, Drug, and Cosmetic Act (as
20 added by section 823).

21 (vi) The development of guidance, pol-
22 icy documents, or regulations to improve
23 the process for the review of premarket ap-
24 plications, technology certification applica-
25 tions, and supplements.

1 (vii) The development of voluntary
2 test methods, consensus standards, or
3 mandatory performance standards in con-
4 nection with the review of such applica-
5 tions, supplements, or submissions and re-
6 lated activities.

7 (viii) The provision of technical assist-
8 ance to in vitro clinical test developers in
9 connection with the submission of such ap-
10 plications, reports, supplements, or submis-
11 sions.

12 (ix) Any activity undertaken in con-
13 nection with the initial classification or re-
14 classification of an in vitro clinical test in
15 connection with any requirement for ap-
16 proval or eligibility for an exemption from
17 premarket review of an in vitro clinical
18 test.

19 (x) Any activity undertaken in connec-
20 tion with making a pathway determination
21 of an in vitro clinical test, including the
22 identification, establishment, and imple-
23 mentation of mitigation measures.

24 (xi) Evaluation of postmarket studies
25 required as a condition of an approval of

1 a premarket application of an in vitro clin-
2 ical test and ensuring such studies are con-
3 ducted as required.

4 (xii) Any activity undertaken in con-
5 nection with ensuring in vitro clinical tests
6 marketed under an exemption from pre-
7 market review pursuant to section 587C or
8 587G meet the criteria for such exemption
9 and the applicable standard.

10 (xiii) Compiling, developing, and re-
11 viewing information on in vitro clinical
12 tests necessary to identify issues with the
13 ability of in vitro clinical tests to meet the
14 applicable standard, as applicable.

15 (B) RESOURCE REQUIREMENTS.—Fees col-
16 lected and assessed under this section shall be
17 used for the process for the review of in vitro
18 clinical test applications, as described in sub-
19 paragraph (A), and shall—

20 (i) be subject to the limitation under
21 section 738(g)(3) of the Federal Food,
22 Drug, and Cosmetic Act (21 U.S.C.
23 379j(g)(3)), in the same manner that fees
24 collected and assessed under section

1 737(9)(C) of such Act (21 U.S.C.
2 379i(9)(C)) are subject to such limitation;

3 (ii) include travel expenses for officers
4 and employees of the Food and Drug Ad-
5 ministration only if the Secretary deter-
6 mines that such travel is directly related to
7 an activity described in subparagraph (A);
8 and

9 (iii) not be allocated to purposes de-
10 scribed under section 722(a) of the Con-
11 solidated Appropriations Act, 2018 (Public
12 Law 115–141).

13 (c) REPORTS.—

14 (1) PERFORMANCE REPORT.—

15 (A) IN GENERAL.—

16 (i) GENERAL REQUIREMENTS.—Be-
17 ginning with fiscal year 2028, for each fis-
18 cal year for which fees are collected under
19 this section, the Secretary shall prepare
20 and submit to the Committee on Health,
21 Education, Labor, and Pensions of the
22 Senate and the Committee on Energy and
23 Commerce of the House of Representatives
24 annual reports concerning the progress of
25 the Food and Drug Administration in

1 achieving the goals identified in the rec-
2 ommendations transmitted to Congress by
3 the Secretary pursuant to subsection
4 (b)(1)(E) during such fiscal year and the
5 future plans of the Food and Drug Admin-
6 istration for meeting the goals.

7 (ii) ADDITIONAL INFORMATION.—Be-
8 ginning with fiscal year 2028, the annual
9 report under this subparagraph shall in-
10 clude the progress of the Food and Drug
11 Administration in achieving the goals, and
12 future plans for meeting the goals, includ-
13 ing—

14 (I) the number of premarket ap-
15 plications filed under section 587B of
16 the Federal Food, Drug, and Cos-
17 metic Act during the applicable fiscal
18 year;

19 (II) the number of technology
20 certification applications submitted
21 under section 587D of the Federal
22 Food, Drug, and Cosmetic Act during
23 the applicable fiscal year for each re-
24 view division;

1 (III) the number of breakthrough
2 designations under section 587I of the
3 Federal Food, Drug, and Cosmetic
4 Act during the applicable fiscal year;
5 and

6 (IV) the number of information
7 requests requested by the Secretary
8 pursuant to section 587G(d) of such
9 Act.

10 (iii) REAL-TIME REPORTING.—

11 (I) IN GENERAL.—Not later than
12 30 calendar days after the end of the
13 second quarter of fiscal year 2028,
14 and not later than 30 calendar days
15 after the end of each quarter of each
16 fiscal year thereafter, the Secretary
17 shall post the data described in sub-
18 clause (II) on the website of the Food
19 and Drug Administration for such
20 quarter and on a cumulative basis for
21 such fiscal year, and may remove du-
22 plicative data from the annual report
23 under this subparagraph.

405

1 (II) DATA.—The Secretary shall
2 post the following data in accordance
3 with subclause (I):

4 (aa) The number and titles
5 of draft and final regulations on
6 topics related to the process for
7 the review of in vitro clinical test
8 submissions and applications,
9 and whether such regulations
10 were required by statute or pur-
11 suant to the recommendations
12 transmitted to Congress by the
13 Secretary pursuant to subsection
14 (b)(1)(E).

15 (bb) The number and titles
16 of draft and final guidance on
17 topics related to the process for
18 the review of in vitro clinical test
19 submissions and applications,
20 and whether such guidances were
21 issued as required by statute or
22 pursuant to the recommendations
23 transmitted to Congress by the
24 Secretary pursuant to subsection
25 (b)(1)(E).

1 (cc) The number and titles
2 of public meetings held on topics
3 related to the process for the re-
4 view of in vitro clinical tests, and
5 if such meetings were required by
6 statute or pursuant to the rec-
7 ommendations transmitted to
8 Congress by the Secretary pursu-
9 ant to subsection (b)(1)(E).

10 (iv) RATIONALE FOR IVCT USER FEE
11 PROGRAM CHANGES.—Beginning with fis-
12 cal year 2028, the Secretary shall include
13 in the annual performance report under
14 paragraph (1)—

15 (I) data, analysis, and discussion
16 of the changes in the number of full-
17 time equivalents hired as agreed upon
18 in the recommendations transmitted
19 to Congress by the Secretary pursuant
20 to subsection (b)(1)(E) and the num-
21 ber of full-time equivalents funded by
22 budget authority at the Food and
23 Drug Administration by each division
24 within the Center for Devices and Ra-
25 diological Health, the Center for Bio-

1 logics Evaluation and Research, the
2 Office of Regulatory Affairs, and the
3 Office of the Commissioner;

4 (II) data, analysis, and discus-
5 sion of the changes in the fee revenue
6 amounts and costs for the process for
7 the review of in vitro clinical test sub-
8 missions and applications, including
9 identifying drivers of such changes;
10 and

11 (III) for each of the Center for
12 Devices and Radiological Health, the
13 Center for Biologics Evaluation and
14 Research, the Office of Regulatory Af-
15 fairs, and the Office of the Commis-
16 sioner, the number of employees for
17 whom time reporting is required and
18 the number of employees for whom
19 time reporting is not required.

20 (v) ANALYSIS.—For each fiscal year,
21 the Secretary shall include in the report
22 under clause (i) an analysis of the fol-
23 lowing:

24 (I) The difference between the
25 aggregate number of premarket appli-

1 cations filed under section 587B or
2 section 587D of the Federal Food,
3 Drug, and Cosmetic Act and the ag-
4 gregate number of major deficiency
5 letters, not approvable letters, and de-
6 nials for such applications issued by
7 the agency, accounting for—

8 (aa) the number of applica-
9 tions filed under each of sections
10 587B and 587D of the Federal
11 Food, Drug, and Cosmetic Act
12 during one fiscal year for which a
13 decision is not scheduled to be
14 made until the following fiscal
15 year; and

16 (bb) the aggregate number
17 of applications under each of sec-
18 tions 587B and 587D of the
19 Federal Food, Drug, and Cos-
20 metic Act for each fiscal year
21 that did not meet the goals as
22 identified by the recommenda-
23 tions transmitted to Congress by
24 the Secretary pursuant to sub-
25 section (b)(1)(E).

1 (II) Relevant data to determine
2 whether the Center for Devices and
3 Radiological Health has met perform-
4 ance enhancement goals identified by
5 the recommendations transmitted to
6 Congress by the Secretary pursuant to
7 subsection (b)(1)(E).

8 (III) The most common causes
9 and trends for external or other cir-
10 cumstances affecting the ability of the
11 Food and Drug Administration to
12 meet review time and performance en-
13 hancement goals identified by the rec-
14 ommendations transmitted to Con-
15 gress by the Secretary pursuant to
16 subsection (b)(1)(E).

17 (B) PUBLICATION.—With regard to infor-
18 mation to be reported by the Food and Drug
19 Administration to industry on a quarterly and
20 annual basis pursuant to recommendations
21 transmitted to Congress by the Secretary pur-
22 suant to subsection (b)(1)(E), the Secretary
23 shall make such information publicly available
24 on the website of the Food and Drug Adminis-
25 tration not later than 60 days after the end of

1 each quarter or 120 days after the end of each
2 fiscal year, respectively, to which such informa-
3 tion applies.

4 (C) UPDATES.—The Secretary shall in-
5 clude in each report under subparagraph (A)
6 information on all previous cohorts for which
7 the Secretary has not given a complete response
8 on all in vitro clinical test premarket applica-
9 tions and technology certification orders and
10 supplements, premarket, and technology certifi-
11 cation notifications in the cohort.

12 (2) CORRECTIVE ACTION REPORT.—Beginning
13 with fiscal year 2022, for each fiscal year for which
14 fees are collected under this section, the Secretary
15 shall prepare and submit a corrective action report
16 to the Committee on Health, Education, Labor, and
17 Pensions and the Committee on Appropriations of
18 the Senate and the Committee on Energy and Com-
19 merce and the Committee on Appropriations of the
20 House of Representatives. The report shall include
21 the following information, as applicable:

22 (A) GOALS MET.—For each fiscal year, if
23 the Secretary determines, based on the analysis
24 under paragraph (1)(A)(v), that each of the
25 goals identified by the recommendations trans-

1 mitted to Congress by the Secretary pursuant
2 to subsection (b)(1)(E) for the applicable fiscal
3 year have been met, the corrective action report
4 shall include recommendations on ways in which
5 the Secretary can improve and streamline the in
6 vitro clinical test premarket application and
7 technology certification review process.

8 (B) GOALS MISSED.—For each of the goals
9 identified by the letters described in rec-
10 ommendations transmitted to Congress by the
11 Secretary pursuant to subsection (b)(1)(E) for
12 the applicable fiscal year that the Secretary de-
13 termines to not have been met, the corrective
14 action report shall include—

15 (i) a justification for such determina-
16 tion;

17 (ii) a description of the types of cir-
18 cumstances, in the aggregate, under which
19 applications or reports submitted under
20 sections 587B and 587D of the Federal
21 Food, Drug, and Cosmetic Act missed the
22 review goal times but were approved dur-
23 ing the first cycle review, as applicable;

1 (iii) a summary and any trends with
2 regard to the circumstances for which a re-
3 view goal was missed; and

4 (iv) the performance enhancement
5 goals that were not achieved during the
6 previous fiscal year and a description of ef-
7 forts the Food and Drug Administration
8 has put in place for the fiscal year in
9 which the report is submitted to improve
10 the ability of such agency to meet each
11 such goal for the such fiscal year.

12 (3) FISCAL REPORT.—

13 (A) IN GENERAL.—For fiscal years 2028
14 and annually thereafter, not later than 120
15 days after the end of each fiscal year during
16 which fees are collected under this section, the
17 Secretary shall prepare and submit to the Com-
18 mittee on Health, Education, Labor, and Pen-
19 sions of the Senate and the Committee on En-
20 ergy and Commerce of the House of Represent-
21 atives, a report on the implementation of the
22 authority for such fees during such fiscal year
23 and the use, by the Food and Drug Administra-
24 tion, of the fees collected during such fiscal
25 year for which the report is made.

1 (B) CONTENTS.—Such report shall include
2 expenditures delineated by budget authority and
3 user fee dollars related to administrative ex-
4 penses and information technology infrastruc-
5 ture contracts and expenditures.

6 (C) OPERATING RESERVE.—Such report
7 shall provide the amount of operating reserves
8 of carryover user fees available each year, and
9 any planned allocations or obligations of such
10 balance of operating reserves for the program.

11 (4) PUBLIC AVAILABILITY.—The Secretary
12 shall make the reports required under paragraphs
13 (1) through (3) available to the public on the website
14 of the Food and Drug Administration.

15 (5) ENHANCED COMMUNICATION.—

16 (A) COMMUNICATIONS WITH CONGRESS.—
17 Each fiscal year, as applicable and requested,
18 representatives from the Centers with expertise
19 in the review of in vitro clinical tests shall meet
20 with representatives from the Committee on
21 Health, Education, Labor, and Pensions of the
22 Senate and the Committee on Energy and Com-
23 merce of the House of Representatives to report
24 on the contents described in the reports under
25 this section.

1 (B) PARTICIPATION IN CONGRESSIONAL
2 HEARING.—Each fiscal year, as applicable and
3 requested, representatives from the Food and
4 Drug Administration shall participate in a pub-
5 lic hearing before the Committee on Health,
6 Education, Labor, and Pensions of the Senate
7 and the Committee on Energy and Commerce
8 of the House of Representatives, to report on
9 the contents described in the reports under this
10 section. Such hearing shall occur not later than
11 120 days after the end of each fiscal year for
12 which fees are collected under this section.

13 **SEC. 830. AUTHORIZATION OF APPROPRIATIONS.**

14 For purposes of funding implementation of this sub-
15 title (including the amendments made by this subtitle), in-
16 cluding undertaking activities for the development of regu-
17 lations and guidances, hiring of necessary staff, and the
18 development of technology systems to implement this sub-
19 title (including the amendments made by this subtitle) in
20 a timely, effective, and efficient manner, there is author-
21 ized to be appropriated \$480,000,000, to remain available
22 through the end of fiscal year 2028.

23 **SEC. 831. GUIDANCE ON DIAGNOSTIC INNOVATION.**

24 Not later than January 1, 2025, the Secretary shall
25 issue guidance to assist developers of in vitro clinical tests

1 intended to identify or diagnose rare diseases and in vitro
2 clinical tests intended to address an unmet medical need.
3 Such guidance shall include considerations for addressing
4 barriers to developing sufficient data to demonstrate clin-
5 ical validity for such tests, such as challenges associated
6 with data collection and obstacles to the timely generation
7 of evidence.

8 **TITLE IX—OTHER PROVISIONS**

9 **SEC. 901. FACILITIES MANAGEMENT.**

10 (a) PDUFA AUTHORITY.—Section 736(g)(2) of the
11 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
12 379h(g)(2)) is amended—

13 (1) in subparagraph (A)(ii)—

14 (A) by striking “shall be available to de-
15 fray” and inserting the following: “shall be
16 available—

17 “(I) for fiscal year 2023, to de-
18 fray”;

19 (B) by striking the period and inserting “;
20 and”; and

21 (C) by adding at the end the following:

22 “(II) for fiscal year 2024 and
23 each subsequent fiscal year, to defray
24 the costs of the resources allocated for
25 the process for the review of human

1 drug applications (including such
2 costs for an additional number of full-
3 time equivalent positions in the De-
4 partment of Health and Human Serv-
5 ices to be engaged in such process),
6 only if the sum of the amounts allo-
7 cated by the Secretary for such costs,
8 excluding costs paid from fees col-
9 lected under this section, plus other
10 costs for the maintenance, renovation,
11 and repair of facilities and acquisition,
12 maintenance, and repair of fixtures,
13 furniture, and other necessary mate-
14 rials and supplies in connection with
15 the process for the review of human
16 drug applications, is no less than the
17 amount allocated for such costs, ex-
18 cluding any such costs paid from fees
19 collected under this section, for fiscal
20 year 1997, multiplied by the adjust-
21 ment factor.”; and

22 (2) in subparagraph (B), by striking “for the
23 process for the review of human drug applications”
24 and inserting “as described in subclause (I) or (II)
25 of such subparagraph, as applicable”.

1 (b) BSUFA AUTHORITY.—Section 744H(f)(2) of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
3 52(f)(2)) is amended—

4 (1) in subparagraph (B)(i)—

5 (A) by striking “available for a fiscal year
6 beginning after fiscal year 2012” and inserting
7 the following: “available—

8 “(I) for fiscal year 2023”;

9 (B) by striking “the fiscal year involved.”
10 and inserting “such fiscal year; and”; and

11 (C) by adding at the end the following:

12 “(II) for fiscal year 2024 and
13 each subsequent fiscal year, to defray
14 the costs of the process for the review
15 of biosimilar biological product appli-
16 cations (including such costs for an
17 additional number of full-time equiva-
18 lent positions in the Department of
19 Health and Human Services to be en-
20 gaged in such process), only if the
21 sum of the amounts allocated by the
22 Secretary for such costs, excluding
23 costs paid from fees collected under
24 this section, plus other costs for the
25 maintenance, renovation, and repair

1 of facilities and acquisition, mainte-
2 nance, and repair of fixtures, fur-
3 niture, and other necessary materials
4 and supplies in connection with the
5 process for the review of biosimilar bi-
6 ological product applications, is no
7 less than \$20,000,000, multiplied by
8 the adjustment factor applicable to
9 the fiscal year involved.”; and

10 (2) in subparagraph (C), by striking “subpara-
11 graph (B) in any fiscal year if the costs described
12 in such subparagraph” and inserting “subparagraph
13 (B)(i) in any fiscal year if the costs allocated as de-
14 scribed in subclause (I) or (II) of such subpara-
15 graph, as applicable,”.

16 (c) GDUFA AUTHORITY.—Section 744B of the Fed-
17 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42)
18 is amended—

19 (1) in subsection (e)(2), by striking
20 “744A(11)(C)” and inserting “744A(12)(C)”;

21 (2) in subsection (i)(2)—

22 (A) in subparagraph (A)(ii)—

23 (i) by striking “available for a fiscal
24 year beginning after fiscal year 2012” and
25 inserting the following: “available—

1 “(I) for fiscal year 2023”;

2 (ii) by striking “the fiscal year in-
3 volved.” and inserting “such fiscal year;
4 and”; and

5 (iii) by adding at the end the fol-
6 lowing:

7 “(II) for fiscal year 2024 and
8 each subsequent fiscal year, to defray
9 the costs of human generic drug ac-
10 tivities (including such costs for an
11 additional number of full-time equiva-
12 lent positions in the Department of
13 Health and Human Services to be en-
14 gaged in such activities), only if the
15 sum of the amounts allocated by the
16 Secretary for such costs, excluding
17 costs paid from fees collected under
18 this section, plus other costs for the
19 maintenance, renovation, and repair
20 of facilities and acquisition, mainte-
21 nance, and repair of fixtures, fur-
22 niture, and other necessary materials
23 and supplies in connection with
24 human generic drug activities, is no
25 less than \$97,000,000 multiplied by

1 the adjustment factor defined in sec-
2 tion 744A(3) applicable to the fiscal
3 year involved.”; and

4 (B) in subparagraph (B), by striking “for
5 human generic activities” and inserting “as de-
6 scribed in subclause (I) or (II) of such subpara-
7 graph, as applicable.”.

8 (d) MDUFA AUTHORITY.—Section 738 of the Fed-
9 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is
10 amended—

11 (1) in subsection (h)(2)—

12 (A) in subparagraph (A)(ii)—

13 (i) by striking “shall be available to
14 defray” and inserting the following: “shall
15 be available—

16 “(I) for fiscal year 2023, to de-
17 fray”;

18 (ii) by striking the period and insert-
19 ing “; and”; and

20 (iii) by adding at the end the fol-
21 lowing:

22 “(II) for fiscal year 2024 and
23 each subsequent fiscal year, to defray
24 the costs of the resources allocated for
25 the process for the review of device

1 applications (including such costs for
2 an additional number of full-time
3 equivalent positions in the Depart-
4 ment of Health and Human Services
5 to be engaged in such process), only if
6 the sum of the amounts allocated by
7 the Secretary for such costs, excluding
8 costs paid from fees collected under
9 this section, plus other costs for the
10 maintenance, renovation, and repair
11 of facilities and acquisition, mainte-
12 nance, and repair of fixtures, fur-
13 niture and other necessary materials
14 and supplies in connection with the
15 process for the review of device appli-
16 cations, is no less than the amount al-
17 located for such costs, excluding any
18 such costs paid from fees collected
19 under this section, for fiscal year
20 2009 multiplied by the adjustment
21 factor.”; and

22 (B) in subparagraph (B)(i), in the matter
23 preceding subclause (I), by striking “for the
24 process for the review of device applications”

1 and inserting “as described in subclause (I) or
2 (II) of such subparagraph, as applicable”; and
3 (2) in subsection (g)(3), by striking
4 “737(9)(C)” and inserting “737(10)(C)”.

5 (e) TECHNICAL CORRECTION.—

6 (1) IN GENERAL.—Section 905(b)(2) of the
7 FDA Reauthorization Act of 2017 (Public Law 115–
8 52) is amended by striking “Section 738(h) of the
9 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
10 379j(h)) is amended” and inserting “Subsection (g)
11 of section 738 of the Federal Food, Drug, and Cos-
12 metic Act (21 U.S.C. 379j), as so redesignated by
13 section 203(f)(2)(B)(i), is amended”.

14 (2) EFFECTIVE DATE.—The amendment made
15 by paragraph (1) shall take effect as though in-
16 cluded in the enactment of section 905 of the FDA
17 Reauthorization Act of 2017 (Public Law 115–52).

18 **SEC. 902. USER FEE PROGRAM TRANSPARENCY AND AC-**

19 **COUNTABILITY.**

20 (a) PDUFA.—

21 (1) REAUTHORIZATION; REPORTING REQUIRE-
22 MENTS.—Section 736B(a) of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C. 379h–2(a)) is
24 amended—

25 (A) in paragraph (1)—

1 (i) in subparagraph (B)—

2 (I) in clause (vii), by striking “;
3 and” and inserting a semicolon;

4 (II) in clause (viii), by striking
5 the period and inserting “; and”; and

6 (III) by adding at the end the
7 following:

8 “(ix) the number of investigational
9 new drug applications submitted per fiscal
10 year, including for each review division.”;
11 and

12 (ii) by adding at the end the following
13 flush text:

14 “Nothing in subparagraph (B) shall be construed to
15 authorize the disclosure of information that is pro-
16 hibited from disclosure under section 301(j) of this
17 Act or section 1905 of title 18, United States Code,
18 or that is subject to withholding under section
19 552(b)(4) of title 5, United States Code.”; and

20 (B) in paragraph (4)—

21 (i) by amending subparagraph (A) to
22 read as follows:

23 “(A) data, analysis, and discussion of the
24 changes in the number of individuals hired as
25 agreed upon in the letters described in section

1 101(b) of the Prescription Drug User Fee
2 Amendments of 2022 and the number of re-
3 maining vacancies, the number of full-time
4 equivalents funded by fees collected pursuant to
5 section 736, and the number of full-time
6 equivalents funded by budget authority at the
7 Food and Drug Administration by each division
8 within the Center for Drug Evaluation and Re-
9 search, the Center for Biologics Evaluation and
10 Research, the Office of Regulatory Affairs, and
11 the Office of the Commissioner;”;

12 (ii) by amending subparagraph (B) to
13 read as follows:

14 “(B) data, analysis, and discussion of the
15 changes in the fee revenue amounts and costs
16 for the process for the review of human drug
17 applications, including identifying—

18 “(i) drivers of such changes; and

19 “(ii) changes in the average total cost
20 per full-time equivalent in the prescription
21 drug review program;”;

22 (iii) in subparagraph (C), by striking
23 the period and inserting “; and”; and

24 (iv) by adding at the end the fol-
25 lowing:

1 (5) to the Congress, the” and insert-
2 ing “The”; and

3 (II) by inserting “, not later than
4 30 days after each such negotiation
5 meeting” before the period at the end;
6 and

7 (ii) in subparagraph (B), by inserting
8 “, in sufficient detail,” after “shall sum-
9 marize”.

10 (b) MDUFA.—

11 (1) REAUTHORIZATION; REPORTING REQUIRE-
12 MENTS.—Section 738A(a)(1)(A) of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 379j-
14 1(a)(1)(A)), as amended by section 204, is further
15 amended—

16 (A) in clause (ii)—

17 (i) in subclause (II), by striking “;
18 and” and inserting a semicolon;

19 (ii) in subclause (III), by striking the
20 period and inserting a semicolon; and

21 (iii) by adding at the end the fol-
22 lowing:

23 “(IV) the number of investiga-
24 tional device exemption applications
25 submitted under section 520(g) per

1 fiscal year, including for each review
2 division; and

3 “(V) the number of expedited de-
4 velopment and priority review requests
5 and designations under section 515B
6 per fiscal year, including for each re-
7 view division.

8 Nothing in this clause shall be construed
9 to authorize the disclosure of information
10 that is prohibited from disclosure under
11 section 301(j) of this Act or section 1905
12 of title 18, United States Code, or that is
13 subject to withholding under section
14 552(b)(4) of title 5, United States Code.”;
15 and

16 (B) in clause (iv) (relating to rationale for
17 MDUFA program changes)—

18 (i) by amending subclause (I) to read
19 as follows:

20 “(I) data, analysis, and discus-
21 sion of the changes in the number of
22 individuals hired as agreed upon in
23 the letters described in section 201(b)
24 of the Medical Device User Fee
25 Amendments of 2022 and the number

1 of remaining vacancies, the number of
2 full-time equivalents funded by fees
3 collected pursuant to section 738, and
4 the number of full time equivalents
5 funded by budget authority at the
6 Food and Drug Administration by
7 each division within the Center for
8 Devices and Radiological Health, the
9 Center for Biologics Evaluation and
10 Research, the Office of Regulatory Af-
11 fairs, and the Office of the Commis-
12 sioner;”;

13 (ii) by amending subclause (II) to
14 read as follows:

15 “(II) data, analysis, and discus-
16 sion of the changes in the fee revenue
17 amounts and costs for the process for
18 the review of device applications, in-
19 cluding identifying—

20 “(aa) drivers of such
21 changes; and

22 “(bb) changes in the average
23 total cost per full-time equivalent
24 in the medical device review pro-
25 gram;”;

1 (iii) in subclause (III), by striking the
2 period and inserting “; and”; and

3 (iv) by adding at the end the fol-
4 lowing:

5 “(IV) data, analysis, and discus-
6 sion of the changes in the average
7 full-time equivalent hours required to
8 complete review of medical device ap-
9 plication types.”.

10 (2) REAUTHORIZATION.—Section 738A(b) of
11 the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 379j–1(b)), as amended by section 204, is
13 further amended—

14 (A) by redesignating paragraphs (4)
15 through (6) as paragraphs (5) through (7), re-
16 spectively;

17 (B) by inserting after paragraph (3) the
18 following:

19 “(4) UPDATES TO CONGRESS.—The Secretary,
20 in consultation with regulated industry, shall provide
21 regular updates on negotiations on the reauthoriza-
22 tion of this part to the Committee on Health, Edu-
23 cation, Labor, and Pensions of the Senate and the
24 Committee on Energy and Commerce of the House
25 of Representatives.”; and

1 (C) in paragraph (7), as so redesignated—

2 (i) in subparagraph (A)—

3 (I) by striking “Before pre-
4 senting the recommendations devel-
5 oped under paragraphs (1) through
6 (5) to the Congress, the” and insert-
7 ing “The”; and

8 (II) by inserting “, not later than
9 30 days after each such negotiation
10 meeting” before the period at the end;
11 and

12 (ii) in subparagraph (B), by inserting
13 “, in sufficient detail,” after “shall sum-
14 marize”.

15 (c) GDUFA.—

16 (1) REAUTHORIZATION; REPORTING REQUIRE-
17 MENTS.—Section 744C(a)(3) of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 379j-43(a)(3))
19 is amended—

20 (A) in the matter preceding subparagraph
21 (A), by striking “fiscal year 2020” and insert-
22 ing “fiscal year 2023”;

23 (B) by amending subparagraph (A) to read
24 as follows:

1 “(A) data, analysis, and discussion of the
2 changes in the number of individuals hired as
3 agreed upon in the letters described in section
4 301(b) of the Generic Drug User Fee Amend-
5 ments of 2022 and the number of remaining va-
6 cancies, the number of full-time equivalents
7 funded by fees collected pursuant to section
8 744B, and the number of full time equivalents
9 funded by budget authority at the Food and
10 Drug Administration by each division within
11 the Center for Drug Evaluation and Research,
12 the Center for Biologics Evaluation and Re-
13 search, the Office of Regulatory Affairs, and
14 the Office of the Commissioner;”;

15 (C) by amending subparagraph (B) to read
16 as follows:

17 “(B) data, analysis, and discussion of the
18 changes in the fee revenue amounts and costs
19 for human generic drug activities, including—

20 “(i) identifying drivers of such
21 changes; and

22 “(ii) changes in the total average cost
23 per full-time equivalent in the generic drug
24 review program;”;

1 (D) in subparagraph (C), by striking the
2 period at the end and inserting “; and”;

3 (E) by adding at the end the following:

4 “(D) data, analysis, and discussion of the
5 changes in the average full-time equivalent
6 hours required to complete review of each type
7 of abbreviated new drug application.”.

8 (2) REAUTHORIZATION.—Section 744C(f) of
9 the Federal Food, Drug, and Cosmetic Act (21
10 U.S.C. 379j–43(f)) is amended—

11 (A) by redesignating paragraphs (4)
12 through (6) as paragraphs (5) through (7), re-
13 spectively;

14 (B) by inserting after paragraph (3) the
15 following:

16 “(4) UPDATES TO CONGRESS.—The Secretary,
17 in consultation with regulated industry, shall provide
18 regular updates on negotiations on the reauthoriza-
19 tion of this part to the Committee on Health, Edu-
20 cation, Labor, and Pensions of the Senate and the
21 Committee on Energy and Commerce of the House
22 of Representatives.”; and

23 (C) in paragraph (7), as so redesignated—

24 (i) in subparagraph (A)—

1 (I) by striking “Before pre-
2 senting the recommendations devel-
3 oped under paragraphs (1) through
4 (5) to the Congress, the” and insert-
5 ing “The”; and

6 (II) by inserting “, not later than
7 30 days after each such negotiation
8 meeting” before the period at the end;
9 and

10 (ii) in subparagraph (B), by inserting
11 “, in sufficient detail,” after “shall sum-
12 marize”.

13 (d) BSUFA.—

14 (1) REAUTHORIZATION; REPORTING REQUIRE-
15 MENTS.—Section 744I(a)(4) of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 379j–53(a)(4))
17 is amended—

18 (A) by amending subparagraph (A) to read
19 as follows:

20 “(A) data, analysis, and discussion of the
21 changes in the number of individuals hired as
22 agreed upon in the letters described in section
23 401(b) of the Biosimilar User Fee Amendments
24 of 2022 and the number of remaining vacan-
25 cies, the number of full-time equivalents funded

1 by fees collected pursuant to section 744H, and
2 the number of full time equivalents funded by
3 budget authority at the Food and Drug Admin-
4 istration by each division within the Center for
5 Drug Evaluation and Research, the Center for
6 Biologics Evaluation and Research, the Office
7 of Regulatory Affairs, and the Office of the
8 Commissioner;”;

9 (B) by amending subparagraph (B) to read
10 as follows:

11 “(B) data, analysis, and discussion of the
12 changes in the fee revenue amounts and costs
13 for the process for the review of biosimilar bio-
14 logical product applications, including identi-
15 fying—

16 “(i) drivers of such changes; and

17 “(ii) changes in the average total cost
18 per full-time equivalent in the biosimilar
19 biological product review program;”;

20 (C) in subparagraph (C), by striking the
21 period at the end and inserting “; and”; and

22 (D) by adding at the end the following:

23 “(D) data, analysis, and discussion of the
24 changes in the average full-time equivalent

1 hours required to complete review of each type
2 of biosimilar biological product application.”.

3 (2) REAUTHORIZATION.—Section 744I(f) of the
4 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
5 379j–53(f)) is amended—

6 (A) by redesignating paragraphs (2) and
7 (3) as paragraphs (5) and (6), respectively;

8 (B) by inserting after paragraph (1) the
9 following:

10 “(2) PRIOR PUBLIC INPUT.—Prior to beginning
11 negotiations with the regulated industry on the reau-
12 thorization of this part, the Secretary shall—

13 “(A) publish a notice in the Federal Reg-
14 ister requesting public input on the reauthoriza-
15 tion;

16 “(B) hold a public meeting at which the
17 public may present its views on the reauthoriza-
18 tion;

19 “(C) provide a period of 30 days after the
20 public meeting to obtain written comments from
21 the public suggesting changes to this part; and

22 “(D) publish the comments on the Food
23 and Drug Administration’s website.

24 “(3) PERIODIC CONSULTATION.—Not less fre-
25 quently than once every month during negotiations

1 with the regulated industry, the Secretary shall hold
2 discussions with representatives of patient and con-
3 sumer advocacy groups to continue discussions of
4 their views on the reauthorization and their sugges-
5 tions for changes to this part as expressed under
6 paragraph (2).

7 “(4) UPDATES TO CONGRESS.—The Secretary,
8 in consultation with regulated industry, shall provide
9 regular updates on negotiations on the reauthoriza-
10 tion of this part to the Committee on Health, Edu-
11 cation, Labor, and Pensions of the Senate and the
12 Committee on Energy and Commerce of the House
13 of Representatives.”; and

14 (C) by adding at the end the following:

15 “(7) MINUTES OF NEGOTIATION MEETINGS.—

16 “(A) PUBLIC AVAILABILITY.—The Sec-
17 retary shall make publicly available, on the pub-
18 lic website of the Food and Drug Administra-
19 tion, minutes of all negotiation meetings con-
20 ducted under this subsection between the Food
21 and Drug Administration and the regulated in-
22 dustry, not later than 30 days after each such
23 negotiation meeting.

24 “(B) CONTENT.—The minutes described
25 under subparagraph (A) shall summarize, in

1 sufficient detail, any substantive proposal made
2 by any party to the negotiations as well as sig-
3 nificant controversies or differences of opinion
4 during the negotiations and their resolution.”.

5 **SEC. 903. OTC HEARING AIDS FINAL RULE.**

6 Not later than 30 days after the date of enactment
7 of this Act, the Secretary of Health and Human Services
8 shall issue a final rule to establish a category of over-the-
9 counter hearing aids, as defined in subsection (q) of sec-
10 tion 520 of the Federal Food, Drug, and Cosmetic Act
11 (21 U.S.C. 360j), as described in section 709(b) of the
12 FDA Reauthorization Act of 2017 (Public Law 115–52).

13 **SEC. 904. ENHANCING COORDINATION AND TRANS-**
14 **PARENCY ON INSPECTIONS.**

15 (a) COORDINATION.—Section 506D of the Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C. 356d) is
17 amended—

18 (1) by adding at the end the following:

19 “(g) COORDINATION.—The Secretary shall ensure
20 timely and effective internal coordination and alignment
21 among the field investigators of the Food and Drug Ad-
22 ministration and the staff of the Center for Drug Evalua-
23 tion and Research’s Office of Compliance and Drug Short-
24 age Program regarding the reviews of reports shared pur-

1 suant to section 704(b)(2), and any feedback or corrective
2 or preventive actions in response to such reports.”; and

3 (2) by amending subsection (f) to read as fol-
4 lows:

5 “(f) TEMPORARY SUNSET.—Subsection (a) shall
6 cease to be effective on the date that is 5 years after the
7 date of enactment of the Food and Drug Administration
8 Safety and Innovation Act. Subsections (b), (c), and (e)
9 shall not be in effect during the period beginning 5 years
10 after the date of enactment of the Food and Drug Admin-
11 istration Safety and Innovation Act and ending on the
12 date of enactment of the Food and Drug Administration
13 Safety and Landmark Advancements Act of 2022. Sub-
14 sections (b), (c), and (e) shall be in effect beginning on
15 the date of enactment of the Food and Drug Administra-
16 tion Safety and Landmark Advancements Act of 2022.”.

17 (b) REPORTING.—Section 506C–1(a) of the Federal
18 Food, Drug, and Cosmetic Act (21 U.S.C. 356e–1(a)) is
19 amended—

20 (1) by redesignating paragraphs (3) through
21 (7) as paragraphs (4) through (8), respectively;

22 (2) by inserting after paragraph (2) the fol-
23 lowing:

24 “(3) provides the number of reports that were
25 required under section 704(b)(2) to be sent to the

1 appropriate offices of the Food and Drug Adminis-
2 tration with expertise regarding drug shortages, and
3 the number of such reports that were sent;” and

4 (3) in paragraph (4)(A), as so redesignated, by
5 striking “paragraph (7)” and inserting “paragraph
6 (8)”.

7 (c) APPLICABILITY.—

8 (1) SUBSECTION (a).—The amendments made
9 by subsection (a) shall apply beginning on the date
10 of enactment of this Act.

11 (2) SUBSECTION (b).—The amendments made
12 by subsection (b) shall apply beginning on the date
13 that is 1 year after the date of enactment of this
14 Act.

15 (d) REPORTING OF MUTUAL RECOGNITION AGREE-
16 MENTS FOR INSPECTIONS AND REVIEW ACTIVITIES.—
17 Section 510(h) of the Federal Food, Drug, and Cosmetic
18 Act (21 U.S.C. 360(h)) is amended—

19 (1) in paragraph (6)—

20 (A) in subparagraph (A), by striking
21 clauses (i) and (ii) and inserting the following:

22 “(i) the number of domestic and foreign
23 establishments registered pursuant to this sec-
24 tion in the previous fiscal year;

1 “(ii) the number of such registered estab-
2 lishments in each region of interest;

3 “(iii) the number of such domestic estab-
4 lishments and the number of such foreign es-
5 tablishments, including the number of establish-
6 ments in each region of interest, that the Sec-
7 retary inspected in the previous fiscal year;

8 “(iv) the number of inspections to support
9 actions by the Secretary on applications under
10 section 505 of this Act or section 351 of the
11 Public Health Service Act, including the num-
12 ber of inspections to support actions by the Sec-
13 retary on supplemental applications, including
14 changes to manufacturing processes, the Sec-
15 retary conducted in the previous fiscal year;

16 “(v) the number of routine surveillance in-
17 spections the Secretary conducted in the pre-
18 vious fiscal year, including in each region of in-
19 terest;

20 “(vi) the number of for-cause inspections
21 the Secretary conducted in the previous fiscal
22 year, not including inspections described in
23 clause (iv), including in each region of interest;
24 and

1 “(vii) the number of inspections the Sec-
2 retary has recognized pursuant to an agreement
3 entered into pursuant to section 809, or other-
4 wise recognized, for each of the types of inspec-
5 tions described in clauses (v) and (vi), including
6 for inspections of establishments in each region
7 of interest.”;

8 (B) in subparagraph (B), by striking “;
9 and” and inserting a semicolon;

10 (C) in subparagraph (C), by striking the
11 period and inserting “; and”; and

12 (D) by adding at the end the following:

13 “(D) the status of the efforts of the Food
14 and Drug Administration to expand its recogni-
15 tion of inspections conducted or recognized by
16 foreign regulatory authorities under section
17 809, including any obstacles to expanding the
18 use of such recognition.”; and

19 (2) by adding at the end the following:

20 “(7) REGION OF INTEREST.—For purposes of
21 paragraph (6)(A), the term ‘region of interest’
22 means a foreign geographic region or country, in-
23 cluding the People’s Republic of China, India, the
24 European Union, the United Kingdom, and any

1 other country or geographic region, as the Secretary
2 determines appropriate.”.

3 (e) ENHANCING TRANSPARENCY OF DRUG FACILITY
4 INSPECTION TIMELINES.—Section 902 of the FDA Reau-
5 thorization Act of 2017 (21 U.S.C. 355 note) is amended
6 to read as follows:

7 **“SEC. 902. ANNUAL REPORT ON INSPECTIONS.**

8 “Not later than 120 days after the end of each fiscal
9 year, the Secretary of Health and Human Services shall
10 post on the website of the Food and Drug Administration
11 information related to inspections of facilities necessary
12 for approval of a drug under subsection (c) or (j) of sec-
13 tion 505 of the Federal Food, Drug, and Cosmetic Act
14 (21 U.S.C. 355) or approval of a device under section 515
15 of such Act (21 U.S.C. 360e) that were conducted during
16 the previous fiscal year. Such information shall include the
17 following:

18 “(1) The median time following a request from
19 staff of the Food and Drug Administration review-
20 ing an application or report to the beginning of the
21 inspection, including—

22 “(A) the median time for drugs described
23 in 505(j)(11)(A)(i) of the Federal Food, Drug,
24 and Cosmetic Act (21 U.S.C. 355(j)(11)(A)(i));

1 “(B) the median time for drugs for which
2 a notification has been submitted in accordance
3 with section 506C(a) of such Act (21 U.S.C.
4 356c(a)) during the previous fiscal year; and

5 “(C) the median time for drugs on the
6 drug shortage list in effect under section 506E
7 of such Act (21 U.S.C. 356e) at the time of
8 such request.

9 “(2) The median time from the issuance of a
10 report pursuant to section 704(b) of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 374(b))
12 to the sending of a warning letter, issuance of an
13 import alert, or holding of a regulatory meeting for
14 inspections for which the Secretary concluded that
15 regulatory or enforcement action was indicated, in-
16 cluding the median time for each category of drugs
17 listed in subparagraphs (A) through (C) of para-
18 graph (1).

19 “(3) The median time from the sending of a
20 warning letter, issuance of an import alert, or hold-
21 ing of a regulatory meeting related to conditions ob-
22 served by the Secretary during an inspection, to the
23 time at which the Secretary concludes that corrective
24 actions to resolve such conditions have been taken.

1 “(4) The median time spent by staff of the
2 Food and Drug Administration at a facility during
3 an inspection, including—

4 “(A) the median time when records were
5 provided remotely in accordance with a request
6 under section 704(a)(4) of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 374(a)(4))
8 in advance of the inspection; and

9 “(B) the median time when a request for
10 records pursuant to such section 704(a)(4) was
11 not issued, or complied with, in advance of the
12 inspection.

13 “(5) The number and type of violations identi-
14 fied during inspections when a request for records
15 pursuant to such section 704(a)(4) was issued and
16 complied with in advance of the inspection, versus
17 when a request for records pursuant to such section
18 704(a)(4) was not issued or complied with.

19 “(6) The number of facilities that did not im-
20 plement adequate corrective or preventive actions
21 following a report issued pursuant to such section
22 704(b), resulting in a withhold recommendation for
23 an application under review, including the number of
24 such facilities manufacturing each category of drugs

1 listed in subparagraphs (A) through (C) of para-
2 graph (1).”.

3 **SEC. 905. CERTIFICATES TO FOREIGN GOVERNMENTS.**

4 Section 801(e)(4) of the Federal Food, Drug, and
5 Cosmetic Act (21 U.S.C. 381(e)(4)) is amended—

6 (1) in subparagraph (E), by striking clause
7 (iii); and

8 (2) by adding at the end the following:

9 “(F)(i) This paragraph applies to requests for certifi-
10 cation under this subparagraph of a device manufactured
11 by a device establishment located outside of the United
12 States that is registered under section 510, if the device
13 is listed pursuant to section 510(j), the device has been
14 cleared, approved, or is not required to submit a pre-
15 market report pursuant to subsection (l) or (m) of section
16 510, and the device is imported or offered for import into
17 the United States.

18 “(ii) The Secretary shall issue the certification as de-
19 scribed in clause (iii) if the device or devices for which
20 certification is requested under this subparagraph meet
21 the applicable requirements of this Act.

22 “(iii)(I) A certification for a device described in
23 clause (i) shall be subject to the fee described in subpara-
24 graph (B).

1 “(II) Notwithstanding subparagraph (C), a certifi-
2 cation for a device described in clause (i) shall address
3 and include the same material information as a ‘Certifi-
4 cate to Foreign Government’ and shall have a document
5 title including the words ‘Certificate to Foreign Govern-
6 ment’.

7 “(iv) The requirements and procedures of subpara-
8 graph (E) shall apply to a denial of a certification under
9 this subparagraph.”.

10 **SEC. 906. IMPORTATION OF DRUGS.**

11 (a) IN GENERAL.—Section 804 of the Federal Food,
12 Drug, and Cosmetic Act (21 U.S.C. 384) is amended to
13 read as follows:

14 **“SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.**

15 “(a) DEFINITIONS.—In this section:

16 “(1) FOREIGN SELLER.—The term ‘foreign sell-
17 er’ means an establishment within Canada engaged
18 in the distribution of an eligible prescription drug
19 that is imported or offered for importation into the
20 United States, that—

21 “(A) has an active Drug Establishment Li-
22 cense to wholesale drugs by the appropriate Ca-
23 nadian regulatory authority;

24 “(B) is registered with the applicable regu-
25 latory authorities to distribute drugs approved

1 by the appropriate Canadian regulatory author-
2 ity;

3 “(C) is not licensed by a regulatory au-
4 thority with an international pharmacy license
5 that allows it to distribute drugs that are ap-
6 proved by countries other than Canada and that
7 are not approved by the appropriate Canadian
8 regulatory authority for distribution in Canada;
9 and

10 “(D) is registered with the Secretary under
11 this section.

12 “(2) IMPORTER.—The term ‘importer’ means a
13 pharmacist or wholesaler.

14 “(3) PHARMACIST.—The term ‘pharmacist’
15 means a person licensed by a State to practice phar-
16 macy, including the dispensing and selling of pre-
17 scription drugs.

18 “(4) PRESCRIPTION DRUG.—The term ‘pre-
19 scription drug’ means a drug subject to section
20 503(b), other than—

21 “(A) a controlled substance (as defined in
22 section 102 of the Controlled Substances Act
23 (21 U.S.C. 802));

1 “(B) a biological product (as defined in
2 section 351 of the Public Health Service Act
3 (42 U.S.C. 262));

4 “(C) an infused drug (including a peri-
5 toneal dialysis solution);

6 “(D) an intravenously injected drug;

7 “(E) a drug that is inhaled during surgery;

8 “(F) an intrathecally or intraocularly in-
9 jected drug;

10 “(G) a drug that is subject to a risk eval-
11 uation and mitigation strategy under section
12 505-1;

13 “(H) a drug that is not a ‘product’ for
14 purposes of section 582 as defined in section
15 581(13);

16 “(I) a compounded drug; or

17 “(J) a drug the importation of which pur-
18 suant to subsection (b) is determined by the
19 Secretary to pose a threat to the public health.

20 “(5) QUALIFYING LABORATORY.—The term
21 ‘qualifying laboratory’ means a laboratory in the
22 United States that complies with the applicable cur-
23 rent good manufacturing practice requirements and
24 has been approved by the Secretary for the purposes
25 of this section.

1 “(6) SECTION 804 IMPORTATION PROGRAM
2 SPONSOR.—The term ‘section 804 importation pro-
3 gram sponsor’ means a State or Indian Tribe that
4 regulates wholesale drug distribution and the prac-
5 tice of pharmacy, or a pharmacist or wholesaler that
6 is not the importer, as the Secretary may determine,
7 that submits a proposal to the Secretary that de-
8 scribes a program to facilitate the importation of
9 prescription drugs from Canada under this section
10 and is responsible for oversight of the implementa-
11 tion of the program.

12 “(7) WHOLESALER.—The term ‘wholesaler’—
13 “(A) means a person licensed (as defined
14 in section 581(9)(A)) as a wholesale distributor
15 (as defined in section 581(29)); and

16 “(B) excludes a person authorized to im-
17 port drugs under section 801(d)(1).

18 “(b) REGULATIONS.—The Secretary, after consulta-
19 tion with the United States Trade Representative and the
20 Commissioner of Customs, shall promulgate regulations
21 permitting time-limited section 804 importation programs,
22 which shall be authorized by the Secretary and managed
23 by States or Indian Tribes, or in certain circumstances
24 by pharmacists and wholesalers, to import prescription
25 drugs from Canada into the United States. The time limit

1 for a section 804 importation program authorized by the
2 Secretary may be extended for a period not to exceed the
3 initial time limit authorized by the Secretary.

4 “(c) LIMITATION.—The regulations under subsection
5 (b) shall—

6 “(1) require that safeguards be in place to en-
7 sure that each prescription drug imported under the
8 regulations complies with section 505 (including
9 with respect to being safe and effective for the in-
10 tended use of the prescription drug), with sections
11 501 and 502, and with other applicable require-
12 ments of this Act;

13 “(2) require that a section 804 importation pro-
14 gram sponsor and an importer of a prescription drug
15 under the regulations comply with subsections
16 (d)(1), (d)(2), (d)(3), and (e);

17 “(3) require that the section 804 importation
18 program sponsor demonstrates that the importation
19 program meets the certification requirements under
20 subsection (l)(1); and

21 “(4) contain any additional provisions deter-
22 mined by the Secretary to be appropriate as a safe-
23 guard to protect the public health or as a means to
24 facilitate the importation of prescription drugs.

25 “(d) INFORMATION AND RECORDS.—

1 “(1) IN GENERAL.—The regulations under sub-
2 section (b) shall require an importer of a prescrip-
3 tion drug under subsection (b) to submit to the Sec-
4 retary the following information and documentation:

5 “(A) The name and quantity of the active
6 ingredient of the prescription drug.

7 “(B) A description of the dosage form of
8 the prescription drug.

9 “(C) The date on which the prescription
10 drug is shipped.

11 “(D) The quantity of the prescription drug
12 that is shipped.

13 “(E) The point of origin and destination of
14 the prescription drug.

15 “(F) The price paid by the importer for
16 the prescription drug.

17 “(G) Documentation from the foreign sell-
18 er specifying—

19 “(i) the original source of the pre-
20 scription drug; and

21 “(ii) the quantity of each lot of the
22 prescription drug originally received by the
23 seller from that source.

1 “(H) The lot or control number assigned
2 to the prescription drug by the manufacturer of
3 the prescription drug.

4 “(I) The name, address, telephone number,
5 and professional license number (if any) of the
6 importer.

7 “(J) Documentation demonstrating that
8 the prescription drug was received by the for-
9 eign seller from the manufacturer and subse-
10 quently shipped by the foreign seller to the im-
11 porter.

12 “(K) Documentation of the quantity of
13 each lot of the prescription drug received by the
14 foreign seller demonstrating that the quantity
15 being imported into the United States is not
16 more than the quantity that was received by the
17 foreign seller.

18 “(L)(i) In the case of an initial imported
19 shipment, documentation demonstrating that
20 each batch of the prescription drug in the ship-
21 ment was statistically sampled and tested for
22 authenticity and degradation.

23 “(ii) In the case of any subsequent ship-
24 ment, documentation demonstrating that a sta-

1 tistically valid sample of the shipment was test-
2 ed for authenticity and degradation.

3 “(M) Documentation that each supply
4 chain under a section 804 importation program
5 proposal is limited to one manufacturer, one
6 foreign seller, and one importer.

7 “(N) For each prescription drug imported
8 under a section 804 importation program, docu-
9 mentation that the prescription drug was pur-
10 chased directly from the manufacturer by the
11 foreign seller and that the foreign seller sold
12 the prescription drug directly to the importer.

13 “(O) Certification from the importer that
14 the prescription drug—

15 “(i) is approved for marketing in the
16 United States and is not adulterated or
17 misbranded; and

18 “(ii) is relabeled after the Secretary
19 has accepted the results of testing required
20 by subparagraphs (J) through (P)) and
21 meets all labeling requirements under this
22 Act.

23 “(P) Laboratory records, including com-
24 plete data derived from all tests necessary to
25 ensure that the prescription drug is in compli-

1 ance with established specifications and stand-
2 ards.

3 “(Q) Documentation demonstrating that
4 the testing required by subparagraphs (J)
5 through (P) was conducted at a qualifying lab-
6 oratory in the United States.

7 “(R) Any other information that the Sec-
8 retary determines is necessary to ensure the
9 protection of the public health.

10 “(2) SECTION 804 IMPORTATION PROGRAM PRO-
11 POSAL.—The regulations under subsection (b) shall
12 require a sponsor of a time-limited section 804 im-
13 portation program authorized under such subsection
14 to submit to the Secretary the following information
15 and documentation in its proposal to the Secretary:

16 “(A) The names of all participants in the
17 supply chain, including—

18 “(i) the foreign seller;

19 “(ii) the importer;

20 “(iii) the repackager or relabeler, if
21 different from the importer, that will
22 relabel the eligible prescription drugs; and

23 “(iv) the qualifying laboratory that
24 will conduct testing for the importer.

1 “(B) Information about how the section
2 804 importation program sponsor will ensure
3 that—

4 “(i) the prescription drug meets the
5 testing requirements in subparagraphs (J)
6 through (P) of paragraph (1);

7 “(ii) the supply chain is secure;

8 “(iii) the prescription drug will meet
9 the labeling requirements of this Act;

10 “(iv) the adverse event-related re-
11 quirements of this Act are met; and

12 “(v) the section 804 importation pro-
13 gram will result in a significant reduction
14 in the cost to the American consumer of
15 the prescription drug.

16 “(C) A compliance plan.

17 “(D) Information about how the section
18 804 importation sponsor will ensure that any
19 trade secrets or commercial or financial infor-
20 mation that is privileged or confidential that
21 the manufacturer supplies are kept in strict
22 confidence and used only for the purposes of
23 testing or otherwise complying with Federal
24 law.

1 “(3) PRE -IMPORT REQUEST.—The regulations
2 under subsection (b) shall require an importer under
3 a program authorized under such subsection to sub-
4 mit a pre-import request to the Secretary at least 30
5 calendar days before the scheduled date of arrival or
6 entry for consumption of a shipment containing a
7 prescription drug covered by the section 804 impor-
8 tation program, whichever is earlier.

9 “(4) MAINTENANCE BY THE SECRETARY.—The
10 Secretary shall maintain information and docu-
11 mentation submitted under paragraphs (1), (2), and
12 (3) for such period of time as the Secretary deter-
13 mines to be necessary.

14 “(e) TESTING.—The regulations under subsection (b)
15 shall require—

16 “(1) that testing described in subparagraphs
17 (J) through (P) of subsection (d)(1) be conducted by
18 the importer or by the manufacturer of the prescrip-
19 tion drug at a qualified laboratory;

20 “(2) if the tests are conducted by the im-
21 porter—

22 “(A) that information needed to—

23 “(i) authenticate the prescription drug
24 being tested; and

1 “(ii) confirm that the labeling of the
2 prescription drug complies with labeling re-
3 quirements under this Act,

4 be supplied by the manufacturer of the pre-
5 scription drug to the pharmacist or wholesaler;
6 and

7 “(B) that the information supplied under
8 subparagraph (A) be kept in strict confidence
9 and used only for purposes of testing or other-
10 wise complying with this Act; and

11 “(3) such additional provisions as the Secretary
12 determines to be appropriate to provide for the pro-
13 tection of trade secrets and commercial or financial
14 information that is privileged or confidential.

15 “(f) REGISTRATION OF FOREIGN SELLERS.—Any es-
16 tablishment within Canada engaged in the distribution of
17 a prescription drug that is imported or offered for impor-
18 tation into the United States shall register with the Sec-
19 retary the name and place of business of the establishment
20 and the name of the United States agent for the establish-
21 ment.

22 “(g) SUSPENSION OF IMPORTATION.—The Secretary
23 shall require that importations of a specific prescription
24 drug or importations by a specific importer under sub-
25 section (b) be immediately suspended on discovery of a

1 pattern of importation of that specific prescription drug
2 or by that specific importer of drugs that are counterfeit
3 or in violation of any requirement under this section, until
4 an investigation is completed and the Secretary deter-
5 mines that the public is adequately protected from coun-
6 terfeit and violative prescription drugs being imported
7 under subsection (b).

8 “(h) APPROVED LABELING.—The manufacturer of a
9 prescription drug shall provide an importer written au-
10 thorization for the importer to use, at no cost, the ap-
11 proved labeling for the prescription drug.

12 “(i) CHARITABLE CONTRIBUTIONS.—Notwith-
13 standing any other provision of this section, section
14 801(d)(1) continues to apply to a prescription drug that
15 is donated or otherwise supplied at no charge by the man-
16 ufacturer of the drug to a charitable or humanitarian or-
17 ganization (including the United Nations and affiliates)
18 or to a government of a foreign country.

19 “(j) IMPORTATION FOR PERSONAL USE.—

20 “(1) DECLARATIONS.—Congress declares that,
21 in implementing the provisions under this section,
22 the Secretary may—

23 “(A) focus enforcement on cases in which
24 the importation by an individual poses a signifi-
25 cant threat to public health; and

1 “(B) exercise discretion to permit individ-
2 uals to make such importations in cir-
3 cumstances in which—

4 “(i) the importation is clearly for per-
5 sonal use; and

6 “(ii) the prescription drug or device
7 imported does not appear to present an
8 unreasonable risk to the individual.

9 “(2) REGULATIONS.—

10 “(A) IN GENERAL.—The Secretary may,
11 by regulation, permit importation of a prescrip-
12 tion drug, or class of prescription drugs, for
13 personal use, provided that such importation—

14 “(i) does not increase the public’s ex-
15 posure to counterfeit prescription drug
16 products;

17 “(ii) does not pose a risk of creating,
18 exacerbating, or prolonging an opioid epi-
19 demic, including by increasing the public’s
20 exposure to counterfeit prescription opioid
21 drug products, such as counterfeit
22 fentanyl, or increasing the public’s misuse
23 of prescription opioid drug products;

24 “(iii) meets the certification require-
25 ments under subsection (l)(1); and

1 “(iv) meets such other conditions as
2 the Secretary determines to be appropriate.

3 “(B) REQUIREMENTS.—Regulations de-
4 scribed in subparagraph (A) may permit impor-
5 tation into the United States of a prescription
6 drug that—

7 “(i) is imported in a quantity that
8 does not exceed a 90-day supply;

9 “(ii) is for personal use by an indi-
10 vidual, not for resale;

11 “(iii) is accompanied by a copy of a
12 valid prescription issued by a health care
13 practitioner licensed by a State to practice
14 in the United States to administer the
15 drug, and is not distributed to anyone
16 other than the individual for whom such
17 prescription is written;

18 “(iv) is imported from Canada, from a
19 licensed pharmacy physically located in
20 Canada and registered with the Secretary;

21 “(v) is a prescription drug that com-
22 plies with section 505 (including with re-
23 spect to being safe and effective for the in-
24 tended use of the prescription drug), with

1 sections 501 and 502, and with other ap-
2 plicable requirements of this Act;

3 “(vi) is accompanied by an electronic
4 import entry for such prescription drug re-
5 gardless of its values, submitted using an
6 authorized electronic data interchange sys-
7 tem;

8 “(vii) is in the form of a final finished
9 dosage that was manufactured in an estab-
10 lishment registered under section 510; and

11 “(viii) is imported under such other
12 conditions as the Secretary determines to
13 be necessary to ensure public safety.

14 “(C) PROCEDURE.—The Secretary shall—

15 “(i) proceed in accordance with sec-
16 tion 553 of title 5 (without regard to any
17 reference in such section to sections 556
18 and 557 of such title) when promulgating
19 a regulation under subparagraph (A), and
20 shall—

21 “(I) publish a notice of proposed
22 rulemaking stating with particularity
23 the reason for the proposed rule;

24 “(II) allow interested persons to
25 submit written data, views, and argu-

1 Federal Register and concurrently publish
2 the record of the consultations described in
3 clause (ii) and the descriptions described in
4 clause (iii).

5 “(k) CONSTRUCTION.—Nothing in this section limits
6 the authority of the Secretary relating to the importation
7 of prescription drugs, including the Secretary’s authority
8 to refuse admission of a drug under section 801(a), other
9 than with respect to section 801(d)(1) as provided in this
10 section.

11 “(l) EFFECTIVENESS OF SECTION.—

12 “(1) COMMENCEMENT OF PROGRAM.—This sec-
13 tion shall become effective only if the Secretary cer-
14 tifies to Congress that the implementation of this
15 section will—

16 “(A) pose no additional risk to the public’s
17 health and safety;

18 “(B) result in a significant reduction in
19 the cost of covered products to the American
20 consumer; and

21 “(C) be subject to adequate and consistent
22 oversight by the Secretary.

23 “(m) TERMINATION OF PROGRAM.—If, after the date
24 that is 1 year after the effective date of the regulations
25 under subsection (b) or (j), the Secretary submits to Con-

1 gress a certification that, in the option of the Secretary,
2 the benefits of implementation of either or both such sub-
3 sections do not outweigh any detriment of implementation
4 of such subsection or subsections and any regulations pro-
5 mulgated thereunder, such subsection or subsections shall
6 cease to be effective as of the date that is 30 days after
7 the date on which the Secretary submits the certification.

8 “(n) **AUTHORIZATION OF APPROPRIATIONS.**—There
9 are authorized to be appropriated such sums as are nec-
10 essary to carry out this section.”.

11 (b) **REQUIREMENT.**—The Secretary of Health and
12 Human Services shall reissue, or amend, as appropriate,
13 the regulations published at part 251 of title 21 of the
14 Code of Federal Regulations pursuant to section 804(b)
15 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 384(b)), as in effect on the day before the date of enact-
17 ment of this Act.

18 **SEC. 907. IMPROVING INFORMATION TECHNOLOGY SYS-**
19 **TEMS OF THE FOOD AND DRUG ADMINISTRA-**
20 **TION.**

21 (a) **FDA STRATEGIC INFORMATION TECHNOLOGY**
22 **PLAN.**—

23 (1) **IN GENERAL.**—Not later than September
24 30, 2023, and at least every 4 years thereafter, the
25 Secretary of Health and Human Services shall de-

1 velop and submit to the appropriate committees of
2 Congress and post on the website of the Food and
3 Drug Administration, a coordinated information
4 technology strategic plan to modernize the informa-
5 tion technology systems of the Food and Drug Ad-
6 ministration. Each such report shall be known as the
7 “Food and Drug Administration Strategic Informa-
8 tion Technology Plan.”. The first such report may
9 include the Data and Technology Modernization
10 Strategy, as set forth in the letters described in sec-
11 tion 101(b) of the Food and Drug Administration
12 Safety and Landmark Advancements Act of 2022.

13 (2) CONTENT OF STRATEGIC PLAN.—The Food
14 and Drug Administration Strategic Information
15 Technology Plan under paragraph (1) shall in-
16 clude—

17 (A) agency-wide strategic goals and prior-
18 ities for modernizing the information technology
19 systems of the Food and Drug Administration
20 to maximize the efficiency and effectiveness of
21 such systems for enabling the Food and Drug
22 Administration to fulfill its public health mis-
23 sion;

24 (B) specific activities and strategies for
25 achieving the goals and priorities identified

1 under subparagraph (A), and specific mile-
2 stones, metrics, and performance measures for
3 assessing progress against the strategic goals
4 and priorities in subparagraph (A);

5 (C) specific activities and strategies for im-
6 proving and streamlining internal coordination
7 and communication within the Food and Drug
8 Administration, including for activities and
9 communications related to signals of potential
10 public health concerns;

11 (D) challenges and risks the Food and
12 Drug Administration will face in meeting its
13 strategic goals and priorities, and the activities
14 the Food and Drug Administration will under-
15 take to overcome those challenges and mitigate
16 those risks;

17 (E) the ways in which the Food and Drug
18 Administration will use the plan to guide and
19 coordinate the projects and activities of the
20 Food and Drug Administration across its of-
21 fices and centers; and

22 (F) a skills inventory, needs assessment,
23 gap analysis, and initiatives to address skills
24 gaps as part of a strategic approach to informa-
25 tion technology human capital planning.

1 (3) EVALUATION OF PROGRESS.—Each Food
2 and Drug Administration Strategic Information
3 Technology Plan issued pursuant to this subsection,
4 with the exception of the first such Food and Drug
5 Administration Strategic Information Technology
6 Plan, shall include an evaluation of—

7 (A) the progress the Secretary has made,
8 based on the metrics, benchmarks, and other
9 milestones that measure successful development
10 and implementation of information technology
11 systems; and

12 (B) whether such actions improved the ca-
13 pacity of the Food and Drug Administration to
14 achieve the strategic goals and priorities set
15 forth in the previous Food and Drug Adminis-
16 tration Strategic Information Technology Plan.

17 (b) GAO REPORT.—

18 (1) IN GENERAL.—Not later than September
19 30, 2026, the Comptroller General of the United
20 States shall submit to the Committee on Health,
21 Education, Labor, and Pensions of the Senate and
22 the Committee on Energy and Commerce of the
23 House of Representatives a report assessing the im-
24 plementation of the Food and Drug Administration

1 Strategic Information Technology Plan adopted pur-
2 suant to subsection (a).

3 (2) CONTENT OF REPORT.—The report re-
4 quired under paragraph (1) shall include an assess-
5 ment of—

6 (A) the development and implementation of
7 the Food and Drug Administration Strategic
8 Information Technology Plan, including the suf-
9 ficiency of the plan, progress of the Food and
10 Drug Administration in meeting the results-ori-
11 ented goals, milestones, and performance meas-
12 ures identified in such plan and any gaps in
13 such implementation;

14 (B) the efficiency and effectiveness of the
15 Food and Drug Administration’s expenditures
16 on information technology systems over the pre-
17 ceeding 10 fiscal years, including the implemen-
18 tation by the Food and Drug Administration of
19 the Technology Modernization Action Plan and
20 Data Modernization Action Plan;

21 (C) challenges posed by the information
22 technology systems of the Food and Drug Ad-
23 ministration for carrying out the Food and
24 Drug Administration’s public health mission,
25 including on meeting user fee agreement per-

1 formance goals, conducting inspections, re-
2 sponding to identified safety concerns, and
3 keeping pace with new scientific and medical
4 advances; and

5 (D) recommendations for the Food and
6 Drug Administration to address the identified
7 challenges, improve its implementation of the
8 Food and Drug Administration Strategic Infor-
9 mation Technology Plan, and to otherwise im-
10 prove the Food and Drug Administration’s in-
11 formation technology systems.

12 **SEC. 908. REGULATION OF CERTAIN PRODUCTS AS DRUGS.**

13 Section 503 of the Federal Food, Drug, and Cosmetic
14 Act (21 U.S.C. 353) is amended by adding at the end the
15 following:

16 “(h) DEEMING CERTAIN PRODUCTS AS DRUGS.—

17 “(1) IN GENERAL.—Any contrast agent, radio-
18 active drug, OTC monograph drug, or ophthalmic
19 drug article shall be deemed to be a drug under sec-
20 tion 201(g) and not a device under section 201(h).

21 “(2) DEFINITIONS.—For purposes of this sub-
22 section—

23 “(A) the term ‘contrast agent’ means an
24 article that is intended for use in conjunction
25 with a medical imaging device, and that—

1 “(i) is a diagnostic radiopharma-
2 ceutical, as defined in section 315.2 and
3 601.31 of title 21, Code of Federal Regula-
4 tions (or any successor regulations), in-
5 cluding PET drugs, as defined in section
6 212.1 of title 21, Code of Federal Regula-
7 tions (or any successor regulations) and
8 positron emission tomography radiotracers;
9 or

10 “(ii) is a diagnostic agent that im-
11 proves the visualization of structure or
12 function within the body by increasing the
13 relative difference in signal intensity within
14 the target tissue, structure, or fluid;

15 “(B) the term ‘ophthalmic drug article’
16 means any eye cup, eye dropper, or other simi-
17 lar dispenser intended for ophthalmic use if
18 packaged with the drug with which such article
19 is intended to be used;

20 “(C) the term ‘OTC monograph drug’ has
21 the meaning given such term in section 744L;
22 and

23 “(D) the term ‘radioactive drug’ has the
24 meaning given such term in section 310.3(n) of
25 title 21, Code of Federal Regulations (or any

1 successor regulations), except that such term
2 does not include—

3 “(i) implants or articles similar to an
4 implant;

5 “(ii) articles that apply radiation from
6 outside of the body; or

7 “(iii) the radiation source of an article
8 described in clause (i) or (ii).

9 “(3) RULE OF CONSTRUCTION.—Nothing in
10 this subsection shall be construed as allowing for the
11 classification of a product as a drug (as defined in
12 section 201(g)) if such product—

13 “(A) is not described in paragraph (1);
14 and

15 “(B) meets the definition of a device under
16 section 201(h), unless another provision of this
17 Act otherwise indicates a different classifica-
18 tion.

19 “(4) FEES.—The Secretary shall waive the ap-
20 plication fee under sections 736 and 744B for appli-
21 cations for products that are, on the date of enact-
22 ment of the Food and Drug Administration Safety
23 and Landmark Advancements Act of 2022, legally
24 marketed as medical devices and that are deemed
25 drugs pursuant to paragraph (1).”.

1 **SEC. 909. REPORTING ON MAILROOM AND OFFICE OF THE**
2 **EXECUTIVE SECRETARIAT OF THE FOOD AND**
3 **DRUG ADMINISTRATION.**

4 (a) REPORT.—Not later than 90 days after the date
5 of enactment of this Act, the Secretary of Health and
6 Human Services (referred to in this section as the “Sec-
7 retary”) shall report to the Committee on Health, Edu-
8 cation, Labor, and Pensions of the Senate and the Com-
9 mittee on Energy and Commerce of the House of Rep-
10 resentatives on—

11 (1) information related to policies, procedures,
12 and activities of the mailroom and the Office of the
13 Executive Secretariat of the Food and Drug Admin-
14 istration, including—

15 (A) taking receipt, tracking, managing,
16 and prioritizing confidential informant com-
17 plaints;

18 (B) taking receipt of common carrier pack-
19 ages to the Food and Drug Administration;

20 (C) the organizational structure and man-
21 agement of the mailroom;

22 (D) the organizational structure and man-
23 agement of the Office of the Executive Secre-
24 tariat;

1 (E) the total number of employees and
2 contractors in the mailroom including those
3 working remotely and those working in person;

4 (F) the total number of employees and
5 contractors in the Office of the Executive Secre-
6 tariat;

7 (G) the number of vacant positions in the
8 mailroom;

9 (H) the number of vacant positions in the
10 Office of the Executive Secretariat;

11 (I) the average number of days for re-
12 sponse to correspondence received by the Office
13 of the Secretariat;

14 (J) the extent to which there is a backlog
15 of common carrier packages received by the
16 mailroom and the number of common carrier
17 packages in any backlog;

18 (K) the extent to which there is a backlog
19 of correspondence in the Office of the Executive
20 Secretariat that has not been appropriately re-
21 sponded to by the Food and Drug Administra-
22 tion and the number of correspondence or com-
23 mon carrier packages in any backlog;

24 (L) a rationale for the failure of the Office
25 of the Executive Secretariat to respond to cor-

1 response in any backlog and the position of
2 the decision-making official who determined not
3 to respond to such correspondence;

4 (M) the number of whistleblower cor-
5 respondence received, including within each
6 agency center;

7 (N) the amount of resources expended for
8 the mailroom, including a breakdown of budget
9 authority and user fee dollars;

10 (O) the amount of resources expended for
11 the Office of the Executive Secretariat and cor-
12 respondence-related activities, including a
13 breakdown of budget authority and user fee dol-
14 lars; and

15 (P) the performance of third-party con-
16 tractors responsible for correspondence-related
17 activities with respect to the receipt and track-
18 ing of correspondence, and efforts by the Food
19 and Drug Administration to improve perform-
20 ance by such contractors; and

21 (2) the development and implementation of new
22 or revised policies and procedures of the Food and
23 Drug Administration to monitor and ensure—

1 (A) the effective receipt, tracking, man-
2 aging, and prioritization of such complaints;
3 and

4 (B) the effective receipt of common carrier
5 packages to the Food and Drug Administration.

6 (b) QUARTERLY REPORTING.— Beginning on the
7 date of enactment of this Act, the Secretary shall issue
8 a report each quarter through September 30, 2024, to the
9 Committee on Health, Education, Labor, and Pensions of
10 the Senate and the Committee on Energy and Commerce
11 of the House of Representatives on the implementation of
12 the new or revised policies of the Food and Drug Adminis-
13 tration reported under subsection (a)(2), and since such
14 implementation—

15 (1) the volume of incoming common carrier
16 packages to the mailroom;

17 (2) the volume of incoming correspondence to
18 the Office of the Executive Secretariat;

19 (3) the extent to which new backlogs occur in
20 the processing of common carrier packages received
21 by the mailroom;

22 (4) the extent to which new backlogs occur in
23 the processing of correspondence received by the Of-
24 fice of the Executive Secretariat;

1 (5) the length of time required to resolve each
2 such backlog;

3 (6) any known issues of unreasonable delays in
4 correspondence being provided to the intended re-
5 cipient, or in correspondence being lost, and the
6 measures taken to remedy such delays or lost items;

7 (7) the average number of days it takes to re-
8 spond to correspondence received by the Office of
9 the Executive Secretariat;

10 (8) the resources expended by the mailroom, in-
11 cluding a breakdown of budget authority and user
12 fee dollars; and

13 (9) the resources expended by the Office of the
14 Executive Secretariat on correspondence-related ac-
15 tivities, including a breakdown of budget authority
16 and user fee dollars.

17 (c) GAO REPORT.—Not later than 18 months after
18 the date of enactment of this Act, the Comptroller General
19 of the United States shall submit to the Committee on
20 Health, Education, Labor, and Pensions of the Senate and
21 the Committee on Energy and Commerce of the House
22 of Representatives a report assessing the policies and
23 practices of the Division of Executive Operations of the
24 Office of the Executive Secretariat of the Food and Drug

1 Administration with respect to the receipt, tracking, man-
2 aging, and prioritization of correspondence.

3 **SEC. 910. PROTECTING INFANTS AND IMPROVING FOR-**
4 **MULA SUPPLY.**

5 (a) DEFINITIONS.—

6 (1) IN GENERAL.—In this section—

7 (A) the term “infant formula” has the
8 meaning given such term in section 201 of the
9 Federal Food, Drug, and Cosmetic Act (21
10 U.S.C. 321); and

11 (B) the term “Secretary” means the Sec-
12 retary of Health and Human Services.

13 (2) CRITICAL FOOD.—Section 201 of the Fed-
14 eral Food, Drug, and Cosmetic Act (21 U.S.C. 321),
15 as amended by section 822, is further amended by
16 adding at the end the following:

17 “(tt) The term ‘critical food’ means a food that—

18 “(1) is an infant formula;

19 “(2) is a medical food, as defined in section
20 5(b)(3) of the Orphan Drug Act; or

21 “(3) is intended for use by individuals with cer-
22 tain inborn errors of metabolism or other conditions
23 requiring a medical food.”.

24 (b) OFFICE OF CRITICAL FOODS.—

1 (1) IN GENERAL.—The Secretary shall establish
2 within the Center for Food Safety and Applied Nu-
3 trition an office to be known as the Office of Critical
4 Foods. The Secretary shall appoint a Director to
5 lead such Office.

6 (2) DUTIES.—The Office of Critical Foods shall
7 be responsible for oversight, coordination, and facili-
8 tation of activities related to critical foods, as de-
9 fined in section 201(tt) of the Federal Food, Drug,
10 and Cosmetic Act, as added by subsection (a)(2),
11 and any other food determined by the Secretary to
12 be critical.

13 (c) PREMARKET SUBMISSIONS OF INFANT FORMULA
14 TO ADDRESS SHORTAGES.—Section 412 of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C. 350a) is
16 amended by adding at the end the following:

17 “(j) PREMARKET SUBMISSIONS TO ADDRESS SHORT-
18 AGES.—

19 “(1) IN GENERAL.—The Secretary shall waive
20 the 90 day premarket submission requirement under
21 section 412(c) and apply a 30-day premarket sub-
22 mission requirement, for any person who intends to
23 introduce or deliver for introduction into interstate
24 commerce any new infant formula.

1 “(2) EFFECTIVE PERIOD.—The waiver author-
2 ity under this subsection shall remain in effect for
3 90 days beginning on the date that the Secretary
4 distributes information under section 424(a)(2), or
5 such longer period as the Secretary determines ap-
6 propriate to prevent or mitigate a shortage of infant
7 formula.

8 “(3) REPORT.—Not later than one year after
9 the date of enactment of the Food and Drug Admin-
10 istration Safety and Landmark Advancements Act of
11 2022, the Secretary shall submit a report to the
12 Committee on Health, Education, Labor, and Pen-
13 sions of the Senate and the Committee on Energy
14 and Commerce of the House of Representatives that
15 includes—

16 “(A) the number of premarket submissions
17 for new infant formula the Secretary has re-
18 ceived under subsection (d) each year since
19 2012;

20 “(B) how many of such submissions re-
21 ceived requests from the Secretary for addi-
22 tional information;

23 “(C) how long after receiving such submis-
24 sions the Secretary sent such requests for addi-
25 tional information;

1 “(D) what additional information the Sec-
2 retary requested of the persons submitting such
3 submissions; and

4 “(E) the date each new infant formula
5 product described in subparagraph (A) was first
6 marketed, if available.”.

7 (d) INFANT FORMULA FLEXIBILITIES.—The Sec-
8 retary shall publish a list on the website of the Food and
9 Drug Administration detailing which infant formula prod-
10 ucts may be appropriate substitutes for infant formula
11 products in shortage that are relied upon by infants and
12 other individuals with amino-acid and metabolic condi-
13 tions.

14 (e) INTERNATIONAL HARMONIZATION OF INFANT
15 FORMULA REQUIREMENTS.—

16 (1) IN GENERAL.—The Secretary—

17 (A) shall participate in meetings with rep-
18 resentatives from other countries to discuss
19 methods and approaches to harmonizing regu-
20 latory requirements for infant formula, includ-
21 ing with respect to inspections, labeling, and
22 nutritional requirements; and

23 (B) may enter into agreements regarding
24 such requirements with other countries, as ap-
25 propriate.

1 (2) STUDY ON INFANT FORMULA.—

2 (A) IN GENERAL.—Not later than 60 days
3 after the date of enactment of this Act, the Sec-
4 retary shall seek to enter into an agreement
5 with the National Academies of Sciences, Engi-
6 neering, and Medicine (referred to in this para-
7 graph as the “National Academies”) to examine
8 and report on challenges in supply, market
9 competition, and regulation of infant formula in
10 the United States.

11 (B) REQUIREMENTS OF FOREIGN COUN-
12 TRIES.—The report developed pursuant to the
13 agreement under subparagraph (A) shall assess
14 and evaluate infant formula marketed in the
15 United States, any challenges in supply, market
16 competition, and any differences in infant for-
17 mula marketed in the European Union, includ-
18 ing with respect to nutritional content and ap-
19 plicable labeling and other regulatory require-
20 ments.

21 (C) FINAL REPORT.—The agreement
22 under subparagraph (A) shall specify that the
23 National Academies shall, not later than 1 year
24 after the date of enactment of this Act, com-
25 plete such study and submit a report on the re-

1 sults of such study to the Committee on Health,
2 Education, Labor, and Pensions of the Senate
3 and the Committee on Energy and Commerce
4 of the House of Representatives.

5 (f) TRANSPARENCY AND ACCOUNTABILITY TO SUP-
6 PORT INFANT FORMULA INNOVATION.—

7 (1) ANNUAL REPORT TO CONGRESS.—Section
8 412 of the Federal Food, Drug, and Cosmetic Act
9 (21 U.S.C. 350a), as amended by subsection (c), is
10 further amended by adding at the end the following:

11 “(k) ANNUAL REPORT TO CONGRESS.—

12 “(1) IN GENERAL.—Not later than March 30 of
13 each year, the Secretary shall submit a report to
14 Congress containing, with respect to the preceding
15 calendar year, the following information:

16 “(A) The number of submissions received
17 by the Secretary under subsection (d).

18 “(B) The number of submissions that in-
19 cluded any new ingredients that were not in-
20 cluded in any infant formula already on the
21 market.

22 “(C) The number of inspections conducted
23 by the Food and Drug Administration or any
24 agent thereof to evaluate compliance with the

1 requirements for infant formulas under sub-
2 section (b)(2).

3 “(D) The time between any inspection re-
4 ferred to in paragraph (3) and any necessary
5 reinspection to evaluate compliance with the re-
6 quirements for infant formulas under sub-
7 section (b)(2).

8 “(E) A breakdown of the information de-
9 scribed in subparagraphs (A) through (D) be-
10 tween foreign and domestic manufacturers and
11 facilities.

12 “(2) CONFIDENTIALITY.—The Secretary shall
13 ensure that the reports under paragraph (1) do not
14 include any information that is a trade secret or
15 confidential information subject to section 552(b)(4)
16 of title 5, United States Code, or section 1905 of
17 title 18, United States Code.”.

18 (2) MARKETING SUBMISSIONS.—Section 412 of
19 the Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 350a), as amended by paragraph (1), is fur-
21 ther amended by adding at the end the following:

22 “(1) MARKETING SUBMISSIONS.—

23 “(1) IN GENERAL.—Subject to paragraph (2),
24 the Secretary shall respond to a submission under

1 subsection (d) for infant formula not later than 65
2 days after receiving such submission.

3 “(2) EXPEDITED RESPONSE.—The Secretary
4 shall respond to a submission under subsection (d)
5 for infant formula not later than 45 days after re-
6 ceiving such notification if it—

7 “(A) is submitted by a manufacturer that
8 is not already marketing infant formula in the
9 United States; or

10 “(B) is a new infant formula, as defined in
11 subsection (c)(2).”.

12 (3) LIST OF NUTRIENTS.—Section 412(i)(1) of
13 the Federal Food, Drug, and Cosmetic Act (21
14 U.S.C. 350a(i)) is amended by striking “or, if re-
15 vised by the Secretary under paragraph (2), as so
16 revised” and inserting the following: “, which shall
17 be reviewed by the Secretary every 4 years as appro-
18 priate. In reviewing such table, the Secretary shall
19 consider any new scientific data or information re-
20 lated to infant formula nutrients, including inter-
21 national infant formula standards. The Secretary
22 may revise the list of nutrients and the required
23 level for any nutrient required by the table”.

24 (4) TECHNICAL CORRECTION.—Section
25 412(c)(1)(B) of the Federal Food, Drug, and Cos-

1 metric Act (21 U.S.C. 350a(c)(1)(B)) is amended by
2 striking “subsection (c)(1)” and inserting “sub-
3 section (d)(1)”.

4 (g) RESPONSE TO RECALL.—

5 (1) MANUFACTURER SUBMISSION.—

6 (A) IN GENERAL.—Promptly after the ini-
7 tiation of a recall of infant formula, the manu-
8 facturer of the recalled infant formula shall
9 submit information to the Secretary regarding
10 such recall.

11 (B) CONTENTS.—A submission under sub-
12 paragraph (A) shall include the following:

13 (i) A plan (including an estimated
14 timeline, as applicable) of actions the man-
15 ufacturer will take, suited to the individual
16 circumstances of the particular recall, in-
17 cluding—

18 (I) to identify and address any
19 cause of adulteration or misbranding;
20 and

21 (II) if appropriate, to restore op-
22 eration of the impacted facilities.

23 (ii) In the case that a recall of the
24 manufacturer’s infant formula products,
25 and subsequent actions to respond to such

1 recall, impacts over 10 percent of the pro-
2 duction of the infant formula intended for
3 sale in the United States, a plan to backfill
4 the supply of the manufacturer's infant
5 formula supply if the current domestic
6 supply of such infant formula has fallen, or
7 is expected to fall, below the expected de-
8 mand for the formula.

9 (2) REPORT TO CONGRESS.—

10 (A) IN GENERAL.—Promptly after a sub-
11 mission under paragraph (1) is received, the
12 Secretary shall provide such submission, to-
13 gether with the information specified in sub-
14 paragraph (B), in a report to the Committee on
15 Health, Education, Labor, and Pensions of the
16 Senate and the Committee on Energy and Com-
17 merce of the House of Representatives.

18 (B) CONTENTS.—A submission under sub-
19 paragraph (A) shall include the following:

20 (i) Information concerning the current
21 domestic supply of infant formula, includ-
22 ing—

23 (I) a breakdown of the specific
24 types of formula involved; and

1 (II) an estimate of how long cur-
2 rent supplies will last.

3 (ii) In the case that a submission or
4 submissions under paragraph (1) show
5 that the recall and subsequent actions to
6 respond to the recall impact over 10 per-
7 cent of the domestic production of infant
8 formula intended for sale in the United
9 States—

10 (I) actions to work with the im-
11 pacted manufacturer or other manu-
12 facturers to increase production; and

13 (II) specification of—

14 (aa) any additional authori-
15 ties needed regarding production
16 or importation to fill a supply
17 gap; and

18 (bb) any supplemental fund-
19 ing necessary to address the
20 shortage.

21 (3) SUNSET.—This subsection shall cease to
22 have force or effect on of September 30, 2026.

23 (h) COORDINATION WITH MANUFACTURER.—

24 (1) INSPECTIONS.—The Secretary shall ensure
25 timely communication with a manufacturer of infant

1 formula following an inspection of a facility engaged
2 in the manufacturing of infant formula for consump-
3 tion in the United States. If a reinspection of a
4 manufacturer of an infant formula is required to en-
5 sure that such manufacturer completed any remedi-
6 ation actions or addressed any deficiencies, the Sec-
7 retary shall reinspect such facility in a timely man-
8 ner. The Secretary shall prioritize and expedite an
9 inspection or reinspection of an establishment that
10 could help mitigate or prevent a shortage of an in-
11 fant formula.

12 (2) ANNUAL INSPECTIONS.—Not later than 6
13 months after the date of enactment of this Act, and
14 not less than once per calendar year thereafter, the
15 Secretary shall conduct inspections, including unan-
16 nounced inspections, of the facilities (including for-
17 eign facilities) of each manufacturer of an infant
18 formula required to be registered under section
19 412(c)(1)(A) of the Federal Food, Drug, and Cos-
20 metic Act (21 U.S.C. 350a(e)(1)(A)), in accordance
21 with a risk based approach and ensure timely and
22 effective internal coordination and alignment among
23 the investigators and the Center for Food Safety
24 and Applied Nutrition.

25 (i) NATIONAL STRATEGY ON INFANT FORMULA.—

1 (1) IN GENERAL.—The Secretary, in consulta-
2 tion with the Secretary of Agriculture and other
3 heads of relevant departments and agencies, shall
4 develop and issue, not later than 90 days after the
5 date of enactment of this Act, a national strategy on
6 infant formula to increase the resiliency of the in-
7 fant formula supply chain, protect against future
8 contamination and other potential causes of short-
9 ages, and ensure parents and caregivers have access
10 to formula and information they need.

11 (2) NATIONAL STRATEGY.—The national strat-
12 egy under paragraph (1) shall—

13 (A) increase the resiliency of the infant
14 formula supply chain in the short-term by—

15 (i) assessing causes of the current
16 shortage and potential causes of future
17 shortages,

18 (ii) assessing and addressing imme-
19 diate infant formula needs associated with
20 the shortage, and

21 (iii) developing a plan to increase in-
22 fant formula supply, including through in-
23 creased competition;

24 (B) improve preparedness against infant
25 formula shortages in the long-term by—

1 (i) outlining methods to improve infor-
2 mation-sharing between the Federal Gov-
3 ernment and State and local governments,
4 and other entities as appropriate, regard-
5 ing shortages;

6 (ii) recommending measures for pro-
7 tecting the integrity of infant formula sup-
8 ply and preventing contamination;

9 (iii) outlining methods to incentivize
10 new infant formula manufacturers to in-
11 crease supply and mitigate future short-
12 ages; and

13 (iv) recommending other necessary
14 authorities to gain insight into the supply
15 chain and risk for shortages, and to
16 incentivize new infant formula manufactur-
17 ers; and

18 (C) ensure the development and updating
19 of education and communication materials for
20 parents and caregivers that cover—

21 (i) where and how to find infant for-
22 mula;

23 (ii) comparable infant formulas on the
24 market,

- 1 (iii) what to do if a medical or spe-
2 cialty infant formula is unavailable;
3 (iv) safe practices for handling infant
4 formula; and
5 (v) other topics, as appropriate.

6 (j) MEANINGFUL DISRUPTION IN THE PRODUCTION
7 OF CRITICAL FOOD.—Chapter IV of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amend-
9 ed by adding at the end the following:

10 **“SEC. 424. REQUIREMENTS FOR CRITICAL FOOD.**

11 “(a) NOTIFICATION OF MEANINGFUL DISRUPTION
12 FOR CRITICAL FOOD.—

13 “(1) IN GENERAL.—A manufacturer of a crit-
14 ical food (as defined in section 201(tt)) shall notify
15 the Secretary of a permanent discontinuance in the
16 manufacture or an interruption of the manufacture
17 of such food that is likely to lead to a meaningful
18 disruption in the supply of such food in the United
19 States, and the reasons for such discontinuance or
20 interruption, as soon as practicable, but not later
21 than 5 business days after such discontinuance or
22 such interruption.

23 “(2) DISTRIBUTION OF INFORMATION.—Not
24 later than 5 calendar days after receiving a notifica-
25 tion under paragraph (1), the Secretary shall dis-

1 tribute, to the Secretary of Agriculture and to the
2 maximum extent practicable to the appropriate enti-
3 ties, as determined by the Secretary through such
4 means as the Secretary determines appropriate, in-
5 formation on the meaningful disruption of a critical
6 food reported under this subsection.

7 “(3) CONFIDENTIALITY.—Nothing in this sub-
8 section authorizes the Secretary to disclose any in-
9 formation that is a trade secret or confidential infor-
10 mation subject to section 552(b)(4) of title 5, United
11 States Code, or section 1905 of title 18, United
12 States Code.

13 “(4) MEANINGFUL DISRUPTION.—In this sub-
14 section, the term ‘meaningful disruption’—

15 “(A) means a change in production that is
16 reasonably likely to lead to a significant reduc-
17 tion in the supply of a critical food by a manu-
18 facturer that affects the ability of the manufac-
19 turer to meet expected demand for its product;
20 and

21 “(B) does not include interruptions in
22 manufacturing due to matters such as routine
23 maintenance or insignificant changes in manu-
24 facturing so long as the manufacturer expects
25 to resume operations in a short period of time.

1 “(b) RISK MANAGEMENT PLANS.—Each manufac-
2 turer of a critical food shall develop, maintain, and imple-
3 ment, as appropriate, a redundancy risk management plan
4 that identifies and evaluates risks to the supply of the
5 food, as applicable, for each establishment in which such
6 food is manufactured. A risk management plan under this
7 subsection—

8 “(1) may identify and evaluate risks to the sup-
9 ply of more than one critical food, or critical food
10 category, manufactured at the same establishment;
11 and

12 “(2) shall be subject to inspection and copying
13 by the Secretary pursuant to an inspection under
14 section 704.

15 “(c) FAILURE TO MEET REQUIREMENTS.—

16 “(1) IN GENERAL.—If a person fails to submit
17 information required under, and in accordance with,
18 subsection (a)—

19 “(A) the Secretary shall issue a letter to
20 such person informing such person of such fail-
21 ure; and

22 “(B) not later than 45 calendar days after
23 the issuance of a letter under subparagraph
24 (A), subject to paragraph (2), the Secretary
25 shall make available to the public on the

1 website of the Food and Drug Administration,
2 with appropriate redactions made to protect the
3 information described in subsection (a)(3)—

4 “(i) the letter issued under subpara-
5 graph (A); and

6 “(ii) at the request of such person,
7 any response to such letter such person
8 submitted to the Secretary.

9 “(2) EXCEPTION.—If the Secretary determines
10 that the letter under paragraph (1) was issued in
11 error or, after review of such response, the person
12 had a reasonable basis for not submitting a notifica-
13 tion as required under subsection (m), the require-
14 ments of paragraph (1)(B) shall not apply.”.