

AMENDMENT NO. _____ Calendar No. _____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—115th Cong., 1st Sess.

S. 934

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 _____

Viz:

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “FDA Reauthorization
5 Act of 2017”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 The table of contents for this Act is as follows:

- Sec. 1. Short title.
- Sec. 2. Table of contents.

TITLE I—FEES RELATING TO DRUGS

- Sec. 101. Short title; finding.
- Sec. 102. Authority to assess and use drug fees.
- Sec. 103. Reauthorization; reporting requirements.
- Sec. 104. Sunset dates.

- Sec. 105. Effective date.
- Sec. 106. Savings clause.

TITLE II—FEES RELATING TO DEVICES

- Sec. 201. Short title; findings.
- Sec. 202. Definitions.
- Sec. 203. Authority to assess and use device fees.
- Sec. 204. Reauthorization; reporting requirements.
- Sec. 205. Conformity assessment pilot program.
- Sec. 206. Reauthorization of review.
- Sec. 207. Electronic format for submissions.
- Sec. 208. Savings clause.
- Sec. 209. Effective date.
- Sec. 210. Sunset clause.

TITLE III—FEES RELATING TO GENERIC DRUGS

- Sec. 301. Short title; finding.
- Sec. 302. Definitions.
- Sec. 303. Authority to assess and use human generic drug fees.
- Sec. 304. Reauthorization; reporting requirements.
- Sec. 305. Sunset dates.
- Sec. 306. Effective date.
- Sec. 307. 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 fees.
- Sec. 404. Reauthorization; reporting requirements.
- Sec. 405. Sunset dates.
- Sec. 406. Effective date.
- Sec. 407. Savings clause.

TITLE V—PEDIATRIC DRUGS AND DEVICES

- Sec. 501. Pediatric devices.
- Sec. 502. Pediatric drug development.
- Sec. 503. Guidance on molecular targets in pediatric oncology.
- Sec. 504. Best pharmaceuticals for children.

TITLE VI—REAUTHORIZATIONS AND IMPROVEMENTS RELATED TO DRUGS

- Sec. 601. Reauthorization of provision relating to exclusivity of certain drugs containing single enantiomers.
- Sec. 602. Reauthorization of the critical path public-private partnerships.
- Sec. 603. Reauthorization of orphan grants program.
- Sec. 604. Guidance regarding bioequivalence.
- Sec. 605. Patient experience data.
- Sec. 606. Communications plans.
- Sec. 607. Protecting and strengthening the drug supply chain.
- Sec. 608. Technical corrections.

1 the Chairman of the Committee on Energy and Commerce
2 of the House of Representatives, as set forth in the Con-
3 gressional Record.

4 **SEC. 102. AUTHORITY TO ASSESS AND USE DRUG FEES.**

5 (a) TYPES OF FEES.—

6 (1) IN GENERAL.—Section 736(a) of the Fed-
7 eral Food, Drug, and Cosmetic Act (21 U.S.C.
8 379h(a)) is amended—

9 (A) in the matter preceding paragraph (1),
10 by striking “fiscal year 2013” and inserting
11 “fiscal year 2018”;

12 (B) in the heading of paragraph (1), by
13 striking “AND SUPPLEMENT”;

14 (C) in paragraph (1), by striking “or a
15 supplement” and “or supplement” each place
16 either appears;

17 (D) in paragraph (1)(A)—

18 (i) in clause (i), by striking “(c)(4)”
19 and inserting “(c)(5)”; and

20 (ii) in clause (ii), by striking “A fee
21 established” and all that follows through
22 “are required.” and inserting the following:
23 “A fee established under subsection (c)(5)
24 for a human drug application for which
25 clinical data (other than bioavailability or

1 bioequivalence studies) with respect to
2 safety or effectiveness are not required for
3 approval.”;

4 (E) in the heading of paragraph (1)(C), by
5 striking “OR SUPPLEMENT”;

6 (F) in paragraph (1)(F)—

7 (i) in the heading, by striking “OR IN-
8 DICATION”; and

9 (ii) by striking the second sentence;

10 (G) by striking paragraph (2) (relating to
11 a prescription drug establishment fee);

12 (H) by redesignating paragraph (3) as
13 paragraph (2);

14 (I) in the heading of paragraph (2), as so
15 redesignated, by striking “PRESCRIPTION DRUG
16 PRODUCT FEE” and inserting “PRESCRIPTION
17 DRUG PROGRAM FEE”;

18 (J) in subparagraph (A) of such paragraph
19 (2), by amending the first sentence to read as
20 follows: “Except as provided in subparagraphs
21 (B) and (C), each person who is named as the
22 applicant in a human drug application, and
23 who, after September 1, 1992, had pending be-
24 fore the Secretary a human drug application or
25 supplement, shall pay the annual prescription

1 drug program fee established for a fiscal year
2 under subsection (c)(5) for each prescription
3 drug product that is identified in such a human
4 drug application approved as of October 1 of
5 such fiscal year.”;

6 (K) in subparagraph (B) of such para-
7 graph (2)—

8 (i) in the heading of subparagraph
9 (B), by inserting after “EXCEPTION” the
10 following: “FOR CERTAIN PRESCRIPTION
11 DRUG PRODUCTS”; and

12 (ii) by striking “A prescription drug
13 product shall not be assessed a fee” and
14 inserting “A prescription drug program fee
15 shall not be assessed for a prescription
16 drug product”; and

17 (L) by adding at the end of such para-
18 graph (2) the following:

19 “(C) LIMITATION.—A person who is
20 named as the applicant in an approved human
21 drug application shall not be assessed more
22 than 5 prescription drug program fees for a fis-
23 cal year for prescription drug products identi-
24 fied in such approved human drug applica-
25 tion.”.

1 “(D) the dollar amount equal to the oper-
2 ating reserve adjustment for the fiscal year, if
3 applicable (as determined under subsection
4 (c)(3));

5 “(E) the dollar amount equal to the addi-
6 tional direct cost adjustment for the fiscal year
7 (as determined under subsection (c)(4)); and

8 “(F) additional dollar amounts for each
9 fiscal year as follows:

10 “(i) \$20,077,793 for fiscal year 2018;

11 “(ii) \$21,317,472 for fiscal year 2019;

12 “(iii) \$16,953,329 for fiscal year
13 2020;

14 “(iv) \$5,426,896 for fiscal year 2021;

15 and

16 “(v) \$2,769,609 for fiscal year 2022.

17 “(2) TYPES OF FEES.—Of the total revenue
18 amount determined for a fiscal year under para-
19 graph (1)—

20 “(A) 20 percent shall be derived from
21 human drug application fees under subsection
22 (a)(1); and

23 “(B) 80 percent shall be derived from pre-
24 scription drug program fees under subsection
25 (a)(2).

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

4 “(A) for fiscal year 2018, \$878,590,000;
5 and

6 “(B) for fiscal years 2019 through 2022,
7 the dollar amount of the total revenue amount
8 established under paragraph (1) for the pre-
9 vious fiscal year, not including any adjustments
10 made under subsection (c)(3) or (c)(4).”.

11 (c) ADJUSTMENTS; ANNUAL FEE SETTING.—Sub-
12 section (c) of section 736 of the Federal Food, Drug, and
13 Cosmetic Act (21 U.S.C. 379h) is amended to read as fol-
14 lows:

15 “(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

16 “(1) INFLATION ADJUSTMENT.—

17 “(A) IN GENERAL.—For purposes of sub-
18 section (b)(1)(B), the dollar amount of the in-
19 flation adjustment to the annual base revenue
20 for each fiscal year shall be equal to the prod-
21 uct of—

22 “(i) such annual base revenue for the
23 fiscal year under subsection (b)(1)(A); and

24 “(ii) the inflation adjustment percent-
25 age under subparagraph (B).

1 “(B) INFLATION ADJUSTMENT PERCENT-
2 AGE.—The inflation adjustment percentage
3 under this subparagraph for a fiscal year is
4 equal to the sum of—

5 “(i) the average annual percent
6 change in the cost, per full-time equivalent
7 position of the Food and Drug Administra-
8 tion, of all personnel compensation and
9 benefits paid with respect to such positions
10 for the first 3 years of the preceding 4 fis-
11 cal years, multiplied by the proportion of
12 personnel compensation and benefits costs
13 to total costs of the process for the review
14 of human drug applications (as defined in
15 section 735(6)) for the first 3 years of the
16 preceding 4 fiscal years; and

17 “(ii) the average annual percent
18 change that occurred in the Consumer
19 Price Index for urban consumers (Wash-
20 ington-Baltimore, DC–MD–VA–WV; Not
21 Seasonally Adjusted; All items; Annual
22 Index) for the first 3 years of the pre-
23 ceding 4 years of available data multiplied
24 by the proportion of all costs other than
25 personnel compensation and benefits costs

1 to total costs of the process for the review
2 of human drug applications (as defined in
3 section 735(6)) for the first 3 years of the
4 preceding 4 fiscal years.

5 “(2) CAPACITY PLANNING ADJUSTMENT.—

6 “(A) IN GENERAL.—For each fiscal year,
7 after the annual base revenue established in
8 subsection (b)(1)(A) is adjusted for inflation in
9 accordance with paragraph (1), such revenue
10 shall be adjusted further for such fiscal year, in
11 accordance with this paragraph, to reflect
12 changes in the resource capacity needs of the
13 Secretary for the process for the review of
14 human drug applications.

15 “(B) INTERIM METHODOLOGY.—

16 “(i) IN GENERAL.—Until the capacity
17 planning methodology described in sub-
18 paragraph (C) is effective, the adjustment
19 under this paragraph for a fiscal year shall
20 be based on the product of—

21 “(I) the annual base revenue for
22 such year, as adjusted for inflation
23 under paragraph (1); and

24 “(II) the adjustment percentage
25 under clause (ii).

1 “(ii) ADJUSTMENT PERCENTAGE.—

2 The adjustment percentage under this
3 clause for a fiscal year is the weighted
4 change in the 3-year average ending in the
5 most recent year for which data are avail-
6 able, over the 3-year average ending in the
7 previous year, for—

8 “(I) the total number of human
9 drug applications, efficacy supple-
10 ments, and manufacturing supple-
11 ments submitted to the Secretary;

12 “(II) the total number of active
13 commercial investigational new drug
14 applications; and

15 “(III) the total number of formal
16 meetings scheduled by the Secretary,
17 and written responses issued by the
18 Secretary in lieu of such formal meet-
19 ings, as identified in section I.H of
20 the letters described in section 101(b)
21 of the Prescription Drug User Fee
22 Amendments of 2017.

23 “(C) CAPACITY PLANNING METHODOLOGY.—
24

1 “(II) incorporate such ap-
2 proaches and attributes as the Sec-
3 retary determines appropriate; and

4 “(III) be effective beginning with
5 the first fiscal year for which fees are
6 set after such capacity planning meth-
7 odology is established.

8 “(D) LIMITATION.—Under no cir-
9 cumstances shall an adjustment under this
10 paragraph result in fee revenue for a fiscal year
11 that is less than the sum of the amounts under
12 subsections (b)(1)(A) (the annual base revenue
13 for the fiscal year) and (b)(1)(B) (the dollar
14 amount of the inflation adjustment for the fis-
15 cal year).

16 “(E) PUBLICATION IN FEDERAL REG-
17 ISTER.—The Secretary shall publish in the Fed-
18 eral Register notice under paragraph (5) the fee
19 revenue and fees resulting from the adjustment
20 and the methodologies under this paragraph.

21 “(3) OPERATING RESERVE ADJUSTMENT.—

22 “(A) INCREASE.—For fiscal year 2018 and
23 subsequent fiscal years, the Secretary may, in
24 addition to adjustments under paragraphs (1)
25 and (2), further increase the fee revenue and

1 fees if such an adjustment is necessary to pro-
2 vide for not more than 14 weeks of operating
3 reserves of carryover user fees for the process
4 for the review of human drug applications.

5 “(B) DECREASE.—If the Secretary has
6 carryover balances for such process in excess of
7 14 weeks of such operating reserves, the Sec-
8 retary shall decrease such fee revenue and fees
9 to provide for not more than 14 weeks of such
10 operating reserves.

11 “(C) NOTICE OF RATIONALE.—If an ad-
12 justment under subparagraph (A) or (B) is
13 made, the rationale for the amount of the in-
14 crease or decrease (as applicable) in fee revenue
15 and fees shall be contained in the annual Fed-
16 eral Register notice under paragraph (5) estab-
17 lishing fee revenue and fees for the fiscal year
18 involved.

19 “(4) ADDITIONAL DIRECT COST ADJUST-
20 MENT.—

21 “(A) IN GENERAL.—The Secretary shall,
22 in addition to adjustments under paragraphs
23 (1), (2), and (3), further increase the fee rev-
24 enue and fees—

1 “(i) for fiscal year 2018, by
2 \$8,730,000; and

3 “(ii) for fiscal year 2019 and subse-
4 quent fiscal years, by the amount deter-
5 mined under subparagraph (B).

6 “(B) AMOUNT.—The amount determined
7 under this subparagraph is—

8 “(i) \$8,730,000, multiplied by

9 “(ii) the Consumer Price Index for
10 urban consumers (Washington-Baltimore,
11 DC–MD–VA–WV; Not Seasonally Ad-
12 justed; All Items; Annual Index) for the
13 most recent year of available data, divided
14 by such Index for 2016.

15 “(5) ANNUAL FEE SETTING.—The Secretary
16 shall, not later than 60 days before the start of each
17 fiscal year that begins after September 30, 2017—

18 “(A) establish, for the next fiscal year,
19 human drug application fees and prescription
20 drug program fees under subsection (a), based
21 on the revenue amounts established under sub-
22 section (b) and the adjustments provided under
23 this subsection; and

24 “(B) publish such fee revenue and fees in
25 the Federal Register.

1 “(6) LIMIT.—The total amount of fees charged,
2 as adjusted under this subsection, for a fiscal year
3 may not exceed the total costs for such fiscal year
4 for the resources allocated for the process for the re-
5 view of human drug applications.”.

6 (d) FEE WAIVER OR REDUCTION.—Section 736(d) of
7 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
8 379h(d)) is amended—

9 (1) in paragraph (1)—

10 (A) by inserting “or” at the end of sub-
11 paragraph (B);

12 (B) by striking subparagraph (C); and

13 (C) by redesignating subparagraph (D) as
14 subparagraph (C);

15 (2) by striking paragraph (3) (relating to use of
16 standard costs);

17 (3) by redesignating paragraph (4) as para-
18 graph (3); and

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

20 (A) in subparagraphs (A) and (B), by
21 striking “paragraph (1)(D)” and inserting
22 “paragraph (1)(C)”; and

23 (B) in subparagraph (B)—

24 (i) by striking clause (ii);

1 (ii) by striking “shall pay” through
2 “(i) application fees” and inserting “shall
3 pay application fees”; and

4 (iii) by striking “; and” at the end
5 and inserting a period.

6 (e) EFFECT OF FAILURE TO PAY FEES.—Section
7 736(e) of the Federal Food, Drug, and Cosmetic Act (21
8 U.S.C. 379h(e)) is amended by striking “all fees” and in-
9 serting “all such fees”.

10 (f) LIMITATIONS.—Section 736(f)(2) of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 379h(f)(2)) is
12 amended by striking “supplements, prescription drug es-
13 tablishments, and prescription drug products” and insert-
14 ing “prescription drug program fees”.

15 (g) CREDITING AND AVAILABILITY OF FEES.—Sec-
16 tion 736(g) of the Federal Food, Drug, and Cosmetic Act
17 (21 U.S.C. 379h(g)) is amended—

18 (1) in paragraph (3)—

19 (A) by striking “2013 through 2017” and
20 inserting “2018 through 2022”; and

21 (B) by striking “and paragraph (4) of this
22 subsection”; and

23 (2) by striking paragraph (4).

24 (h) ORPHAN DRUGS.—Section 736(k) of the Federal
25 Food, Drug, and Cosmetic Act (21 U.S.C. 379h(k)) is

1 amended by striking “product and establishment fees”
2 each place it appears and inserting “prescription drug pro-
3 gram fees”.

4 **SEC. 103. REAUTHORIZATION; REPORTING REQUIREMENTS.**

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

7 (1) in subsection (a)(1)—

8 (A) in the matter before subparagraph (A),
9 by striking “2013” and inserting “2018”; and

10 (B) in subparagraph (A), by striking “Pre-
11 scription Drug User Fee Amendments of 2012”
12 and inserting “Prescription Drug User Fee
13 Amendments of 2017”;

14 (2) in subsection (b), by striking “2013” and
15 inserting “2018”; and

16 (3) in subsection (d), by striking “2017” each
17 place it appears and inserting “2022”.

18 **SEC. 104. SUNSET DATES.**

19 (a) AUTHORIZATION.—Sections 735 and 736 of the
20 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g;
21 379h) shall cease to be effective October 1, 2022.

22 (b) REPORTING REQUIREMENTS.—Section 736B of
23 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 379h–2) shall cease to be effective January 31, 2023.

1 (c) PREVIOUS SUNSET PROVISION.—Effective Octo-
2 ber 1, 2017, subsections (a) and (b) of section 105 of the
3 Food and Drug Administration Safety and Innovation Act
4 (Public Law 112–144) are repealed.

5 **SEC. 105. EFFECTIVE DATE.**

6 The amendments made by this title shall take effect
7 on October 1, 2017, or the date of the enactment of this
8 Act, whichever is later, except that fees under part 2 of
9 subchapter C of chapter VII of the Federal Food, Drug,
10 and Cosmetic Act shall be assessed for all human drug
11 applications received on or after October 1, 2017, regard-
12 less of the date of the enactment of this Act.

13 **SEC. 106. SAVINGS CLAUSE.**

14 Notwithstanding the amendments made by this title,
15 part 2 of subchapter C of chapter VII of the Federal Food,
16 Drug, and Cosmetic Act, as in effect on the day before
17 the date of the enactment of this title, shall continue to
18 be in effect with respect to human drug applications and
19 supplements (as defined in such part as of such day) that
20 on or after October 1, 2012, but before October 1, 2017,
21 were accepted by the Food and Drug Administration for
22 filing with respect to assessing and collecting any fee re-
23 quired by such part for a fiscal year prior to fiscal year
24 2018.

1 “(8) The term ‘de novo classification request’
2 means a request made under section 513(f)(2)(A)
3 with respect to the classification of a device.”;

4 (3) in subparagraph (D) of paragraph (10) (as
5 redesignated by paragraph (1)), by striking “and
6 submissions” and inserting “submissions, and de
7 novo classification requests”; and

8 (4) in paragraph (11) (as redesignated by para-
9 graph (1)), by striking “2011” and inserting
10 “2016”.

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

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

15 (1) in paragraph (1), by striking “fiscal year
16 2013” and inserting “fiscal year 2018”; and

17 (2) in paragraph (2)—

18 (A) in subparagraph (A)—

19 (i) in the matter preceding clause (i),
20 by striking “October 1, 2012” and insert-
21 ing “October 1, 2017”;

22 (ii) in clause (viii), by striking “2”
23 and inserting “3.4”; and

24 (iii) by adding at the end the fol-
25 lowing new clause:

1 “(xi) For a de novo classification re-
 2 quest, a fee equal to 30 percent of the fee
 3 that applies under clause (i).”; and
 4 (B) in subparagraph (B)(v)(I), by striking
 5 “or premarket notification submission” and in-
 6 serting “premarket notification submission, or
 7 de novo classification request”.

8 (b) FEE AMOUNTS.—Section 738(b) of the Federal
 9 Food, Drug, and Cosmetic Act (21 U.S.C. 379j(b)) is
 10 amended to read as follows:

11 “(b) FEE AMOUNTS.—

12 “(1) IN GENERAL.—Subject to subsections (c),
 13 (d), (e), and (h), for each of fiscal years 2018
 14 through 2022, fees under subsection (a) shall be de-
 15 rived from the base fee amounts specified in para-
 16 graph (2), to generate the total revenue amounts
 17 specified in paragraph (3).

18 “(2) BASE FEE AMOUNTS SPECIFIED.—For
 19 purposes of paragraph (1), the base fee amounts
 20 specified in this paragraph are as follows:

“Fee Type	Fiscal Year 2018	Fiscal Year 2019	Fiscal Year 2020	Fiscal Year 2021	Fiscal Year 2022
Premarket Application	\$294,000	\$300,000	\$310,000	\$328,000	\$329,000
Establishment Registration	\$4,375	\$4,548	\$4,760	\$4,975	\$4,978

21 “(3) TOTAL REVENUE AMOUNTS SPECIFIED.—
 22 For purposes of paragraph (1), the total revenue
 23 amounts specified in this paragraph are as follows:

1 “(A) \$183,280,756 for fiscal year 2018.

2 “(B) \$190,654,875 for fiscal year 2019.

3 “(C) \$200,132,014 for fiscal year 2020.

4 “(D) \$211,748,789 for fiscal year 2021.

5 “(E) \$213,687,660 for fiscal year 2022.”.

6 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section
7 738(c) of the Federal Food, Drug, and Cosmetic Act (21
8 U.S.C. 379j(c)) is amended—

9 (1) in paragraph (1), by striking “2012” and
10 inserting “2017”;

11 (2) in paragraph (2)—

12 (A) in subparagraph (A), by striking
13 “2014” and inserting “2018”;

14 (B) by striking subparagraph (B) and in-
15 serting the following new subparagraph:

16 “(B) APPLICABLE INFLATION ADJUST-
17 MENT.—The applicable inflation adjustment for
18 fiscal year 2018 and each subsequent fiscal
19 year is the product of—

20 “(i) the base inflation adjustment
21 under subparagraph (C) for such fiscal
22 year; and

23 “(ii) the product of the base inflation
24 adjustment under subparagraph (C) for

1 each of the fiscal years preceding such fis-
2 cal year, beginning with fiscal year 2016.”;

3 (C) in subparagraph (C), in the heading,
4 by striking “TO TOTAL REVENUE AMOUNTS”;
5 and

6 (D) by amending subparagraph (D) to
7 read as follows:

8 “(D) ADJUSTMENT TO BASE FEE
9 AMOUNTS.—For each of fiscal years 2018
10 through 2022, the Secretary shall—

11 “(i) adjust the base fee amounts spec-
12 ified in subsection (b)(2) for such fiscal
13 year by multiplying such amounts by the
14 applicable inflation adjustment under sub-
15 paragraph (B) for such year; and

16 “(ii) if the Secretary determines nec-
17 essary, increase (in addition to the adjust-
18 ment under clause (i)) such base fee
19 amounts, on a uniform proportionate basis,
20 to generate the total revenue amounts
21 under subsection (b)(3), as adjusted for in-
22 flation under subparagraph (A).”;

23 (3) in paragraph (3)—

24 (A) by striking “2014 through 2017” and
25 inserting “2018 through 2022”; and

1 (B) by striking “further adjusted” and in-
2 serting “increased”.

3 (d) SMALL BUSINESSES; FEE WAIVER AND FEE RE-
4 DUCATION REGARDING PREMARKET APPROVAL FEES.—
5 Section 738(d) of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 379j(d)) is amended—

7 (1) in paragraph (1), by striking “specified in
8 clauses (i) through (v) and clauses (vii), (ix), and
9 (x)” and inserting “specified in clauses (i) through
10 (vii) and clauses (ix), (x), and (xi)”; and

11 (2) in paragraph (2)(C)—

12 (A) by striking “supplement, or” and in-
13 serting “supplement,”; and

14 (B) by inserting “, or a de novo classifica-
15 tion request” after “class III device”.

16 (e) SMALL BUSINESSES; FEE REDUCTION REGARD-
17 ING PREMARKET NOTIFICATION SUBMISSIONS.—Section
18 738(e)(2)(C) of the Federal Food, Drug, and Cosmetic
19 Act (21 U.S.C. 379j(e)(2)(C)) is amended by striking
20 “50” and inserting “25”.

21 (f) FEE WAIVER OR REDUCTION.—

22 (1) REPEAL.—Section 738 of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C. 379j) is amend-
24 ed by striking subsection (f).

25 (2) CONFORMING CHANGES.—

1 (A) Section 515(c)(4)(A) of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C.
3 360e(c)(4)(A)) is amended by striking “738(h)”
4 and inserting “738(g)”.

5 (B) Section 738 of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 379j), as
7 amended by paragraph (1), is further amend-
8 ed—

9 (i) by redesignating subsections (g)
10 through (l) as subsections (f) through (k);

11 (ii) in subsection (a)(2)(A), by strik-
12 ing “(d), (e), and (f)” and inserting “(d)
13 and (e)”; and

14 (iii) in subsection (a)(3)(A), by strik-
15 ing “and subsection (f)”.

16 (g) EFFECT OF FAILURE TO PAY FEES.—Subsection
17 (f)(1), as redesignated, of section 738 of the Federal
18 Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amend-
19 ed—

20 (1) by striking “or periodic reporting con-
21 cerning a class III device” and inserting “periodic
22 reporting concerning a class III device, or de novo
23 classification request”; and

24 (2) by striking “all fees” and inserting “all
25 such fees”.

1 (h) CONDITIONS.—Subsection (g)(1)(A), as redesignig-
2 nated, of section 738 of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 379j) is amended by striking
4 “\$280,587,000” and inserting “\$320,825,000”.

5 (i) CREDITING AND AVAILABILITY OF FEES.—Sub-
6 section (h), as redesignated, of section 738 of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amend-
8 ed—

9 (1) in paragraph (3)—

10 (A) by striking “2013 through 2017” and
11 inserting “2018 through 2022”; and

12 (B) by striking “subsection (c)” and all
13 that follows through the period at the end and
14 inserting “subsection (c).”; and

15 (2) by striking paragraph (4).

16 **SEC. 204. REAUTHORIZATION; REPORTING REQUIREMENTS.**

17 (a) PERFORMANCE REPORTS.—Section 738A(a) of
18 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
19 379j–1(a)) is amended—

20 (1) in paragraph (1)—

21 (A) in subparagraph (A)—

22 (i) by striking “2013” and inserting
23 “2018”; and

24 (ii) by striking “the Medical Device
25 User Fee Amendments of 2012” and in-

1 serting “Medical Device User Fee Amend-
2 ments of 2017”; and

3 (B) in subparagraph (B), by striking “the
4 Medical Device User Fee Amendments of
5 2012” and inserting “Medical Device User Fee
6 Amendments of 2017”; and

7 (2) in paragraph (2), by striking “2013
8 through 2017” and inserting “2018 through 2022”.

9 (b) REAUTHORIZATION.—Section 738A(b) of the
10 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
11 1(b)) is amended—

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

14 (2) in paragraph (5), by striking “2017” and
15 inserting “2022”.

16 **SEC. 205. CONFORMITY ASSESSMENT PILOT PROGRAM.**

17 (a) IN GENERAL.—Section 514 of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 360d) is amended by
19 adding at the end the following:

20 “(d) PILOT ACCREDITATION SCHEME FOR CON-
21 FORMITY ASSESSMENT.—

22 “(1) IN GENERAL.—The Secretary shall estab-
23 lish a pilot program under which—

24 “(A) testing laboratories may be accred-
25 ited, by accreditation bodies meeting criteria

1 specified by the Secretary, to assess the con-
2 formance of a device with certain standards rec-
3 ognized under this section; and

4 “(B) subject to paragraph (2), determina-
5 tions by testing laboratories so accredited that
6 a device conforms with such standard or stand-
7 ards shall be accepted by the Secretary for pur-
8 poses of demonstrating such conformity under
9 this section unless the Secretary finds that a
10 particular such determination shall not be so
11 accepted.

12 “(2) SECRETARIAL REVIEW OF ACCREDITED
13 LABORATORY DETERMINATIONS.—The Secretary
14 may—

15 “(A) review determinations by testing lab-
16 oratories accredited pursuant to this subsection,
17 including by conducting periodic audits of such
18 determinations or processes of accredited bodies
19 or testing laboratories and, following such re-
20 view, taking additional measures under this
21 Act, such as suspension or withdrawal of ac-
22 creditation of such testing laboratory under
23 paragraph (1)(A) or requesting additional infor-
24 mation with respect to such device, as the Sec-
25 retary determines appropriate; and

1 “(B) if the Secretary becomes aware of in-
2 formation materially bearing on safety or effec-
3 tiveness of a device assessed for conformity by
4 a testing laboratory so accredited, take such ad-
5 ditional measures under this Act as the Sec-
6 retary determines appropriate, such as suspen-
7 sion or withdrawal of accreditation of such test-
8 ing laboratory under paragraph (1)(A), or re-
9 questing additional information with regard to
10 such device.

11 “(3) IMPLEMENTATION AND REPORTING.—

12 “(A) PUBLIC MEETING.—The Secretary
13 shall publish in the Federal Register a notice of
14 a public meeting to be held no later than Sep-
15 tember 30, 2018, to discuss and obtain input
16 and recommendations from stakeholders regard-
17 ing the goals and scope of, and a suitable
18 framework and procedures and requirements
19 for, the pilot program under this subsection.

20 “(B) PILOT PROGRAM GUIDANCE.—The
21 Secretary shall—

22 “(i) not later than September 30,
23 2019, issue draft guidance regarding the
24 goals and implementation of the pilot pro-
25 gram under this subsection; and

1 “(ii) not later than September 30,
2 2021, issue final guidance with respect to
3 the implementation of such program.

4 “(C) PILOT PROGRAM INITIATION.—Not
5 later than September 30, 2020, the Secretary
6 shall initiate the pilot program under this sub-
7 section.

8 “(D) REPORT.—The Secretary shall make
9 available on the website of the Food and Drug
10 Administration an annual report on the
11 progress of the pilot program under this sub-
12 section.

13 “(4) SUNSET.—As of October 1, 2022—

14 “(A) the authority for accreditation bodies
15 to accredit testing laboratories pursuant to
16 paragraph (1)(A) shall cease to have force or
17 effect;

18 “(B) the Secretary—

19 “(i) may not accept a determination
20 pursuant to paragraph (1)(B) made by a
21 testing laboratory after such date; and

22 “(ii) may accept such a determination
23 made prior to such date;

24 “(C) except for purposes of accepting a de-
25 termination described in subparagraph (B)(ii),

1 the Secretary shall not continue to recognize
2 the accreditation of testing laboratories accred-
3 ited under paragraph (1)(A); and

4 “(D) the Secretary may take actions in ac-
5 cordance with paragraph (2) with respect to the
6 determinations made prior to such date and
7 recognition of the accreditation of testing lab-
8 oratories pursuant to determinations made
9 prior to such date.”.

10 **SEC. 206. REAUTHORIZATION OF REVIEW.**

11 Section 523 of the Federal Food, Drug, and Cosmetic
12 Act (21 U.S.C. 360m) is amended—

13 (1) in subsection (a)(3)—

14 (A) in subparagraph (A), by striking
15 clauses (ii) and (iii) and inserting the following:

16 “(ii) a device classified under section
17 513(f)(2) or designated under section
18 515C(d);

19 “(iii) a device that is intended to be
20 life sustaining or life supporting, unless
21 otherwise determined by the Secretary in
22 accordance with subparagraph (B)(i)(II)
23 and listed as eligible for review under sub-
24 paragraph (B)(iii); or

1 “(iv) a device that is of a type, or sub-
2 set of a type, listed as not eligible for re-
3 view under subparagraph (B)(iii).”;

4 (B) by striking subparagraph (B) and in-
5 serting the following:

6 “(B) DESIGNATION FOR REVIEW.—The
7 Secretary shall—

8 “(i) issue draft guidance on the fac-
9 tors the Secretary will use in determining
10 whether a class I or class II device type, or
11 subset of such device types, is eligible for
12 review by an accredited person, includ-
13 ing—

14 “(I) the risk of the device type,
15 or subset of such device type; and

16 “(II) whether the device type, or
17 subset of such device type, is perma-
18 nently implantable, life sustaining, or
19 life supporting, and whether there is a
20 detailed public health justification for
21 permitting the review by an accredited
22 person of a specific life sustaining or
23 life supporting device;

24 “(ii) not later than 24 months after
25 the date on which the Secretary issues

1 such draft guidance, finalize such guid-
2 ance; and

3 “(iii) beginning on the date such guid-
4 ance is finalized, designate and post on the
5 Internet website of the Food and Drug Ad-
6 ministration, an updated list of class I and
7 class II device types, or subsets of such de-
8 vice types, and the Secretary’s determina-
9 tion with respect to whether each such de-
10 vice type, or subset of a device type, is eli-
11 gible or not eligible for review by an ac-
12 credited person under this section based on
13 the factors described in clause (i).”; and

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

15 “(C) INTERIM RULE.—Until the date on
16 which the updated list is designated and posted
17 in accordance with subparagraph (B)(iii), the
18 list in effect on the date of enactment the Med-
19 ical Device User Fee Amendments of 2017 shall
20 be in effect.”;

21 (2) in subsection (b)—

22 (A) in paragraph (2)—

23 (i) by striking subparagraph (D); and

24 (ii) by redesignating subparagraph

25 (E) as subparagraph (D); and

1 (B) in paragraph (3)—

2 (i) by redesignating subparagraph (E)
3 as subparagraph (F);

4 (ii) in subparagraph (F) (as so reded-
5 igned), by striking “The operations of”
6 and all that follows through “it will—”
7 and inserting “Such person shall agree, at
8 a minimum, to include in its request for
9 accreditation a commitment to, at the time
10 of accreditation, and at any time it is per-
11 forming any review pursuant to this sec-
12 tion—”; and

13 (iii) by inserting after subparagraph
14 (D) the following new subparagraph:

15 “(E) The operations of such person shall
16 be in accordance with generally accepted profes-
17 sional and ethical business practices.”; and

18 (3) in subsection (c), by striking “2017” and
19 inserting “2022”.

20 **SEC. 207. ELECTRONIC FORMAT FOR SUBMISSIONS.**

21 Section 745A(b) of the Federal Food, Drug, and Cos-
22 metic Act (21 U.S.C. 379k–1(b)) is amended by adding
23 at the end the following new paragraph:

24 “(3) PRESUBMISSIONS AND SUBMISSIONS SOLE-
25 LY IN ELECTRONIC FORMAT.—

1 “(A) IN GENERAL.—Beginning such date
2 as the Secretary specifies in final guidance
3 issued under subparagraph (C), presubmissions
4 and submissions for devices described in para-
5 graph (1) (and any appeals of action taken by
6 the Secretary with respect to such
7 presubmissions or submissions) shall be sub-
8 mitted solely in such electronic format as speci-
9 fied by the Secretary in such guidance.

10 “(B) DRAFT GUIDANCE.—The Secretary
11 shall, not later than October 1, 2019, issue
12 draft guidance providing for—

13 “(i) any further standards for the
14 submission by electronic format required
15 under subparagraph (A);

16 “(ii) a timetable for the establishment
17 by the Secretary of such further standards;
18 and

19 “(iii) set forth criteria for waivers of
20 and exemptions from the requirements of
21 this subsection.

22 “(C) FINAL GUIDANCE.—The Secretary
23 shall, not later than 1 year after the close of
24 the public comment period on the draft guid-

1 ance issued under subparagraph (B), issue final
2 guidance.”.

3 **SEC. 208. SAVINGS CLAUSE.**

4 Notwithstanding the amendments made by this title,
5 part 3 of subchapter C of chapter VII of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in
7 effect on the day before the date of the enactment of this
8 title, shall continue to be in effect with respect to the sub-
9 missions listed in section 738(a)(2)(A) of such Act (as de-
10 fined in such part as of such day) that on or after October
11 1, 2012, but before October 1, 2017, were accepted by
12 the Food and Drug Administration for filing with respect
13 to assessing and collecting any fee required by such part
14 for a fiscal year prior to fiscal year 2018.

15 **SEC. 209. EFFECTIVE DATE.**

16 The amendments made by this title shall take effect
17 on October 1, 2017, or the date of the enactment of this
18 Act, whichever is later, except that fees under part 3 of
19 subchapter C of chapter VII of the Federal Food, Drug,
20 and Cosmetic Act shall be assessed for all submissions list-
21 ed in section 738(a)(2)(A) of such Act received on or after
22 October 1, 2017, regardless of the date of the enactment
23 of this Act.

1 **SEC. 210. SUNSET CLAUSE.**

2 (a) AUTHORIZATION.—Sections 737 and 738 of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 739i;
4 739j) shall cease to be effective October 1, 2022.

5 (b) REPORTING REQUIREMENTS.—Section 738A (21
6 U.S.C. 739j–1) of the Federal Food, Drug, and Cosmetic
7 Act (regarding reauthorization and reporting require-
8 ments) shall cease to be effective January 31, 2023.

9 (c) PREVIOUS SUNSET PROVISION.—

10 (1) IN GENERAL.—Effective October 1, 2017,
11 section 207(a) of the Medical Device User Fee
12 Amendments of 2012 (Public Law 112–144) is re-
13 pealed.

14 (2) CONFORMING AMENDMENT.—The Food and
15 Drug Administration Safety and Innovation Act
16 (Public Law 112–144) is amended in the table of
17 contents in section 2 by striking the item relating to
18 section 207.

19 **TITLE III—FEES RELATING TO**
20 **GENERIC DRUGS**

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

22 (a) SHORT TITLE.—This title may be cited as the
23 “Generic Drug User Fee Amendments of 2017”.

24 (b) FINDING.—The Congress finds that the fees au-
25 thorized by the amendments made in this title will be dedi-
26 cated to human generic drug activities, as set forth in the

1 goals identified for purposes of part 7 of subchapter C
2 of chapter VII of the Federal Food, Drug, and Cosmetic
3 Act, in the letters from the Secretary of Health and
4 Human Services to the Chairman of the Committee on
5 Health, Education, Labor, and Pensions of the Senate and
6 the Chairman of the Committee on Energy and Commerce
7 of the House of Representatives, as set forth in the Con-
8 gressional Record.

9 **SEC. 302. DEFINITIONS.**

10 Section 744A of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 379j-41) is amended—

12 (1) in paragraph (1)(B), by striking “applica-
13 tion for a positron emission tomography drug.” and
14 inserting “application—

15 “(i) for a positron emission tomog-
16 raphy drug; or

17 “(ii) submitted by a State or Federal
18 governmental entity for a drug that is not
19 distributed commercially.”;

20 (2) by redesignating paragraphs (5) through
21 (12) as paragraphs (6) through (13), respectively;
22 and

23 (3) by inserting after paragraph (4) the fol-
24 lowing:

1 “(5) The term ‘contract manufacturing organi-
2 zation facility’ means a manufacturing facility of a
3 finished dosage form of a drug approved pursuant to
4 an abbreviated new drug application, where such
5 manufacturing facility is not identified in an ap-
6 proved abbreviated new drug application held by the
7 owner of such facility or an affiliate of such owner
8 or facility.”.

9 **SEC. 303. AUTHORITY TO ASSESS AND USE HUMAN GE-**
10 **NERIC DRUG FEES.**

11 (a) TYPES OF FEES.—Section 744B(a) of the Fed-
12 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j-
13 42(a)) is amended—

14 (1) in the matter preceding paragraph (1), by
15 striking “fiscal year 2013” and inserting “fiscal year
16 2018”;

17 (2) in paragraph (1), by adding at the end the
18 following:

19 “(E) SUNSET.—This paragraph shall cease
20 to be effective October 1, 2022.”;

21 (3) in paragraph (2)—

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

24 “(C) NOTICE.—Not later than 60 days be-
25 fore the start of each of fiscal years 2018

1 through 2022, the Secretary shall publish in the
2 Federal Register the amount of the drug mas-
3 ter file fee established by this paragraph for
4 such fiscal year.”; and

5 (B) in subparagraph (E)—

6 (i) in clause (i)—

7 (I) by striking “no later than the
8 date” and inserting “on the earlier
9 of—

10 “(I) the date”;

11 (II) by striking the period and
12 inserting “; or”; and

13 (III) by adding at the end the
14 following:

15 “(II) the date on which the drug
16 master file holder requests the initial
17 completeness assessment.”; and

18 (ii) in clause (ii), by striking “notice
19 provided for in clause (i) or (ii) of subpara-
20 graph (C), as applicable” and inserting
21 “notice provided for in subparagraph (C)”;

22 (4) in paragraph (3)—

23 (A) in the heading, by striking “AND
24 PRIOR APPROVAL SUPPLEMENT”;

1 (B) in subparagraph (A), by striking “or a
2 prior approval supplement to an abbreviated
3 new drug application”;

4 (C) by amending subparagraphs (B) and
5 (C) to read as follows:

6 “(B) NOTICE.—Not later than 60 days be-
7 fore the start of each of fiscal years 2018
8 through 2022, the Secretary shall publish in the
9 Federal Register the amount of the fees under
10 subparagraph (A) for such fiscal year.

11 “(C) FEE DUE DATE.—The fees required
12 by subparagraphs (A) and (F) shall be due no
13 later than the date of submission of the abbrevi-
14 ated new drug application or prior approval
15 supplement for which such fee applies.”;

16 (D) in subparagraph (D)—

17 (i) in the heading, by inserting “, IS
18 WITHDRAWN PRIOR TO BEING RECEIVED,
19 OR IS NO LONGER RECEIVED” after “RE-
20 CEIVED”; and

21 (ii) by striking “The Secretary shall”
22 and all that follows through the period and
23 inserting the following:

24 “(i) APPLICATIONS NOT CONSIDERED
25 TO HAVE BEEN RECEIVED AND APPLICA-

1 TIONS WITHDRAWN PRIOR TO BEING RE-
2 CEIVED.—The Secretary shall refund 75
3 percent of the fee paid under subparagraph
4 (A) for any abbreviated new drug applica-
5 tion that the Secretary considers not to
6 have been received within the meaning of
7 section 505(j)(5)(A) for a cause other than
8 failure to pay fees, or that has been with-
9 drawn prior to being received within the
10 meaning of section 505(j)(5)(A).

11 “(ii) APPLICATIONS NO LONGER RE-
12 CEIVED.—The Secretary shall refund 100
13 percent of the fee paid under subparagraph
14 (A) for any abbreviated new drug applica-
15 tion if the Secretary initially receives the
16 application under section 505(j)(5)(A) and
17 subsequently determines that an exclusivity
18 period for a listed drug should have pre-
19 vented the Secretary from receiving such
20 application, such that the abbreviated new
21 drug application is no longer received with-
22 in the meaning of section 505(j)(5)(A).”;

23 (E) in subparagraph (E), by striking “or
24 prior approval supplement”; and

1 (F) in the matter preceding clause (i) of
2 subparagraph (F)—

3 (i) by striking “2012” and inserting
4 “2017”; and

5 (ii) by striking “subsection (d)(3)”
6 and inserting “subsection (d)(2)”;

7 (5) in paragraph (4)—

8 (A) in subparagraph (A)—

9 (i) in the matter preceding clause (i)
10 and in clause (iii), by striking “, or in-
11 tended to be identified, in at least one ge-
12 neric drug submission that is pending or”
13 and inserting “in at least one generic drug
14 submission that is”;

15 (ii) in clause (i), by striking “or in-
16 tended to be identified in at least one ge-
17 neric drug submission that is pending or”
18 and inserting “in at least one generic drug
19 submission that is”;

20 (iii) in clause (ii), by striking “pro-
21 duces,” and all that follows through “such
22 a” and inserting “is identified in at least
23 one generic drug submission in which the
24 facility is approved to produce one or more
25 active pharmaceutical ingredients or in a

1 Type II active pharmaceutical ingredient
2 drug master file referenced in at least one
3 such”; and

4 (iv) in clause (iii), by striking “to fees
5 under both such clauses” and inserting
6 “only to the fee attributable to the manu-
7 facture of the finished dosage forms”; and
8 (B) by amending subparagraphs (C) and
9 (D) to read as follows:

10 “(C) NOTICE.—Within the timeframe spec-
11 ified in subsection (d)(1), the Secretary shall
12 publish in the Federal Register the amount of
13 the fees under subparagraph (A) for such fiscal
14 year.”.

15 “(D) FEE DUE DATE.—For each of fiscal
16 years 2018 through 2022, the fees under sub-
17 paragraph (A) for such fiscal year shall be due
18 on the later of—

19 “(i) the first business day on or after
20 October 1 of each such year; or

21 “(ii) the first business day after the
22 enactment of an appropriations Act pro-
23 viding for the collection and obligation of
24 fees for such year under this section for
25 such year.”;

1 (6) by redesignating paragraph (5) as para-
2 graph (6); and

3 (7) by inserting after paragraph (4) the fol-
4 lowing:

5 “(5) GENERIC DRUG APPLICANT PROGRAM
6 FEE.—

7 “(A) IN GENERAL.—A generic drug appli-
8 cant program fee shall be assessed annually as
9 described in subsection (b)(2)(E).

10 “(B) AMOUNT.—The amount of fees estab-
11 lished under subparagraph (A) shall be estab-
12 lished under subsection (d).

13 “(C) NOTICE.—Within the timeframe spec-
14 ified in subsection (d)(1), the Secretary shall
15 publish in the Federal Register the amount of
16 the fees under subparagraph (A) for such fiscal
17 year.

18 “(D) FEE DUE DATE.—For each of fiscal
19 years 2018 through 2022, the fees under sub-
20 paragraph (A) for such fiscal year shall be due
21 on the later of—

22 “(i) the first business day on or after
23 October 1 of each such fiscal year; or

24 “(ii) the first business day after the
25 date of enactment of an appropriations Act

1 providing for the collection and obligation
2 of fees for such fiscal year under this sec-
3 tion for such fiscal year.”.

4 (b) FEE REVENUE AMOUNTS.—Section 744B(b) of
5 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 379j–42(b)) is amended—

7 (1) in paragraph (1)—

8 (A) in subparagraph (A)—

9 (i) in the heading, by striking “2013”
10 and inserting “2018”;

11 (ii) by striking “2013” and inserting
12 “2018”;

13 (iii) by striking “\$299,000,000” and
14 inserting “\$493,600,000”; and

15 (iv) by striking “Of that amount” and
16 all that follows through the end of clause
17 (ii); and

18 (B) in subparagraph (B)—

19 (i) in the heading, by striking “2014
20 THROUGH 2017” and inserting “2019
21 THROUGH 2022”;

22 (ii) by striking “2014 through 2017”
23 and inserting “2019 through 2022”;

1 (iii) by striking “paragraphs (2)
2 through (4)” and inserting “paragraphs
3 (2) through (5)”; and

4 (iv) by striking “\$299,000,000” and
5 inserting “\$493,600,000”; and

6 (2) in paragraph (2)—

7 (A) in the matter preceding subparagraph

8 (A)—

9 (i) by striking “paragraph (1)(A)(ii)
10 for fiscal year 2013 and paragraph (1)(B)
11 for each of fiscal years 2014 through
12 2017” and inserting “such paragraph for a
13 fiscal year”; and

14 (ii) by striking “through (4)” and in-
15 serting “through (5)”; and

16 (B) in subparagraph (A), by striking “Six
17 percent” and inserting “Five percent”; and

18 (C) by amending subparagraphs (B) and
19 (C) to read as follows:

20 “(B) Thirty-three percent shall be derived
21 from fees under subsection (a)(3) (relating to
22 abbreviated new drug applications).

23 “(C) Twenty percent shall be derived from
24 fees under subsection (a)(4)(A)(i) (relating to
25 generic drug facilities). The amount of the fee

1 for a contract manufacturing organization facil-
2 ity shall be equal to one-third the amount of the
3 fee for a facility that is not a contract manufac-
4 turing organization facility. The amount of the
5 fee for a facility located outside the United
6 States and its territories and possessions shall
7 be \$15,000 higher than the amount of the fee
8 for a facility located in the United States and
9 its territories and possessions.”;

10 (D) in subparagraph (D)—

11 (i) by striking “Fourteen percent”
12 and inserting “Seven percent”;

13 (ii) by striking “not less than \$15,000
14 and not more than \$30,000” and inserting
15 “\$15,000”; and

16 (iii) by striking “, as determined” and
17 all that follows through the period at the
18 end and inserting a period; and

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

20 “(E)(i) Thirty-five percent shall be derived
21 from fees under subsection (a)(5) (relating to
22 generic drug applicant program fees). For pur-
23 poses of this subparagraph, if a person has af-
24 filiates, a single program fee shall be assessed
25 with respect to that person, including its affili-

1 ates, and may be paid by that person or any
2 one of its affiliates. The Secretary shall deter-
3 mine the fees as follows:

4 “(I) If a person (including its affili-
5 ates) owns at least one but not more than
6 5 approved abbreviated new drug applica-
7 tions on the due date for the fee under this
8 subsection, the person (including its affili-
9 ates) shall be assessed a small business ge-
10 neric drug applicant program fee equal to
11 one-tenth of the large size operation ge-
12 neric drug applicant program fee.

13 “(II) If a person (including its affili-
14 ates) owns at least 6 but not more than 19
15 approved abbreviated new drug applica-
16 tions on the due date for the fee under this
17 subsection, the person (including its affili-
18 ates) shall be assessed a medium size oper-
19 ation generic drug applicant program fee
20 equal to two-fifths of the large size oper-
21 ation generic drug applicant program fee.

22 “(III) If a person (including its affili-
23 ates) owns 20 or more approved abbrevi-
24 ated new drug applications on the due
25 date for the fee under this subsection, the

1 person (including its affiliates) shall be as-
2 sessed a large size operation generic drug
3 applicant program fee.

4 “(ii) For purposes of this subparagraph,
5 an abbreviated new drug application shall be
6 deemed not to be approved if the applicant has
7 submitted a written request for withdrawal of
8 approval of such abbreviated new drug applica-
9 tion by April 1 of the previous fiscal year.”.

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

13 (1) in paragraph (1)—

14 (A) by striking “2014” and inserting
15 “2019”;

16 (B) by inserting “to equal the product of
17 the total revenues established in such notice for
18 the prior fiscal year multiplied” after “a fiscal
19 year,”; and

20 (C) by striking the flush text following
21 subparagraph (C); and

22 (2) in paragraph (2)—

23 (A) by striking “2017” each place it ap-
24 pears and inserting “2022”; and

1 (B) by striking “2018” and inserting
2 “2023”.

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

6 (1) in subsection (c)(2), by striking “Such fees
7 may only be used in fiscal year 2018.”; and

8 (2) in subsection (d)—

9 (A) by striking paragraphs (1) and (2) and
10 inserting the following:

11 “(1) FISCAL YEARS 2018 THROUGH 2022.—Not
12 more than 60 days before the first day of each of
13 fiscal years 2018 through 2022, the Secretary shall
14 establish the fees described in paragraphs (2)
15 through (5) of subsection (a), based on the revenue
16 amounts established under subsection (b) and the
17 adjustments provided under subsection (c).”;

18 (B) by redesignating paragraph (3) as
19 paragraph (2); and

20 (C) in paragraph (2) (as so redesignated),
21 in the matter preceding subparagraph (A), by
22 striking “fees under paragraphs (1) and (2)”
23 and inserting “fee under paragraph (1)”.

1 (e) IDENTIFICATION OF FACILITIES.—Section
2 744B(f) of the Federal Food, Drug, and Cosmetic Act (21
3 U.S.C. 379j–42(f)) is amended—

4 (1) by striking paragraph (1);

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

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

8 (A) by striking “paragraph (4)” and in-
9 serting “paragraph (3)”; and

10 (B) by striking “Such information shall”
11 and all that follows through the end of subpara-
12 graph (B) and inserting “Such information
13 shall, for each fiscal year, be submitted, up-
14 dated, or reconfirmed on or before June 1 of
15 the previous fiscal year.”; and

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

17 (A) in the heading, by striking “CONTENTS
18 OF NOTICE” and inserting “INFORMATION RE-
19 QUIRED TO BE SUBMITTED”;

20 (B) in the matter preceding subparagraph
21 (A), by striking “paragraph (2)” and inserting
22 “paragraph (1)”;

23 (C) in subparagraph (A), by striking “or
24 intended to be identified”;

1 (D) in subparagraph (D), by striking
2 “and” at the end;

3 (E) in subparagraph (E), by striking the
4 period and inserting “; and”; and

5 (F) by adding at the end the following:

6 “(F) whether the facility is a contract
7 manufacturing organization facility.”.

8 (f) EFFECT OF FAILURE TO PAY FEES.—Section
9 744B(g) of the Federal Food, Drug, and Cosmetic Act
10 (21 U.S.C. 379–42(g)) is amended—

11 (1) in paragraph (1), by adding at the end the
12 following: “This paragraph shall cease to be effective
13 on October 1, 2022.”;

14 (2) in paragraph (2)(C)(ii), by striking “of
15 505(j)(5)(A)” and inserting “of section
16 505(j)(5)(A)”; and

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

18 “(5) GENERIC DRUG APPLICANT PROGRAM
19 FEE.—

20 “(A) IN GENERAL.—A person who fails to
21 pay a fee as required under subsection (a)(5) by
22 the date that is 20 calendar days after the due
23 date, as specified in subparagraph (D) of such
24 subsection, shall be subject to the following:

1 “(i) The Secretary shall place the per-
2 son on a publicly available arrears list.

3 “(ii) Any abbreviated new drug appli-
4 cation submitted by the generic drug appli-
5 cant or an affiliate of such applicant shall
6 not be received, within the meaning of sec-
7 tion 505(j)(5)(A).

8 “(iii) All drugs marketed pursuant to
9 any abbreviated new drug application held
10 by such applicant or an affiliate of such
11 applicant shall be deemed misbranded
12 under section 502(aa).

13 “(B) APPLICATION OF PENALTIES.—The
14 penalties under subparagraph (A) shall apply
15 until the fee required under subsection (a)(5) is
16 paid.”.

17 (g) LIMITATIONS.—Section 744B(h)(2) of the Fed-
18 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379-
19 42(h)(2)) is amended by striking “for Type II active phar-
20 maceutical ingredient drug master files, abbreviated new
21 drug applications and prior approval supplements, and ge-
22 neric drug facilities and active pharmaceutical ingredient
23 facilities”.

1 (h) CREDITING AND AVAILABILITY OF FEES.—Sec-
2 tion 744B(i) of the Federal Food, Drug, and Cosmetic Act
3 (21 U.S.C. 379–42(i)) is amended—

4 (1) in paragraph (2)—

5 (A) by striking subparagraph (C) (relating
6 to fee collection during first program year);

7 (B) in subparagraph (D)—

8 (i) in the heading, by striking “IN
9 SUBSEQUENT YEARS”; and

10 (ii) by striking “(after fiscal year
11 2013)”; and

12 (C) by redesignating subparagraph (D) as
13 subparagraph (C); and

14 (2) in paragraph (3), by striking “fiscal years
15 2013 through 2017” and inserting “fiscal years
16 2018 through 2022”.

17 (i) INFORMATION ON ABBREVIATED NEW DRUG AP-
18 PPLICATIONS HELD BY APPLICANTS AND THEIR AFFILI-
19 ATES.—Section 744B of the Federal Food, Drug, and
20 Cosmetic Act (21 U.S.C. 379–42) is amended by adding
21 at the end the following:

22 “(o) INFORMATION ON ABBREVIATED NEW DRUG
23 APPLICATIONS OWNED BY APPLICANTS AND THEIR AF-
24 FILIATES.—

1 “(1) IN GENERAL.—By April 1 of each year,
2 each person that owns an abbreviated new drug ap-
3 plication, or any affiliate of such person, shall sub-
4 mit to the Secretary a list of—

5 “(A) all approved abbreviated new drug
6 applications owned by such person; and

7 “(B) if any affiliate of such person also
8 owns an abbreviated new drug application, all
9 affiliates that own any such abbreviated new
10 drug application and all approved abbreviated
11 new drug applications owned by any such affil-
12 iate.

13 “(2) FORMAT AND METHOD.—The Secretary
14 shall specify in guidance the format and method for
15 submission of lists under this subsection.”.

16 **SEC. 304. REAUTHORIZATION; REPORTING REQUIREMENTS.**

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

19 (1) in subsection (a)—

20 (A) by striking “2013” and inserting
21 “2018”; and

22 (B) by striking “Generic Drug User Fee
23 Amendments of 2012” and inserting “Generic
24 Drug User Fee Amendments of 2017”;

1 (2) in subsection (b), by striking “2013” and
2 inserting “2018”; and

3 (3) in subsection (d), by striking “2017” each
4 place it appears and inserting “2022”.

5 **SEC. 305. SUNSET DATES.**

6 (a) **AUTHORIZATION.**—Sections 744A and 744B of
7 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
8 379j–41; 379j–42) shall cease to be effective October 1,
9 2022.

10 (b) **REPORTING REQUIREMENTS.**—Section 744C of
11 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
12 379j–43) shall cease to be effective January 31, 2023.

13 (c) **PREVIOUS SUNSET PROVISION.**—Effective Octo-
14 ber 1, 2017, subsections (a) and (b) of section 304 of the
15 Food and Drug Administration Safety and Innovation Act
16 (Public Law 112–144) are repealed.

17 **SEC. 306. EFFECTIVE DATE.**

18 The amendments made by this title shall take effect
19 on October 1, 2017, or the date of the enactment of this
20 Act, whichever is later, except that fees under part 7 of
21 subchapter C of chapter VII of the Federal Food, Drug,
22 and Cosmetic Act shall be assessed for all abbreviated new
23 drug applications received on or after October 1, 2017,
24 regardless of the date of the enactment of this Act.

1 **SEC. 307. SAVINGS CLAUSE.**

2 Notwithstanding the amendments made by this title,
3 part 7 of subchapter C of chapter VII of the Federal Food,
4 Drug, and Cosmetic Act, as in effect on the day before
5 the date of the enactment of this title, shall continue to
6 be in effect with respect to abbreviated new drug applica-
7 tions (as defined in such part as of such day) that on or
8 after October 1, 2012, but before October 1, 2017, were
9 received by the Food and Drug Administration within the
10 meaning of 505(j)(5)(A) of such Act (21 U.S.C.
11 355(j)(5)(A)), prior approval supplements that were sub-
12 mitted, and drug master files for Type II active pharma-
13 ceutical ingredients that were first referenced with respect
14 to assessing and collecting any fee required by such part
15 for a fiscal year prior to fiscal year 2018.

16 **TITLE IV—FEES RELATING TO**
17 **BIOSIMILAR BIOLOGICAL**
18 **PRODUCTS**

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

20 (a) **SHORT TITLE.**—This title may be cited as the
21 “Biosimilar User Fee Amendments of 2017”.

22 (b) **FINDING.**—The Congress finds that the fees au-
23 thorized by the amendments made in this title will be dedi-
24 cated to expediting the process for the review of biosimilar
25 biological product applications, including postmarket safe-
26 ty activities, as set forth in the goals identified for pur-

1 poses of part 8 of subchapter C of chapter VII of the Fed-
2 eral Food, Drug, and Cosmetic Act, in the letters from
3 the Secretary of Health and Human Services to the Chair-
4 man of the Committee on Health, Education, Labor, and
5 Pensions of the Senate and the Chairman of the Com-
6 mittee on Energy and Commerce of the House of Rep-
7 resentatives, as set forth in the Congressional Record.

8 **SEC. 402. DEFINITIONS.**

9 (a) ADJUSTMENT FACTOR.—Section 744G(1) of the
10 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
11 51(1)) is amended to read as follows:

12 “(1) The term ‘adjustment factor’ applicable to
13 a fiscal year is the Consumer Price Index for all
14 urban consumers (all items; United States city aver-
15 age) (Washington-Baltimore, DC-MD, VA-WV; Not
16 Seasonally Adjusted; All items) for October of the
17 preceding fiscal year divided by such Index for Octo-
18 ber 2011 divided by such index for September
19 2011.”.

20 (b) BIOSIMILAR BIOLOGICAL PRODUCT.—Section
21 744G(3) of the Federal Food, Drug, and Cosmetic Act
22 (21 U.S.C. 379j–51(3)) is amended by striking “means
23 a product” and inserting “means a specific strength of
24 a biological product in final dosage form”.

1 **SEC. 403. AUTHORITY TO ASSESS AND USE BIOSIMILAR**
2 **FEES.**

3 (a) TYPES OF FEES.—Section 744H(a) of the Fed-
4 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j-
5 52(a)) is amended—

6 (1) in the matter preceding paragraph (1), by
7 striking “fiscal year 2013” and inserting “fiscal year
8 2018”;

9 (2) in the heading of paragraph (1), by striking
10 “BIOSIMILAR” and inserting “BIOSIMILAR BIOLOGI-
11 CAL PRODUCT”;

12 (3) in paragraph (1)(A)(i), by striking
13 “(b)(1)(A)” and inserting “(c)(5)”;

14 (4) in paragraph (1)(B)(i), by striking
15 “(b)(1)(B) for biosimilar biological product develop-
16 ment” and inserting “(c)(5) for the biosimilar bio-
17 logical product development program”;

18 (5) in paragraph (1)(B)(ii), by striking “annual
19 biosimilar biological product development program
20 fee” and inserting “annual biosimilar biological
21 product development fee”;

22 (6) in paragraph (1)(B)(iii), by striking “an-
23 nual biosimilar development program fee” and in-
24 serting “annual biosimilar biological product devel-
25 opment fee”;

1 (7) in paragraph (1)(B), by adding at the end
2 the following:

3 “(iv) REFUND.—If a person submits a
4 marketing application for a biosimilar bio-
5 logical product before October 1 of a fiscal
6 year and such application is accepted for
7 filing on or after October 1 of such fiscal
8 year, the person may request a refund
9 equal to the annual biosimilar development
10 fee paid by the person for the product for
11 such fiscal year. To qualify for consider-
12 ation for a refund under this clause, a per-
13 son shall submit to the Secretary a written
14 request for such refund not later than 180
15 days after the marketing application is ac-
16 cepted for filing.”;

17 (8) in paragraph (1)(C), by striking “for a
18 product effective October 1 of a fiscal year by,” and
19 inserting “for a product, effective October 1 of a fis-
20 cal year, by,”;

21 (9) in paragraph (1)(D)—

22 (A) in clause (i) in the matter preceding
23 subclause (I), by inserting “, if the person seeks
24 to resume participation in such program,” be-
25 fore “pay a fee”;

1 (B) in clause (i)(I), by inserting after
2 “grants a request” the following: “by such per-
3 son”; and

4 (C) in clause (i)(II), by inserting after
5 “discontinued)” the following: “by such per-
6 son”;

7 (10) in the heading of paragraph (1)(E), by
8 striking “BIOSIMILAR DEVELOPMENT PROGRAM”;

9 (11) in the heading of subparagraph (F) of
10 paragraph (1), by striking “BIOSIMILAR DEVELOP-
11 MENT PROGRAM FEES” and inserting “BIOSIMILAR
12 BIOLOGICAL PRODUCT DEVELOPMENT FEES”;

13 (12) in paragraph (1)(F)—

14 (A) in the heading of subparagraph (F), by
15 striking “BIOSIMILAR DEVELOPMENT PRO-
16 GRAM” before “FEES”; and

17 (B) by amending clause (i) to read as fol-
18 lows:

19 “(i) REFUNDS.—Except as provided
20 in subparagraph (B)(iv), the Secretary
21 shall not refund any initial or annual bio-
22 similar biological product development fee
23 paid under subparagraph (A) or (B), or
24 any reactivation fee paid under subpara-
25 graph (D).”;

1 (13) in paragraph (2)—

2 (A) in the heading of paragraph (2), by
3 striking “AND SUPPLEMENT”;

4 (B) by amending subparagraphs (A) and
5 (B) to read as follows:

6 “(A) IN GENERAL.—Each person that sub-
7 mits, on or after October 1, 2017, a biosimilar
8 biological product application shall be subject to
9 the following fees:

10 “(i) A fee established under sub-
11 section (c)(5) for a biosimilar biological
12 product application for which clinical data
13 (other than comparative bioavailability
14 studies) with respect to safety or effective-
15 ness are required for approval.

16 “(ii) A fee established under sub-
17 section (c)(5) for a biosimilar biological
18 product application for which clinical data
19 (other than comparative bioavailability
20 studies) with respect to safety or effective-
21 ness are not required for approval. Such
22 fee shall be equal to half of the amount of
23 the fee described in clause (i).

24 “(B) RULE OF APPLICABILITY; TREAT-
25 MENT OF CERTAIN PREVIOUSLY PAID FEES.—

1 Any person who pays a fee under subparagraph
2 (A), (B), or (D) of paragraph (1) for a product
3 before October 1, 2017, but submits a bio-
4 similar biological product application for that
5 product after such date, shall—

6 “(i) be subject to any biosimilar bio-
7 logical product application fees that may
8 be assessed at the time when such bio-
9 similar biological product application is
10 submitted; and

11 “(ii) be entitled to no reduction of
12 such application fees based on the amount
13 of fees paid for that product before Octo-
14 ber 1, 2017, under such subparagraph (A),
15 (B), or (D).”;

16 (C) in the heading of subparagraph (D),
17 by striking “OR SUPPLEMENT”; and

18 (D) in subparagraphs (C) through (F)—

19 (i) by striking “or supplement” each
20 place it appears; and

21 (ii) in subparagraph (D), by striking
22 “or a supplement”; and

23 (14) by amending paragraph (3) to read as fol-
24 lows:

1 “(3) BIOSIMILAR BIOLOGICAL PRODUCT PRO-
2 GRAM FEE.—

3 “(A) IN GENERAL.—Each person who is
4 named as the applicant in a biosimilar biologi-
5 cal product application shall pay the annual bio-
6 similar biological product program fee estab-
7 lished for a fiscal year under subsection (c)(5)
8 for each biosimilar biological product that—

9 “(i) is identified in such a biosimilar
10 biological product application approved as
11 of October 1 of such fiscal year; and

12 “(ii) as of October 1 of such fiscal
13 year, does not appear on a list, developed
14 and maintained by the Secretary, of dis-
15 continued biosimilar biological products.

16 “(B) DUE DATE.—The biosimilar biologi-
17 cal product program fee for a fiscal year shall
18 be due on the later of—

19 “(i) the first business day on or after
20 October 1 of each such year; or

21 “(ii) the first business day after the
22 enactment of an appropriations Act pro-
23 viding for the collection and obligation of
24 fees for such year under this section.

1 “(C) ONE FEE PER PRODUCT PER YEAR.—
2 The biosimilar biological product program fee
3 shall be paid only once for each product for
4 each fiscal year.

5 “(D) LIMITATION.—A person who is
6 named as the applicant in a biosimilar biologi-
7 cal product application shall not be assessed
8 more than 5 biosimilar biological product pro-
9 gram fees for a fiscal year for biosimilar bio-
10 logical products identified in such biosimilar bi-
11 ological product application.”.

12 (b) FEE REVENUE AMOUNTS.—Subsection (b) of sec-
13 tion 744H of the Federal Food, Drug, and Cosmetic Act
14 (21 U.S.C. 379j-52) is amended to read as follows:

15 “(b) FEE REVENUE AMOUNTS.—

16 “(1) FISCAL YEAR 2018.—For fiscal year 2018,
17 fees under subsection (a) shall be established to gen-
18 erate a total revenue amount equal to the sum of—

19 “(A) \$45,000,000; and

20 “(B) the dollar amount equal to the fiscal
21 year 2018 adjustment (as determined under
22 subsection (c)(4)).

23 “(2) SUBSEQUENT FISCAL YEARS.—For each of
24 the fiscal years 2019 through 2022, fees under sub-
25 section (a) shall, except as provided in subsection

1 (c), be established to generate a total revenue
2 amount equal to the sum of—

3 “(A) the annual base revenue for the fiscal
4 year (as determined under paragraph (4));

5 “(B) the dollar amount equal to the infla-
6 tion adjustment for the fiscal year (as deter-
7 mined under subsection (c)(1));

8 “(C) the dollar amount equal to the capac-
9 ity planning adjustment for the fiscal year (as
10 determined under subsection (c)(2)); and

11 “(D) the dollar amount equal to the oper-
12 ating reserve adjustment for the fiscal year, if
13 applicable (as determined under subsection
14 (c)(3)).

15 “(3) ALLOCATION OF REVENUE AMOUNT
16 AMONG FEES; LIMITATIONS ON FEE AMOUNTS.—

17 “(A) ALLOCATION.—The Secretary shall
18 determine the percentage of the total revenue
19 amount for a fiscal year to be derived from, re-
20 spectively—

21 “(i) initial and annual biosimilar de-
22 velopment fees and reactivation fees under
23 subsection (a)(1);

24 “(ii) biosimilar biological product ap-
25 plication fees under subsection (a)(2); and

1 “(iii) biosimilar biological product pro-
2 gram fees under subsection (a)(3).

3 “(B) LIMITATIONS ON FEE AMOUNTS.—
4 Until the first fiscal year for which the capacity
5 planning adjustment under subsection (c)(2) is
6 effective, the amount of any fee under sub-
7 section (a) for a fiscal year after fiscal year
8 2018 shall not exceed 125 percent of the
9 amount of such fee for fiscal year 2018.

10 “(C) BIOSIMILAR BIOLOGICAL PRODUCT
11 DEVELOPMENT FEES.—The initial biosimilar bi-
12 ological product development fee under sub-
13 section (a)(1)(A) for a fiscal year shall be equal
14 to the annual biosimilar biological product de-
15 velopment fee under subsection (a)(1)(B) for
16 that fiscal year.

17 “(D) REACTIVATION FEE.—The reactiva-
18 tion fee under subsection (a)(1)(D) for a fiscal
19 year shall be equal to twice the amount of the
20 annual biosimilar biological product develop-
21 ment fee under subsection (a)(1)(B) for that
22 fiscal year.

23 “(4) ANNUAL BASE REVENUE.—For purposes
24 of paragraph (2), the dollar amount of the annual
25 base revenue for a fiscal year shall be the dollar

1 amount of the total revenue amount for the previous
2 fiscal year, excluding any adjustments to such rev-
3 enue amount under subsection (c)(3).”.

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

7 (1) by redesignating subsections (c) through (h)
8 as subsections (d) through (i), respectively;

9 (2) in subsections (a)(2)(F) and (g), by striking
10 “subsection (c)” and inserting “subsection (d)”;

11 (3) in subsection (a)(4)(A), by striking “sub-
12 section (b)(1)(F)” and inserting “subsection (c)(5)”;
13 and

14 (4) by inserting after subsection (b) the fol-
15 lowing:

16 “(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

17 “(1) INFLATION ADJUSTMENT.—

18 “(A) IN GENERAL.—For purposes of sub-
19 section (b)(2)(B), the dollar amount of the in-
20 flation adjustment to the annual base revenue
21 for each fiscal year shall be equal to the prod-
22 uct of—

23 “(i) such annual base revenue for the
24 fiscal year under subsection (b); and

1 ceding 4 years of available data multiplied
2 by the proportion of all costs other than
3 personnel compensation and benefits costs
4 to total costs of the process for the review
5 of biosimilar biological product applications
6 (as defined in section 744G(13)) for the
7 first 3 years of the preceding 4 fiscal
8 years.

9 “(2) CAPACITY PLANNING ADJUSTMENT.—

10 “(A) IN GENERAL.—Beginning with the
11 fiscal year described in subparagraph
12 (B)(ii)(II), the Secretary shall, in addition to
13 the adjustment under paragraph (1), further in-
14 crease the fee revenue and fees under this sec-
15 tion for a fiscal year to reflect changes in the
16 resource capacity needs of the Secretary for the
17 process for the review of biosimilar biological
18 product applications.

19 “(B) CAPACITY PLANNING METHOD-
20 OLOGY.—

21 “(i) DEVELOPMENT; EVALUATION
22 AND REPORT.—The Secretary shall obtain,
23 through a contract with an independent ac-
24 counting or consulting firm, a report evalu-
25 ating options and recommendations for a

1 new methodology to accurately assess
2 changes in the resource and capacity needs
3 of the process for the review of biosimilar
4 biological product applications. The capac-
5 ity planning methodological options and
6 recommendations presented in such report
7 shall utilize and be informed by personnel
8 time reporting data as an input. The re-
9 port shall be published for public comment
10 not later than September 30, 2020.

11 “(ii) ESTABLISHMENT AND IMPLE-
12 MENTATION.—After review of the report
13 described in clause (i) and receipt and re-
14 view of public comments thereon, the Sec-
15 retary shall establish a capacity planning
16 methodology for purposes of this para-
17 graph, which shall—

18 “(I) incorporate such approaches
19 and attributes as the Secretary deter-
20 mines appropriate; and

21 “(II) be effective beginning with
22 the first fiscal year for which fees are
23 set after such capacity planning meth-
24 odology is established.

1 “(C) LIMITATION.—Under no cir-
2 cumstances shall an adjustment under this
3 paragraph result in fee revenue for a fiscal year
4 that is less than the sum of the amounts under
5 subsections (b)(2)(A) (the annual base revenue
6 for the fiscal year) and (b)(2)(B) (the dollar
7 amount of the inflation adjustment for the fis-
8 cal year).

9 “(D) PUBLICATION IN FEDERAL REG-
10 ISTER.—The Secretary shall publish in the Fed-
11 eral Register notice under paragraph (5) the fee
12 revenue and fees resulting from the adjustment
13 and the methodologies under this paragraph.

14 “(3) OPERATING RESERVE ADJUSTMENT.—

15 “(A) INTERIM APPLICATION; FEE REDUC-
16 TION.—Until the first fiscal year for which the
17 capacity planning adjustment under paragraph
18 (2) is effective, the Secretary may, in addition
19 to the adjustment under paragraph (1), reduce
20 the fee revenue and fees under this section for
21 a fiscal year as the Secretary determines appro-
22 priate for long-term financial planning pur-
23 poses.

24 “(B) GENERAL APPLICATION AND METH-
25 ODOLOGY.—Beginning with the first fiscal year

1 for which the capacity planning adjustment
2 under paragraph (2) is effective, the Secretary
3 may, in addition to the adjustments under
4 paragraphs (1) and (2)—

5 “(i) reduce the fee revenue and fees
6 under this section as the Secretary deter-
7 mines appropriate for long-term financial
8 planning purposes; or

9 “(ii) increase the fee revenue and fees
10 under this section if such an adjustment is
11 necessary to provide for not more than 21
12 weeks of operating reserves of carryover
13 user fees for the process for the review of
14 biosimilar biological product applications.

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

23 “(4) FISCAL YEAR 2018 ADJUSTMENT.—

24 “(A) IN GENERAL.—For fiscal year 2018,
25 the Secretary shall adjust the fee revenue and

1 fees under this section in such amount (if any)
2 as needed to reflect an updated assessment of
3 the workload for the process for the review of
4 biosimilar biological product applications.

5 “(B) METHODOLOGY.—The Secretary shall
6 publish under paragraph (5) a description of
7 the methodology used to calculate the fiscal
8 year 2018 adjustment under this paragraph in
9 the Federal Register notice establishing fee rev-
10 enue and fees for fiscal year 2018.

11 “(C) LIMITATION.—No adjustment under
12 this paragraph shall result in an increase in fee
13 revenue and fees under this section in excess of
14 \$9,000,000.

15 “(5) ANNUAL FEE SETTING.—For fiscal year
16 2018 and each subsequent fiscal year, the Secretary
17 shall, not later than 60 days before the start of each
18 such fiscal year—

19 “(A) establish, for the fiscal year, initial
20 and annual biosimilar biological product devel-
21 opment fees and reactivation fees under sub-
22 section (a)(1), biosimilar biological product ap-
23 plication fees under subsection (a)(2), and bio-
24 similar biological product program fees under
25 subsection (a)(3), based on the revenue

1 amounts established under subsection (b) and
2 the adjustments provided under this subsection;
3 and

4 “(B) publish such fee revenue and fees in
5 the Federal Register.

6 “(6) LIMIT.—The total amount of fees assessed
7 for a fiscal year under this section may not exceed
8 the total costs for such fiscal year for the resources
9 allocated for the process for the review of biosimilar
10 biological product applications.”.

11 (d) APPLICATION FEE WAIVER FOR SMALL BUSI-
12 NESS.—Subsection (d)(1) of section 744H of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52), as
14 redesignated by subsection (c)(1), is amended—

15 (1) by striking subparagraph (B);

16 (2) by striking “shall pay—” and all that fol-
17 lows through “application fees” and inserting “shall
18 pay application fees”; and

19 (3) by striking “; and” at the end and inserting
20 a period.

21 (e) EFFECT OF FAILURE TO PAY FEES.—Subsection
22 (e) of section 744H of the Federal Food, Drug, and Cos-
23 metic Act (21 U.S.C. 379j–52), as redesignated by sub-
24 section (c)(1), is amended by striking “all fees” and in-
25 serting “all such fees”.

1 (f) CREDITING AND AVAILABILITY OF FEES.—Sub-
2 section (f) of section 744H of the Federal Food, Drug,
3 and Cosmetic Act (21 U.S.C. 379j–52), as redesignated
4 by subsection (c)(1), is amended—

5 (1) in paragraph (2)—

6 (A) by striking subparagraph (C) (relating
7 to fee collection during first program year) and
8 inserting the following:

9 “(C) COMPLIANCE.—The Secretary shall
10 be considered to have met the requirements of
11 subparagraph (B) in any fiscal year if the costs
12 described in such subparagraph are not more
13 than 15 percent below the level specified in
14 such subparagraph.”; and

15 (B) in subparagraph (D)—

16 (i) in the heading, by striking “IN
17 SUBSEQUENT YEARS”; and

18 (ii) by striking “(after fiscal year
19 2013)”; and

20 (2) in paragraph (3), by striking “2013
21 through 2017” and inserting “2018 through 2022”.

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

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

25 (1) in subsection (a)—

1 (A) by striking “2013” and inserting
2 “2018”; and

3 (B) by striking “Biosimilar User Fee Act
4 of 2012” and inserting “Biosimilar User Fee
5 Amendments of 2017”;

6 (2) in subsection (b), by striking “2013” and
7 inserting “2018”;

8 (3) by striking subsection (d);

9 (4) by redesignating subsection (e) as sub-
10 section (d); and

11 (5) in subsection (d), as so redesignated, by
12 striking “2017” each place it appears and inserting
13 “2022”.

14 **SEC. 405. SUNSET DATES.**

15 (a) AUTHORIZATION.—Sections 744G and 744H of
16 the Federal Food, Drug, and Cosmetic Act, as amended
17 by section 403 of this Act, shall cease to be effective Octo-
18 ber 1, 2022.

19 (b) REPORTING REQUIREMENTS.—Section 744I of
20 the Federal Food, Drug, and Cosmetic Act, as amended
21 by section 404 of this Act, shall cease to be effective Janu-
22 ary 31, 2023.

23 (c) PREVIOUS SUNSET PROVISION.—

24 (1) IN GENERAL.—Effective October 1, 2017,
25 section 404 of the Food and Drug Administration

1 Safety and Innovation Act (Public Law 112–144) is
2 repealed.

3 (2) CONFORMING AMENDMENT.—The Food and
4 Drug Administration Safety and Innovation Act
5 (Public Law 112–144) is amended in the table of
6 contents in section 2 by striking the item relating to
7 section 404.

8 **SEC. 406. EFFECTIVE DATE.**

9 The amendments made by this title shall take effect
10 on October 1, 2017, or the date of the enactment of this
11 Act, whichever is later, except that fees under part 8 of
12 subchapter C of chapter VII of the Federal Food, Drug,
13 and Cosmetic Act shall be assessed for all biosimilar bio-
14 logical product applications received on or after October
15 1, 2017, regardless of the date of the enactment of this
16 Act.

17 **SEC. 407. SAVINGS CLAUSE.**

18 Notwithstanding the amendments made by this title,
19 part 8 of subchapter C of chapter VII of the Federal Food,
20 Drug, and Cosmetic Act, as in effect on the day before
21 the date of the enactment of this title, shall continue to
22 be in effect with respect to biosimilar biological product
23 applications and supplements (as defined in such part as
24 of such day) that were accepted by the Food and Drug
25 Administration for filing on or after October 1, 2012, but

1 before October 1, 2017, with respect to assessing and col-
2 lecting any fee required by such part for a fiscal year prior
3 to fiscal year 2018.

4 **TITLE V—PEDIATRIC DRUGS**
5 **AND DEVICES**

6 **SEC. 501. PEDIATRIC DEVICES.**

7 (a) PEDIATRIC USE OF DEVICES.—Section 515A of
8 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 360e–1) is amended—

10 (1) in subsection (a)(3)—

11 (A) by redesignating subparagraphs (B)
12 through (D) as subparagraphs (D) through (F),
13 respectively;

14 (B) by inserting after subparagraph (A)
15 the following:

16 “(B) an assessment of pediatric device la-
17 beling needs based on a review of real world evi-
18 dence collected on the off-label use of medical
19 devices in children, using data available to the
20 Secretary;

21 “(C) the number of devices that receive a
22 humanitarian use exemption under section
23 520(m);”;

24 (C) in subparagraph (E), as so redesign-
25 ated, by striking “; and” and inserting “;”;

1 (D) in subparagraph (F) (as so redesignig-
2 nated), by striking “(B), and (C).” and insert-
3 ing “(C), (D), and (E); and”;

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

5 “(G) the number of devices for which ex-
6 trapolation was used to support the approval of
7 pediatric labeling of such devices.

8 For the items described in this paragraph, such re-
9 port shall disaggregate the number of devices by pe-
10 diatric subpopulation.”;

11 (2) by redesignating subsection (c) as sub-
12 section (d); and

13 (3) by inserting after subsection (b), the fol-
14 lowing:

15 “(c) PEDIATRIC DEVICE INNOVATION.—

16 “(1) IN GENERAL.—The Secretary shall, not
17 later than 1 year after the date of enactment of the
18 FDA Reauthorization Act of 2017, establish within
19 the Center for Devices and Radiological Health a
20 structure to—

21 “(A) provide assistance to device manufac-
22 turers that would result in the development, ap-
23 proval, and labeling of medical devices for chil-
24 dren;

1 “(B) oversee an internal pediatrics team
2 that—

3 “(i) is comprised of employees of the
4 Food and Drug Administration with exper-
5 tise in pediatrics and appropriate expertise
6 pertaining to the relevant devices under re-
7 view; and

8 “(ii) provides expertise and consulta-
9 tion, to all applicable divisions within the
10 Center for Devices and Radiological
11 Health, on—

12 “(I) the application of subsection
13 (b), section 520(m), section 510(k),
14 and section 522 of this Act and sec-
15 tion 402 of the Public Health Service
16 Act to pediatric devices; and

17 “(II) pediatrics, as it pertains to
18 reviewing devices;

19 “(C) coordinate pediatric activities within
20 the Center for Devices and Radiological Health;
21 and

22 “(D) collaborate with other programs, of-
23 fices, and centers of the Food and Drug Admin-
24 istration, including the consortia program au-
25 thorized under section 305 of the Pediatric

1 Medical Device Safety and Improvement Act of
2 2007.

3 “(2) STAFF.—Such structure shall include a
4 chief pediatric medical officer and other appropriate
5 individuals as the Secretary determines necessary.”.

6 (b) HUMANITARIAN DEVICE EXEMPTION.—Section
7 520(m) of the Federal Food, Drug, and Cosmetic Act (21
8 U.S.C. 360j(m)) is amended—

9 (1) in paragraph (4)—

10 (A) in subparagraph (B), by inserting “or
11 an appropriate local committee” after “review
12 committee” each place such term appears; and

13 (B) in the matter following subparagraph
14 (B), by inserting “or an appropriate local com-
15 mittee” after “review committee” each place
16 such term appears; and

17 (2) in paragraph (6)(A)(iv), by striking “2017”
18 and inserting “2022”.

19 (c) DEMONSTRATION GRANTS FOR IMPROVING PEDI-
20 ATRIC AVAILABILITY.—Section 305 of the Pediatric Med-
21 ical Device Safety and Improvement Act of 2007 (Public
22 Law 110–85; 42 U.S.C. 282 note) is amended—

23 (1) in subsection (c)—

24 (A) in paragraph (4), by striking “and” at
25 the end;

1 (B) in paragraph (5), by striking the pe-
2 riod and inserting “; and”; and

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

4 “(6) providing regulatory consultation to device
5 sponsors in support of the submission of an applica-
6 tion for a pediatric device, where appropriate.”; and

7 (2) in subsection (e), by striking “2017” and
8 inserting “2022”.

9 (d) MEETING ON PEDIATRIC DEVICE DEVELOP-
10 MENT.—

11 (1) IN GENERAL.—Not later than 1 year after
12 the date of enactment of this Act, the Secretary of
13 Health and Human Services shall convene a public
14 meeting regarding opportunities and barriers to the
15 development, approval, and labeling of pediatric
16 medical devices. Such meeting shall include rep-
17 resentatives from the medical device industry, aca-
18 demia, recipients of funding under section 305 of
19 the Pediatric Medical Device Safety and Improve-
20 ment Act of 2007 (Public Law 110–85; 42 U.S.C.
21 282 note), medical provider organizations, and orga-
22 nizations representing patients and consumers.

23 (2) TOPICS.—The meeting described in para-
24 graph (1) shall include consideration of ways to—

1 (A) improve research infrastructure and
2 research networks to facilitate the conduct of
3 clinical studies of devices for children that
4 would result in the approval and labeling of
5 medical devices for children;

6 (B) appropriately use extrapolation under
7 section 515A(b) of the Federal Food, Drug,
8 and Cosmetic Act (21 U.S.C. 360e–1(b));

9 (C) enhance the appropriate use of
10 postmarket registries and data to increase pedi-
11 atric medical device labeling;

12 (D) increase Food and Drug Administra-
13 tion assistance to medical device manufactures
14 in developing devices for children that are ap-
15 proved and labeled for their use; and

16 (E) identify current barriers to pediatric
17 device development and incentives to address
18 such barriers.

19 (3) REPORT.—Not later than 6 months after
20 the meeting described in paragraph (1), the Sec-
21 retary of Health and Human Services shall submit
22 to the Committee on Energy and Commerce of the
23 House of Representatives and the Committee on
24 Health, Education, Labor, and Pensions of the Sen-
25 ate, and publish, including on the Internet website

1 of the Food and Drug Administration, a report that
2 summarizes and responds to the recommendations
3 raised in such meeting.

4 **SEC. 502. PEDIATRIC DRUG DEVELOPMENT.**

5 (a) EARLY MEETING ON PEDIATRIC STUDY PLAN.—

6 (1) IN GENERAL.—Clause (i) of section
7 505B(e)(2)(C) of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C. 355c(e)(2)(C)) is amended to
9 read as follows:

10 “(i) shall meet with the applicant—

11 “(I) if requested by the applicant
12 with respect to a drug that is in-
13 tended to treat a serious or life-
14 threatening disease or condition, to
15 discuss preparation of the initial pedi-
16 atric study plan, not later than the
17 end-of-Phase 1 meeting (as such term
18 is used in section 312.47(b) of title
19 21, Code of Federal Regulations, or
20 successor regulations) or within 30
21 calendar days of receipt of such re-
22 quest, whichever is later;

23 “(II) to discuss the initial pedi-
24 atric study plan as soon as prac-
25 ticable, but not later than 90 calendar

1 days after the receipt of such plan
2 under subparagraph (A); and

3 “(III) to discuss any scientific or
4 operational challenges that may be the
5 basis of a deferral under subsection
6 (a)(3) or a full or partial waiver under
7 subsection (a)(4);”.

8 (2) CONFORMING CHANGES.—Section 505B(e)
9 of the Federal Food, Drug, and Cosmetic Act (21
10 U.S.C. 355c(e)) is amended—

11 (A) in the heading of paragraph (2), by
12 striking “MEETING” and inserting “MEETINGS”;

13 (B) in the heading of paragraph (2)(C), by
14 striking “MEETING” and inserting “MEET-
15 INGS”;

16 (C) in clauses (ii) and (iii) of paragraph
17 (2)(C), by striking “no meeting” each place it
18 appears and inserting “no meeting under clause
19 (i)(II)”;

20 (D) in paragraph (3) by striking “meeting
21 under paragraph (2)(C)(i)” and inserting
22 “meeting under paragraph (2)(C)(i)(II)”.

23 (b) INFORMING INTERNAL REVIEW COMMITTEE.—
24 Section 505A(f) of the Federal Food, Drug, and Cosmetic

1 Act (21 U.S.C. 355a(f)) is amended by adding at the end
2 the following:

3 “(7) INFORMING INTERNAL REVIEW COM-
4 MITTEE.—The Secretary shall provide to the com-
5 mittee referred to in paragraph (1) any response
6 issued to an applicant or holder with respect to a
7 proposed pediatric study request.”.

8 (c) ACTION ON SUBMISSIONS.—

9 (1) IN GENERAL.—Section 505A(d) of the Fed-
10 eral Food, Drug, and Cosmetic Act (21 U.S.C.
11 355a(d)) is amended—

12 (A) by redesignating paragraphs (3)
13 through (5) as paragraphs (4) through (6), re-
14 spectively; and

15 (B) by inserting after paragraph (2) the
16 following:

17 “(3) ACTION ON SUBMISSIONS.—The Secretary
18 shall review and act upon a submission of a pro-
19 posed pediatric study request or a sponsor’s pro-
20 posed amendment to a written request for pediatric
21 studies within 120 calendar days of the submis-
22 sion.”.

23 (2) CONFORMING AMENDMENTS.—

24 (A) FFDCA.—Section 505A of the Fed-
25 eral Food, Drug, and Cosmetic Act (21 U.S.C.

1 355a), as amended by paragraph (1), is further
2 amended by striking subsection “(d)(3)” each
3 place it appears and inserting “(d)(4)”.

4 (B) PHSA.—Paragraphs (2), (3), and (4)
5 of section 351(m) of the Public Health Service
6 Act (42 U.S.C. 262(m)) are amended by strik-
7 ing “section 505A(d)(3)” each place it appears
8 and inserting “section 505A(d)(4)”.

9 (d) STUDY.—The Secretary of Health and Human
10 Services, acting through the internal review committee es-
11 tablished under section 505C of the Federal Food, Drug,
12 and Cosmetic Act (21 U.S.C. 355d) shall, not later than
13 one year after the date of enactment of this Act, develop
14 and implement a plan to achieve, when appropriate, earlier
15 submission of pediatric studies under section 505A of the
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a)
17 or section 351(m) of the Public Health Service Act (42
18 U.S.C. 262(m)). Such plan shall include recommendations
19 to achieve—

20 (1) earlier discussion of proposed pediatric
21 study requests and written requests with sponsors,
22 and if appropriate, at the meeting required under
23 section 505B(e)(2)(C) of the Federal Food, Drug,
24 and Cosmetic Act (21 U.S.C. 355c(e)(2)(C)), as
25 amended by subsection (a);

1 (2) earlier issuance of written requests for a pe-
2 diatric study under such section 505A, including for
3 investigational new drugs prior to the submission of
4 an application under section 505(b)(1) of the Fed-
5 eral Food, Drug, and Cosmetic Act (21 U.S.C.
6 355(b)(1)); and

7 (3) shorter timelines, when appropriate, for the
8 completion of studies pursuant to a written request
9 under such section 505A or such section 351(m).

10 (e) NEONATOLOGY EXPERTISE.—

11 (1) IN GENERAL.—Section 6(d) of the Best
12 Pharmaceuticals for Children Act (21 U.S.C.
13 393a(d)) is amended by striking “For the 5-year pe-
14 riod beginning on the date of enactment of this sub-
15 section, at” and inserting “At”.

16 (2) DRAFT GUIDANCE.—Not later than 2 years
17 after the date of enactment of this Act, the Sec-
18 retary shall issue draft guidance on clinical pharma-
19 cology considerations for neonatal studies for drugs
20 and biological products.

21 (f) SUBMISSION OF ASSESSMENTS.—Section
22 505B(d)(1) of the Federal Food, Drug, and Cosmetic Act
23 (21 U.S.C. 355c(d)(1)) is amended by adding at the end
24 the following: “The Secretary shall inform the Pediatric

1 Advisory Committee of all letters and responses to such
2 letters issued under this paragraph.”.

3 (g) INTERNAL COMMITTEE.—Section 505C of the
4 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355d)
5 is amended by inserting “or pediatric rare diseases” after
6 “psychiatry”.

7 **SEC. 503. GUIDANCE ON MOLECULAR TARGETS IN PEDI-**
8 **ATRIC ONCOLOGY.**

9 (a) IN GENERAL.—The Secretary of Health and
10 Human Services (referred to in this subsection as the
11 “Secretary”), acting through the Commissioner of Food
12 and Drugs, shall issue guidance on the development of on-
13 cology drugs or biological products directed at molecular
14 targets, including for pediatric populations.

15 (b) COLLABORATION; PUBLIC MEETING.—In devel-
16 oping the guidance under subsection (a), the Secretary,
17 acting through the Commissioner of Food and Drugs and
18 in collaboration with the Director of the National Cancer
19 Institute, shall convene a public meeting not later than
20 180 days after the date of enactment of this Act to solicit
21 feedback from physicians and researchers (including pedi-
22 atric oncologists), patients, and other stakeholders to pro-
23 vide input on development of the guidance. The Secretary
24 shall seek input at such meeting on—

1 (1) the scientific data necessary to determine
2 when an oncology drug or biological product directed
3 at a molecular target is sufficient to support pedi-
4 atric clinical development given the ethical, practical,
5 and other barriers to clinical investigations in the
6 pediatric population;

7 (2) how to determine relevancy of a molecular
8 target to the growth or progression of a pediatric
9 cancer, including the clinical data necessary to make
10 such a determination;

11 (3) how to overcome the challenges related to
12 pediatric oncology drug development, including
13 issues related to conducting clinical trials in pedi-
14 atric rare cancers with small patient populations;

15 (4) the advantages and disadvantages of inno-
16 vative clinical trial designs in addressing the devel-
17 opment of oncology drugs or biological products di-
18 rected at molecular targets in pediatric cancer pa-
19 tients; and

20 (5) the ways in which the Secretary can im-
21 prove the current process outlined under sections
22 505A and 505B of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 355a, 355c) to encourage
24 additional research and development of pediatric
25 cancer treatments.

1 **SEC. 504. BEST PHARMACEUTICALS FOR CHILDREN.**

2 Section 409I of the Public Health Service Act (42
3 U.S.C. 284m) is amended—

4 (1) in subsection (a)(2)(A)(ii), by inserting
5 “and identification of biomarkers for such diseases,
6 disorders, or conditions,” after “biologics,”;

7 (2) in subsection (c)—

8 (A) in paragraph (6)(B)—

9 (i) by striking “shall be assigned a
10 docket number by the Commissioner of
11 Food and Drugs” and inserting “, not
12 later than 90 days after submission, shall
13 be posted on the Internet website of the
14 Food and Drug Administration in an ac-
15 cessible manner”; and

16 (ii) by striking “become part of the
17 docket file with respect to each of the
18 drugs” and inserting “be posted on the
19 Internet website of the Food and Drug Ad-
20 ministration”; and

21 (B) in paragraph (7)—

22 (i) in the matter preceding subpara-
23 graph (A), by striking “submitted” and in-
24 serting “posted”; and

25 (ii) in subparagraph (C), by striking
26 “(i) place” and all that follows through the

1 period at the end and inserting “publish
2 through posting on the Internet website of
3 the Food and Drug Administration a sum-
4 mary of the report and a copy of any re-
5 quested labeling changes.”;

6 (3) by striking subsection (d);

7 (4) by redesignating subsection (e) as sub-
8 section (d); and

9 (5) in paragraph (1) of subsection (d), as so re-
10 designated, by striking “2013 through 2017” and
11 inserting “2018 through 2022”.

12 **TITLE VI—REAUTHORIZATIONS**
13 **AND IMPROVEMENTS RE-**
14 **LATED TO DRUGS**

15 **SEC. 601. REAUTHORIZATION OF PROVISION RELATING TO**
16 **EXCLUSIVITY OF CERTAIN DRUGS CON-**
17 **TAINING SINGLE ENANTIOMERS.**

18 Section 505(u)(4) of the Federal Food, Drug, and
19 Cosmetic Act (21 U.S.C. 355(u)(4)) is amended by strik-
20 ing “2017” and inserting “2022”.

21 **SEC. 602. REAUTHORIZATION OF THE CRITICAL PATH PUB-**
22 **LIC-PRIVATE PARTNERSHIPS.**

23 Section 566(f) of the Federal Food, Drug, and Cos-
24 metic Act (21 U.S.C. 360bbb–5(f)) is amended by striking

1 “2013 through 2017” and inserting “2018 through
2 2022”.

3 **SEC. 603. REAUTHORIZATION OF ORPHAN GRANTS PRO-**
4 **GRAM.**

5 Section 5(c) of the Orphan Drug Act (21 U.S.C.
6 360ee(c)) is amended by striking “2013 through 2017”
7 and inserting “2018 through 2022”.

8 **SEC. 604. GUIDANCE REGARDING BIOEQUIVALENCE.**

9 (a) IN GENERAL.—In accordance with subsection (b),
10 the Secretary of Health and Human Services, acting
11 through the Commissioner of Food and Drugs, shall issue
12 product-specific guidance that—

13 (1) applies to complex non-biologic drugs; and

14 (2) outlines how to demonstrate bioequivalence
15 to the reference drug, in order to facilitate generic
16 development for such drugs.

17 (b) DEADLINE FOR ISSUING GUIDANCE.—After the
18 date of enactment of this Act, the Secretary of Health and
19 Human Services, acting through the Commissioner of
20 Food and Drugs, shall publish a guidance, for each com-
21 plex non-biologic drug that is approved under section
22 505(b) of the Federal Food, Drug, and Cosmetic Act (21
23 U.S.C. 355(b)), not less than 2 years prior to the earliest
24 date on which an abbreviated new drug application may
25 be submitted pursuant to section 505(j) of the Federal,

1 Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) that
2 references such drug.

3 (c) APPLICABILITY.—This section applies to guid-
4 ances for abbreviated new drug applications that reference
5 new drug applications first approved on or after October
6 1, 2017.

7 **SEC. 605. PATIENT EXPERIENCE DATA.**

8 Section 569C(c)(2)(A) of the Federal Food, Drug,
9 and Cosmetic Act (21 U.S.C. 360bbb–8c(c)(2)(A)) is
10 amended by striking “impact of such disease or condition,
11 or a related therapy,” and inserting “physical and psycho-
12 social impacts of such disease or condition, related ther-
13 apy, or clinical investigation”.

14 **SEC. 606. COMMUNICATIONS PLANS.**

15 Section 505–1(e)(3) of the Federal Food, Drug, and
16 Cosmetic Act (21 U.S.C. 355–1(e)(3)) is amended—

17 (1) in subparagraph (B), by striking “; or”;

18 (2) in subparagraph (C), by striking the period
19 and inserting “; or”; and

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

21 “(D) disseminating information to health
22 care providers about the meaning of terms re-
23 lated to drug formulations or properties that
24 are described in the drug labeling, including in-
25 formation about the limitations or patient care

1 implications of such formulations or properties,
2 and how such formulations or properties may
3 be related to serious adverse drug events associ-
4 ated with use of the drug.”.

5 **SEC. 607. PROTECTING AND STRENGTHENING THE DRUG**
6 **SUPPLY CHAIN.**

7 (a) **DIVERTED DRUGS.**—Paragraph (1) of section
8 801(d) of the Federal Food, Drug, and Cosmetic Act (21
9 U.S.C. 381(d)) is amended—

10 (1) by striking “(d)(1) Except as” and insert-
11 ing “(d)(1)(A) Except as”; and

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

13 “(B) Except as authorized by the Secretary in the
14 case of a drug that appears on the drug shortage list
15 under section 506E or in the case of importation pursuant
16 to section 804(j), no drug that is subject to section
17 503(b)(1) may be imported into the United States for
18 commercial use if such drug is manufactured outside the
19 United States, the manufacturer has not authorized the
20 drug to be marketed in the United States, and the manu-
21 facturer has not caused the drug to be labeled to be mar-
22 keted in the United States.”.

23 (b) **COUNTERFEIT DRUGS.**—Subsection (b) of section
24 303 of the Federal Food, Drug, and Cosmetic Act (21

1 U.S.C. 333) is amended by adding at the end the fol-
2 lowing:

3 “(8) Notwithstanding subsection (a), any person who
4 violates section 301(i)(3) by selling or dispensing, or hold-
5 ing for sale or dispensing, a drug that is a counterfeit drug
6 shall be fined under title 18, United States Code, impris-
7 oned for not more than 10 years, or both, unless the per-
8 son acted in good faith and had no reason to believe the
9 drug was a counterfeit drug.”.

10 **SEC. 608. TECHNICAL CORRECTIONS.**

11 Section 527 of the Federal Food, Drug, and Cosmetic
12 Act (21 U.S.C. 360ee) is amended—

13 (1) in subsection (a), in the matter following
14 paragraph (2), by striking “such drug for such dis-
15 ease or condition” and inserting “the same drug for
16 the same disease or condition”;

17 (2) in subsection (b)—

18 (A) in the matter preceding paragraph (1),
19 by striking “If an application” and all that fol-
20 lows through “such license if” and inserting
21 “During the 7-year period described in sub-
22 section (a) for an approved application under
23 section 505 or license under section 351 of the
24 Public Health Service Act, the Secretary may
25 approve an application or issue a license for a

1 drug that is otherwise the same, as determined
2 by the Secretary, as the already approved drug
3 for the same rare disease or condition if”;

4 (B) in paragraph (1), by striking “notice”
5 and all that follows through “assure” and in-
6 serting “of exclusive approval or licensure no-
7 tice and opportunity for the submission of
8 views, that during such period the holder of the
9 exclusive approval or licensure cannot ensure”;
10 and

11 (C) in paragraph (2), by striking “such
12 holder provides” and inserting “the holder pro-
13 vides”; and

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

15 “(c) CONDITION OF CLINICAL SUPERIORITY.—

16 “(1) IN GENERAL.—If a sponsor of a drug that
17 is designated under section 526 and is otherwise the
18 same, as determined by the Secretary, as an already
19 approved or licensed drug is seeking exclusive ap-
20 proval or exclusive licensure described in subsection
21 (a) for the same rare disease or condition as the al-
22 ready approved drug, the Secretary shall require
23 such sponsor, as a condition of such exclusive ap-
24 proval or licensure, to demonstrate that such drug is

1 clinically superior to any already approved or li-
2 censed drug that is the same drug.

3 “(2) DEFINITION.—For purposes of paragraph
4 (1), the term ‘clinically superior’ with respect to a
5 drug means that the drug provides a significant
6 therapeutic advantage over and above an already ap-
7 proved or licensed drug in terms of greater efficacy,
8 greater safety, or by providing a major contribution
9 to patient care.

10 “(d) REGULATIONS.—The Secretary may promulgate
11 regulations for the implementation of subsection (c). Until
12 such time as the Secretary promulgates regulations in ac-
13 cordance with this subsection, any definitions set forth in
14 regulations implementing this section that were promul-
15 gated prior to the date of enactment of the FDA Reau-
16 thorization Act of 2017 shall continue to apply.”.

17 **TITLE VII—DEVICE INSPECTION**
18 **AND REGULATORY IMPROVE-**
19 **MENTS**

20 **SEC. 701. RISK-BASED INSPECTIONS FOR DEVICES.**

21 (a) IN GENERAL.—Section 510(h) of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C. 360(h)) is
23 amended—

24 (1) by striking paragraph (2) and inserting the
25 following:

1 “(2) RISK-BASED SCHEDULE FOR DEVICES.—

2 “(A) IN GENERAL.—The Secretary, acting
3 through one or more officers or employees duly
4 designated by the Secretary, shall inspect estab-
5 lishments described in paragraph (1) that are
6 engaged in the manufacture, propagation,
7 compounding, or processing of a device or de-
8 vices (referred to in this subsection as ‘device
9 establishments’) in accordance with a risk-based
10 schedule established by the Secretary.

11 “(B) FACTORS AND CONSIDERATIONS.—In
12 establishing the risk-based schedule under sub-
13 paragraph (A), the Secretary shall—

14 “(i) apply, to the extent applicable for
15 device establishments, the factors identified
16 in paragraph (4); and

17 “(ii) consider the participation of the
18 device establishment, as applicable, in
19 international device audit programs in
20 which the United States participates or the
21 United States recognizes.”; and

22 (2) in paragraph (4)—

23 (A) in the matter preceding subparagraph
24 (A), by striking “paragraph (3)” and inserting
25 “paragraph (2) or (3)”; and

1 (B) in subparagraph (C), by inserting “or
2 device” after “drug”.

3 (b) FOREIGN INSPECTIONS.—Section 809(a)(1) of
4 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
5 384e(a)(1)) is amended by striking “section 510(h)(3)”
6 and inserting “paragraph (2) or (3) of section 510(h)”.

7 **SEC. 702. IMPROVEMENTS TO INSPECTIONS PROCESS.**

8 (a) INSPECTION PROCEDURE.—Section 704 of the
9 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374)
10 is amended by adding at the end the following:

11 “(h)(1) In the case of inspections that are not for-
12 cause inspections, the Secretary shall review existing proc-
13 esses and standards for inspections of domestic and for-
14 eign device establishments, and update such processes and
15 standards to ensure uniform processes and standards,
16 with exceptions as appropriate. Such processes and stand-
17 ards shall include—

18 “(A) announcing the inspection to the establish-
19 ment within a reasonable time before such inspec-
20 tion, which shall include notification to the owner,
21 operator, or agent in charge of the establishment re-
22 garding the type and nature of the inspection;

23 “(B) providing a reasonable estimate of the
24 timeframe for the duration of the inspection, an op-
25 portunity for advancing communications between the

1 officers or employees carrying out the inspection
2 under subsection (a)(1) and the owner, operator, or
3 agent in charge of the establishment concerning ap-
4 propriate working hours during the inspection, and,
5 to the extent feasible, advance notice of records that
6 will be requested in order to expedite the inspection;
7 and

8 “(C) providing for requirements with respect to
9 the frequency and conditions of communications dur-
10 ing the inspection with the owner, operator, or agent
11 in charge of the establishment regarding inspection
12 status, which may be recorded by either party with
13 advance notice and mutual consent.

14 “(2) Nothing in this subsection affects the authority
15 of the Secretary to conduct inspections otherwise per-
16 mitted under this Act in order to ensure compliance.”.

17 (b) REPORT RESPONSES .—Section 704(b) of the
18 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(b))
19 is amended—

20 (1) by striking “Upon completion” and insert-
21 ing “(1) Upon completion”; and

22 (2) by adding at the end the following:

23 “(2) In the case of establishments registered under
24 section 510 that have received a report pursuant to para-
25 graph (1), and for which the owner, operator, or agent

1 in charge of such establishment submits a timely response
2 to such report that includes a request for feedback to the
3 actions proposed in such response, and which involves a
4 public health priority, the Secretary shall provide non-
5 binding feedback regarding such proposed actions within
6 45 days of receipt of such request.”.

7 (c) GUIDANCE.—

8 (1) DRAFT GUIDANCE.—Not later than 1 year
9 after the date of enactment of this Act, the Sec-
10 retary of Health and Human Services shall issue
11 draft guidance that—

12 (A) specifies how the Food and Drug Ad-
13 ministration will implement the process de-
14 scribed in subsection (h) of section 704 of the
15 Federal Food, Drug, and Cosmetic Act (21
16 U.S.C. 374), as amended by this section, and
17 the requirements described in subsection (b)(2)
18 of such section;

19 (B) provides standard methods for commu-
20 nications described in such subsections;

21 (C) establishes standard timeframes over
22 consecutive days applicable to both domestic
23 and foreign inspections, to which each inspector
24 shall adhere unless an investigator can identify

1 to the establishment a reason that more time is
2 needed; and

3 (D) identifies practices for investigators
4 and device establishments to facilitate the con-
5 tinuity of inspections.

6 (2) FINAL GUIDANCE.—Not later than 18
7 months after the close of the comment period on the
8 draft guidance under paragraph (1), the Secretary
9 shall issue final guidance consistent with such para-
10 graph.

11 **SEC. 703. REAUTHORIZATION OF INSPECTION PROGRAM.**

12 Section 704(g)(11) of the Federal Food, Drug, and
13 Cosmetic Act (21 U.S.C. 374(g)(11)) is amended by strik-
14 ing “October 1, 2017” and inserting “October 1, 2022”.

15 **SEC. 704. CERTIFICATES TO FOREIGN GOVERNMENTS FOR**
16 **DEVICES.**

17 Subsection (e)(4) of section 801 of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 381(e)(4)) is amend-
19 ed—

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

21 “(E)(i)(I) If the Secretary denies a request for certifi-
22 cation under subparagraph (A)(ii) with respect to a device
23 manufactured in an establishment (foreign or domestic)
24 registered under section 510, the Secretary shall provide
25 in writing to the person seeking such certification the

1 basis for such denial, and specifically identify the finding
2 upon which such denial is based.

3 “(II) If the denial of a request as described in sub-
4 clause (I) is based on grounds other than an injunction
5 proceeding pursuant to section 302, seizure action pursu-
6 ant to section 304, or a recall designated Class I or Class
7 II pursuant to part 7, title 21, Code of Federal Regula-
8 tions, the Secretary shall provide a substantive summary
9 of the specific grounds for noncompliance identified.

10 “(III) With respect to a device manufactured in an
11 establishment that has received a report under section
12 704(b), the Secretary shall not deny a request for certifi-
13 cation with respect to a device pursuant to subparagraph
14 (A)(ii) if the Secretary and the owner, operator, or agent
15 in charge of such establishment have agreed to a plan of
16 correction in response to such report.

17 “(ii)(I) The Secretary shall provide a process for a
18 person who is denied a certification as described in clause
19 (i)(I) to request a review that conforms to the standards
20 of section 517A(b).

21 “(II) Notwithstanding any previous review conducted
22 pursuant to subclause (I), a person who has been denied
23 a certification as described in clause (i)(I) may at any time
24 request a review in order to present new information relat-
25 ing to actions taken by such person to address the reasons

1 identified by the Secretary for the denial of certification,
2 including evidence that corrective actions are being or
3 have been implemented to address grounds for noncompli-
4 ance identified by the Secretary.

5 “(III) Not later than 1 year after date of enactment
6 of the FDA Reauthorization Act of 2017, the Secretary
7 shall issue guidance providing for a process to carry out
8 this subparagraph. Not later than 1 year after the close
9 of the comment period for such guidance, the Secretary
10 shall issue final guidance.”; and

11 (2) by moving the margins of subparagraphs
12 (C) and (D) 4 ems to the left.

13 **SEC. 705. FACILITATING INTERNATIONAL HARMONIZATION.**

14 Section 704(g) of the Federal Food, Drug and Cos-
15 metic Act (21 U.S.C. 374) is amended by adding at the
16 end the following:

17 “(15) Notwithstanding any other provision of
18 this subsection, for purposes of conducting inspec-
19 tions of establishments that manufacture, prepare,
20 propagate, compound, or process devices except
21 types of devices licensed under section 351 of the
22 Public Health Service Act, which inspections are re-
23 quired under section 510(h) or are inspections of
24 such establishments required to register pursuant to
25 section 510(i), the Secretary may recognize auditing

1 organizations that are recognized by organizations
2 established by governments to facilitate international
3 harmonization. Nothing in this paragraph affects the
4 authority of the Secretary to inspect any device es-
5 tablishment pursuant to this Act. Nothing in this
6 paragraph affects the authority of the Secretary to
7 determine the official classification of an inspec-
8 tion.”.

9 **SEC. 706. NOTIFICATION OF GUIDANCE RELATED TO LAB-**
10 **DEVELOPED TESTS.**

11 Section 1143 of the Food and Drug Administration
12 Safety and Innovation Act (Public Law 112–144) is
13 amended—

14 (1) in subsection (a), by striking “60” and in-
15 sserting “90”; and

16 (2) in subsection (b), by striking “5” and in-
17 sserting “10”.

18 **SEC. 707. DIAGNOSTIC IMAGING DEVICES INTENDED FOR**
19 **USE WITH CONTRAST AGENTS.**

20 Section 520 of the Federal Food, Drug, and Cosmetic
21 Act (21 U.S.C. 360j) is amended by adding at the end
22 the following:

23 “(p)(1) The Secretary may approve an application or
24 supplement to an application under section 515 for an ap-
25 plicable medical imaging device, may make a substantial

1 equivalence determination as to an applicable medical im-
2 aging device for which a report or a supplement to a report
3 has been submitted under section 510(k), or may grant
4 a request under section 513(f)(2) for an applicable med-
5 ical imaging device if the requirements of this subsection
6 and other applicable premarket requirements are met, and
7 the indications and conditions of use proposed in such ap-
8 plication or notification involve the use of a contrast agent
9 that is not—

10 “(A) in a concentration, rate of administration,
11 or route of administration that is different from
12 those described in the approved labeling of such con-
13 trast agent, unless the Secretary determines, based
14 on information contained in the application or re-
15 port, that the difference does not adversely affect
16 the safety or effectiveness of the contrast agent
17 when used with the device;

18 “(B) in a region, organ, or system of the body
19 that is different from those described in the ap-
20 proved labeling of the contrast agent unless the Sec-
21 retary determines, based on information contained in
22 the device application, request, or report, that any
23 difference does not affect the safety or effectiveness
24 of the contrast agent when used with the device;

1 “(C) in a patient population different from the
2 patient population in the approved labeling for such
3 contrast agent, unless the Secretary determines,
4 based on information contained in the application or
5 report, that the difference does not adversely affect
6 the safety or effectiveness of the contrast agent
7 when used with the device; or

8 “(D) in an imaging modality, such as
9 ultrasound, magnetic resonance, x-ray, fluorescent
10 imaging technology, or diagnostic radiopharma-
11 ceutical-based technology that is different from those
12 described in the approved labeling of the contrast
13 agent.

14 “(2) An applicable medical imaging device that is eli-
15 gible for approval under section 515, clearance under sec-
16 tion 510(k), or classification under section 513(f)(2), or
17 approval, clearance, or classification as described in para-
18 graph (1) shall be subject only to such requirements of
19 this Act that are applicable to devices.

20 “(3) An application under section 515, report under
21 section 510(k), or classification under section 513(f)(2)
22 for an applicable medical imaging device intended for use
23 in conjunction with a contrast agent to which clause (ii)
24 or (iii) of section 505(c)(3)(E) applies shall refer to such
25 contrast agent in such application, report, or request by

1 trade or brand name, rather than to the international non-
2 proprietary name.

3 “(4) In conducting a review of an application or re-
4 port submitted for an applicable medical imaging device,
5 the agency center charged with the premarket review of
6 devices center may consult with the agency center charged
7 with the premarket review of drugs and biological prod-
8 ucts.

9 “(5) For purposes of this subsection—

10 “(A) the term ‘applicable medical imaging de-
11 vice’ means a device intended to be used in conjunc-
12 tion with a contrast agent or class of contrast agents
13 for a use that is not described in the indications and
14 usage section of the approved labeling of such con-
15 trast agent or the approved labeling of any contrast
16 agent in such class, as applicable; and

17 “(B) the term ‘contrast agent’ means a drug
18 that is approved under section 505 or licensed under
19 section 351 of the Public Health Service Act, is in-
20 tended for use in conjunction with an applicable
21 medical imaging device, and—

22 “(i) is a diagnostic radiopharmaceutical, as
23 defined in sections 315.2 and 601.30 of title
24 21, Code of Federal Regulations (or any suc-
25 cessor regulations); or

1 “(ii) is a diagnostic agent that improves
2 the visualization of structure or function within
3 the body by increasing the relative difference in
4 signal intensity within the target tissue, struc-
5 ture, or fluid.”.

6 **SEC. 708. DIAGNOSTIC CLARITY.**

7 Not later than 18 months after the date of enactment
8 of this Act, the Secretary of Health and Human Services
9 (referred to in this section as the “Secretary”) shall up-
10 date guidance with respect to the circumstances under
11 which reagents, new instruments, or new combinations of
12 instruments may be added to groups of instruments that
13 have been cleared under section 510(k) of the Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)). The
15 updated guidance shall provide standard definitions and
16 describe procedures for sponsors seeking to add a new in-
17 strument, reagent, or combination of instruments to a
18 cleared group of instruments to submit information to the
19 Secretary demonstrating that the new reagent, new instru-
20 ment, or new combination of instruments does not alter
21 the assay’s performance, as applicable. The Secretary
22 shall consult with affected entities and other stakeholders
23 in updating the guidance.

1 **SEC. 709. APPROPRIATE CLASSIFICATION OF DEVICE AC-**
2 **CESSORIES.**

3 Section 513(b)(9) of the Federal Food, Drug, and
4 Cosmetic Act (21 U.S.C. 360c(b)(9)) is amended—

5 (1) by striking “(9) The Secretary” and insert-
6 ing “(9)(A) The Secretary”; and

7 (2) by adding at the end the following:

8 “(B) The classification of any accessory classified
9 prior to December 13, 2016, based on the intended use
10 or uses of such accessory, shall continue to apply, unless
11 otherwise determined by the Secretary under section
12 515(e)(1).

13 “(C)(i) If an accessory has been cleared or approved
14 based on the classification of another device with which
15 such accessory is intended to be used and the Secretary
16 has established a classification for such accessory based
17 on the intended use or uses of the accessory, in accordance
18 with subparagraph (A), the manufacturer of such acces-
19 sory may identify the classification so established for such
20 accessory in a written notification to the Secretary.

21 “(ii) Unless the Secretary notifies a manufacturer
22 within 30 calendar days of receipt of a written notification
23 described in clause (i) that the Secretary does not agree
24 that the classification identified in such written notifica-
25 tion is appropriate for the accessory, the accessory shall

1 be automatically reclassified in accordance with the classi-
2 fication identified in such written notification.

3 “(iii) A written notification that the Secretary dis-
4 agrees with the classification identified in a written notifi-
5 cation described in clause (ii) shall include a detailed de-
6 scription and justification for the determination to dis-
7 agree.

8 “(D)(i) A manufacturer of an accessory that has not
9 been classified by the Secretary based on the intended use
10 or uses of the accessory as described in subparagraph (A),
11 and for which the Secretary has not established a classi-
12 fication for the accessory type as a stand-alone device,
13 may submit to the Secretary a written recommendation
14 for the appropriate classification of such accessory based
15 on its intended use or uses. Such submission shall include
16 such information to support the recommendation as the
17 Secretary may require.

18 “(ii) The Secretary shall respond to a submission
19 under clause (i) within 60 calendar days of receiving the
20 submission by approving or denying the recommended
21 classification of the accessory. If the Secretary does not
22 agree with the recommendation for classification sub-
23 mitted by the sponsor, the response shall include a detailed
24 description and justification for such determination to dis-
25 agree. The Secretary shall provide an opportunity for a

1 manufacturer to meet with appropriate personnel to dis-
2 cuss appropriate classification of such accessory prior to
3 submitting a written recommendation.

4 “(E)(i) At the time a sponsor submits an application
5 for premarket approval pursuant to section 515(c) or a
6 report pursuant to 510(k), the sponsor of such application
7 or report may include a recommendation and supporting
8 information for the proper classification of an accessory
9 pursuant to subparagraph (A), if applicable. If such acces-
10 sory type has not been classified by the Secretary based
11 on its intended use or uses as a stand-alone device as de-
12 scribed in subparagraph (A), the Secretary shall—

13 “(I) approve or deny such application pursuant
14 to section 515(d), or find such report substantially
15 equivalent or not substantially equivalent pursuant
16 to section 510(k); and

17 “(II) approve or deny the classification of the
18 accessory proposed in such application or report.

19 “(F) A manufacturer may at any time use the classi-
20 fication process described in section 513(f)(2) to obtain
21 classification of an accessory.”.

22 **SEC. 710. DEVICE PILOT PROJECTS.**

23 (a) POSTMARKET PILOT.—Section 519 of the Fed-
24 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360i) is
25 amended by adding at the end the following:

1 “(i) PILOT PROJECTS.—

2 “(1) IN GENERAL.—In order to provide timely
3 and reliable information on the safety and effective-
4 ness of cleared or approved devices, including re-
5 sponses to adverse events and malfunctions, and to
6 advance the objectives of part 803 of title 21, Code
7 of Federal Regulations (or successor regulations),
8 and advance the objectives of, and evaluate innova-
9 tive new methods of compliance with, this section
10 and section 522, the Secretary shall, within one year
11 of the date of enactment of the FDA Reauthoriza-
12 tion Act of 2017, initiate one or more pilot projects
13 for voluntary participation by a manufacturer or
14 manufacturers of device or device type, or continue
15 existing projects in accordance with paragraph (3),
16 that meet all of the following requirements:

17 “(A) Are designed to efficiently generate
18 reliable and timely safety and active surveil-
19 lance data for use by the Secretary or manufac-
20 turers of the devices that are involved in the
21 pilot project.

22 “(B) Inform the development of methods,
23 systems, data criteria, and programs that could
24 be used to support safety and active surveil-

1 lance activities for devices not included in such
2 project.

3 “(C) Are designed and conducted in co-
4 ordination with a comprehensive system for
5 evaluating medical device technology that oper-
6 ates under a governing board with appropriate
7 representation of stakeholders, including con-
8 sumer groups and device manufacturers.

9 “(D) Use electronic health data including
10 claims data, patient survey data, and any other
11 data, as the Secretary determines appropriate.

12 “(E) Prioritize devices and device types
13 that meet one or more of the following criteria:

14 “(i) Devices and device types for
15 which the collection and analysis of real
16 world evidence regarding a device’s safety
17 and effectiveness is likely to advance public
18 health.

19 “(ii) Devices and device types that are
20 widely used.

21 “(iii) Devices and device types, the
22 failure of which has significant health con-
23 sequences.

24 “(iv) Devices and device types for
25 which the Secretary has received public

1 recommendations in accordance with para-
2 graph (2)(B) and has determined to meet
3 one of the criteria under clauses (i)
4 through (iii) and is appropriate for a
5 project under this subsection.

6 “(2) PARTICIPATION.—The Secretary shall es-
7 tablish the conditions and processes for—

8 “(A) authorizing voluntary participation of
9 a manufacturer of a device in the pilot project
10 described in paragraph (1); and

11 “(B) facilitating public recommendations
12 for devices to be prioritized under the pilot
13 project described in paragraph (1), including re-
14 quirements for the data necessary to support
15 such recommendation.

16 “(3) IMPLEMENTATION.—The Secretary may
17 satisfy the requirements of paragraphs (1) and (2)
18 by continuing or expanding existing projects, or by
19 beginning new projects, that meet the criteria of
20 subparagraphs (A) through (E) of paragraph (1) or
21 by entering into contracts, cooperative agreements,
22 grants, or other appropriate agreements with public
23 or private entities that have a significant presence in
24 the United States, and meet the following additional
25 conditions:

1 “(A) If such public or private entities are
2 a component of another organization, the enti-
3 ties have established appropriate security meas-
4 ures to maintain the confidentiality and privacy
5 of the data described in paragraph (1)(D) and
6 the entity shall not make an unauthorized dis-
7 closure of such data to the other components of
8 the organization in breach of such confiden-
9 tiality and privacy requirements.

10 “(B) In the case of the termination or non-
11 renewal of such contracts, cooperative agree-
12 ments, grants, or other appropriate agreements,
13 the entities shall comply with each of the fol-
14 lowing:

15 “(i) Continue to comply with the con-
16 fidentiality and privacy requirements under
17 this subsection with respect to all data dis-
18 closed to the entity.

19 “(ii) Return any data disclosed to
20 such entity under this subsection to which
21 it would not otherwise have access or, if re-
22 turning the data is not practicable, destroy
23 the data.

24 “(C) Have at least one of the following
25 qualifications:

1 “(i) Research, statistical, epidemio-
2 logic, or clinical capability and expertise to
3 conduct and complete the activities under
4 this subsection, including the capability
5 and expertise to provide the Secretary ac-
6 cess to de-identified data consistent with
7 the requirements of this subsection.

8 “(ii) An information technology infra-
9 structure in place to support electronic
10 data and operational standards to provide
11 security for such data, as appropriate.

12 “(iii) Experience with, and expertise
13 on, the development of device safety and
14 effectiveness research and surveillance
15 using electronic health data.

16 “(iv) Other expertise which the Sec-
17 retary determines necessary to fulfill the
18 activities under this subsection.

19 “(4) REVIEW OF CONTRACT IN THE EVENT OF
20 A MERGER OR ACQUISITION.—The Secretary shall
21 review a contract with a qualified entity under this
22 subsection in the event of a merger or acquisition of
23 the entity in order to ensure that the requirements
24 under this subsection will continue to be met.

1 “(5) REPORT TO CONGRESS.—Not later than
2 18 months after the date of enactment of this Act,
3 and annually thereafter, the Secretary shall submit
4 to the Committee on Health, Education, Labor, and
5 Pensions of the Senate and the Committee on En-
6 ergy and Commerce of the House of Representatives
7 a report containing a description of the pilot projects
8 being conducted pursuant to this subsection, includ-
9 ing for each pilot project—

10 “(A) how the project is being implemented
11 in accordance with paragraph (3) and the con-
12 tractor or grantee as applicable;

13 “(B) the number of manufacturers that
14 have agreed to participate;

15 “(C) the data sources used;

16 “(D) the devices or device categories in-
17 volved; and

18 “(E) the number of patients involved.

19 “(6) COMPLIANCE WITH REQUIREMENTS FOR
20 RECORDS OR REPORTS ON DEVICES.—The participa-
21 tion of a manufacturer in a pilot project under this
22 subsection shall not affect the eligibility of such
23 manufacturer to participate in any quarterly report-
24 ing program implemented under this Act. The Sec-
25 retary may determine that, for the specified time pe-

1 riod to be determined by the Secretary, a manufac-
2 turer’s participation in a pilot project under this
3 subsection may meet certain other requirements of
4 this section or section 522 if—

5 “(A) the project has demonstrated success
6 in capturing relevant adverse event information;
7 and

8 “(B) the Secretary has established proce-
9 dures for making adverse event and safety in-
10 formation collected from the pilot public, to the
11 extent possible, if collected pursuant to this sec-
12 tion or section 522.

13 “(7) PRIVACY REQUIREMENTS.—With respect
14 to the pilot projects conducted pursuant to this sub-
15 section—

16 “(A) individual identifiable health informa-
17 tion shall not be disclosed when presenting any
18 information from such project; and

19 “(B) such projects shall comply with sec-
20 tion 264(e) of the Health Insurance Portability
21 and Accountability Act of 1996 (42 U.S.C.
22 1320d–2 note) and sections 552 and 552a of
23 title 5, United States Code.

24 “(8) OTHER COMPLIANCE.—Any pilot program
25 undertaken in coordination with the comprehensive

1 system described in paragraph (1)(C), including
2 pilot projects under this subsection, that relates to
3 the use of real world evidence for devices shall com-
4 ply with paragraph (1)(B), the conditions listed in
5 subparagraphs (A) and (B) of paragraph (3), and
6 paragraphs (4), (5), (6), and (7).

7 “(9) SUNSET.—This subsection shall cease to
8 have force or effect on October 1, 2022.”.

9 (b) REPORT.—Not later than January 31, 2021, the
10 Secretary of Health and Human Services, acting through
11 the Commissioner of Food and Drugs, shall conduct a re-
12 view through an independent third party to evaluate the
13 strengths, limitations, and appropriate use of evidence col-
14 lected pursuant to real world evidence pilot projects de-
15 scribed in the letters described in section 201(b) of the
16 Medical Device User Fee Amendments of 2017 and sub-
17 section (i) of section 519 of the Federal Food, Drug, and
18 Cosmetic Act (21 U.S.C. 360i), as amended by subsection
19 (a), for informing premarket and postmarket decision-
20 making for multiple device types, and to determine wheth-
21 er the methods, systems, and programs in such pilot
22 projects efficiently generate reliable and timely evidence
23 about the effectiveness or safety surveillance of devices.

1 **SEC. 711. REGULATION OF OVER-THE-COUNTER HEARING**
2 **AIDS.**

3 (a) IN GENERAL.—Section 520 of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 360j), as amended
5 by section 707, is further amended by adding at the end
6 the following:

7 “(q) REGULATION OF OVER-THE-COUNTER HEARING
8 AIDS.—

9 “(1) DEFINITION.—In this subsection, the term
10 ‘over-the-counter hearing aid’ means a device that—

11 “(A) uses the same fundamental scientific
12 technology as air conduction hearing aids (as
13 defined in section 874.3300 of title 21, Code of
14 Federal Regulations) (or any successor regula-
15 tion) or wireless air conduction hearing aids (as
16 defined in section 874.3305 of title 21, Code of
17 Federal Regulations) (or any successor regula-
18 tion);

19 “(B) is intended to be used by adults over
20 the age of 18 to compensate for perceived mild
21 to moderate hearing impairment;

22 “(C) through tools, tests, or software, al-
23 lows the user to control the over-the-counter
24 hearing aid and customize it to the user’s hear-
25 ing needs;

26 “(D) may—

1 “(i) use wireless technology; or

2 “(ii) include tests for self-assessment
3 of hearing loss; and

4 “(E) is available over-the-counter, without
5 the supervision, prescription, or other order, in-
6 volvement, or intervention of a licensed person,
7 to consumers through in-person transactions, by
8 mail, or online.

9 “(2) REGULATION.—An over-the-counter hear-
10 ing aid shall be subject to the regulations promul-
11 gated in accordance with section 710(b) of the FDA
12 Reauthorization Act of 2017 and shall be exempt
13 from sections 801.420 and 801.421 of title 21, Code
14 of Federal Regulations (or any successor regula-
15 tions).”.

16 (b) REGULATIONS TO ESTABLISH CATEGORY.—

17 (1) IN GENERAL.—The Secretary of Health and
18 Human Services (referred to in this section as the
19 “Secretary”), not later than 3 years after the date
20 of enactment of this Act, shall promulgate proposed
21 regulations to establish a category of over-the-
22 counter hearing aids, as defined in subsection (q) of
23 section 520 of the Federal Food, Drug, and Cos-
24 metic Act (21 U.S.C. 360j) as amended by sub-
25 section (a), and, not later than 180 days after the

1 date on which the public comment period on the pro-
2 posed regulations closes, shall issue such final regu-
3 lations.

4 (2) REQUIREMENTS.—In promulgating the reg-
5 ulations under paragraph (1), the Secretary shall—

6 (A) include requirements that provide rea-
7 sonable assurances of the safety and efficacy of
8 over-the-counter hearing aids;

9 (B) include requirements that establish or
10 adopt output limits appropriate for over-the-
11 counter hearing aids;

12 (C) include requirements for appropriate
13 labeling of the over-the-counter hearing aid, in-
14 cluding how consumers may report adverse
15 events, any conditions or contraindications, and
16 any advisements to consult promptly with a li-
17 censed physician; and

18 (D) describe the requirements under which
19 the sale of over-the-counter hearing aids is per-
20 mitted, without the supervision, prescription, or
21 other order, involvement, or intervention of a li-
22 censed person, to consumers through in-person
23 transactions, by mail, or online.

24 (3) PREMARKET NOTIFICATION.—The Sec-
25 retary shall make findings under section 510(m) of

1 the Federal Food, Drug, and Cosmetic Act (21
2 U.S.C. 360(m)) to determine whether over-the-
3 counter hearing aids (as defined in section 520(q) of
4 the Federal Food, Drug, and Cosmetic Act (21
5 U.S.C. 360j), as amended by subsection (a)) require
6 a report under section 510(k) to provide reasonable
7 assurance of safety and effectiveness.

8 (4) EFFECT ON STATE LAW.—No State or local
9 government shall establish or continue in effect any
10 law, regulation, or order specifically applicable to
11 hearing products that would restrict or interfere
12 with the servicing, marketing, sale, dispensing, use,
13 customer support, or distribution of over-the-counter
14 hearing aids (as defined in section 520(q) of the
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 360j), as amended by subsection (a)) through in-per-
17 son transactions, by mail, or online, that is different
18 from, in addition to, or otherwise not identical to,
19 the regulations promulgated under this subsection,
20 including any State or local requirement for the su-
21 pervision, prescription, or other order, involvement,
22 or intervention of a licensed person for consumers to
23 access over-the-counter hearing aids.

24 (c) NEW GUIDANCE ISSUED.—Not later than the
25 date on which final regulations are issued under sub-

1 section (b), the Secretary shall update and finalize the
2 draft guidance of the Department of Health and Human
3 Services entitled, “Regulatory Requirements for Hearing
4 Aid Devices and Personal Sound Amplification Products”,
5 issued on November 7, 2013. Such updated and finalized
6 guidance shall clarify which products, on the basis of
7 claims or other marketing, advertising, or labeling mate-
8 rial, meet the definition of a device in section 201 of the
9 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)
10 and which products meet the definition of a personal
11 sound amplification product, as set forth in such guidance.

12 (d) STUDY.—Not later than 3 years after the date
13 of enactment of this Act, the Comptroller General of the
14 United States shall submit to Congress a report evaluating
15 consumer experience with hearing health care, hearing
16 screening in the primary care setting, and consumer adop-
17 tion, usage, and outcomes related to hearing technology.
18 The Comptroller General shall update such report not
19 later than 2 years after the final regulations described in
20 subsection (b) are issued, and shall evaluate how imple-
21 mentation of such regulations has impacted hearing health
22 care, including recommendations for improving consumer
23 access to appropriate hearing health care.

1 **TITLE VIII—ADDITIONAL**
2 **PROVISIONS**

3 **SEC. 801. GAO REPORT.**

4 (a) IN GENERAL.—Not later than September 30,
5 2018, the Comptroller General of the United States shall
6 issue a report, after consultation with patients and drug
7 and medical device manufacturers, regarding the imple-
8 mentation of sections 569A and 569B of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8a,
10 360bbb–8b). Such report shall assess the progress the
11 Food and Drug Administration has made on—

12 (1) working with other regulatory authorities of
13 similar standing to foster and encourage uniform,
14 scientifically driven clinical trial standards with re-
15 spect to medical products around the world;

16 (2) providing consistent parallel scientific advice
17 to manufacturers seeking simultaneous global devel-
18 opment and approval of new medical products, in co-
19 ordination with regulatory authorities of similar
20 standing; and

21 (3) facilitating the use of foreign clinical trial
22 data to minimize duplicative clinical trials.

23 (b) ADDITIONAL REQUIREMENTS.—The report under
24 subsection (a) shall include specific examples, if possible
25 and available, and a list of activities at the Food and Drug

1 Administration regarding the harmonization of premarket
2 medical product requirements.

3 **SEC. 802. STREAMLINING AND IMPROVING CONSISTENCY**
4 **IN PERFORMANCE REPORTING.**

5 (a) PDUFA.—Section 736B(a) of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 379h–2(a)) is amend-
7 ed—

8 (1) in paragraph (1)(B)—

9 (A) in clause (vi), by inserting “and the
10 number of designations and denials issued by
11 the agency for such applications” before the
12 semicolon;

13 (B) in clause (vii), by striking “; and” and
14 inserting “and the number of designations and
15 denials issued by the agency for such applica-
16 tions;”; and

17 (C) in clause (viii) by striking the period
18 and inserting “and the number of designations
19 and denials issued by the agency for such appli-
20 cations;”; and

21 (2) by inserting after paragraph (2) the fol-
22 lowing:

23 “(3) REAL TIME REPORTING.—

24 “(A) IN GENERAL.—Beginning with fiscal
25 year 2018, every 30 calendar days, the Sec-

1 retary shall post the data described in subpara-
2 graph (B) on the Internet website of the Food
3 and Drug Administration and remove duplica-
4 tive data from the annual performance report.

5 “(B) DATA.—The following data is re-
6 quired to be posted in accordance with subpara-
7 graph (A):

8 “(i) The number and titles of draft
9 and final guidance issued by the Center for
10 Drug Evaluation and Research or the Cen-
11 ter for Biologics Evaluation and Research,
12 and the justification for the issuance and
13 finalization of each such guidance.

14 “(ii) The number and titles of public
15 meetings held by the Center for Drug
16 Evaluation and Research and the Center
17 for Biologics Evaluation and Research
18 each fiscal year.

19 “(iii) The list of standard new drug
20 applications and biologics license applica-
21 tions, by fiscal year of receipt.

22 “(iv) The number of filed applications
23 by each review division.

24 “(4) CAPACITY PLANNING AND IMPROVED TIME
25 REPORTING.—Beginning with fiscal year 2020, the

1 Secretary shall include in the annual report under
2 paragraph (1)—

3 “(A) the number of full-time equivalents
4 agreed upon in the letters described in section
5 101(b) of the Prescription Drug User Fee
6 Amendments of 2017 and the number of appro-
7 priated full time equivalents at the Food and
8 Drug Administration by each division within
9 the Center for Drug Evaluation and Research,
10 the Center for Biologics Evaluation and Re-
11 search, the Office of Regulatory Affairs, and
12 the Office of the Commissioner;

13 “(B) identification by name of all time re-
14 porting categories that Food and Drug Admin-
15 istration uses for capacity planning and time
16 reporting with respect to the Center for Drug
17 Evaluation and Research, the Center for Bio-
18 logics Evaluation and Research, the Office of
19 Regulatory Affairs, and the Office of the Com-
20 missioner, pursuant to the ‘resource capacity
21 planning and modernized time reporting imple-
22 mentation plan’ in the letters described in sec-
23 tion 101(b) of the Prescription Drug User Fee
24 Amendments of 2017;

1 “(C) the processes by which the Center for
2 Drug Evaluation and Research, the Center for
3 Biologics Evaluation and Research, the Office
4 of Regulatory Affairs, and the Office of the
5 Commissioner require reporting on the amount
6 of an employee’s time that is dedicated to the
7 review of human drug applications, as required
8 by the letters described in section 101(b) of the
9 Prescription Drug User Fee Amendments of
10 2017, including information regarding employ-
11 ees dedicated to such activities on a full-time
12 basis, and employees dedicated to such activities
13 on a part-time basis; and

14 “(D) for each of the Center for Drug Eval-
15 uation and Research, the Center for Biologics
16 Evaluation and Research, the Office of Regu-
17 latory Affairs, and the Office of the Commis-
18 sioner, the number of employees described in
19 subparagraph (C) (both full-time equivalents
20 and employees dedicated to such activities on a
21 part-time basis) for whom time reporting is re-
22 quired as described in subparagraph (C), and
23 the number of such employees required to esti-
24 mate time dedicated to the review of human
25 drug applications.”.

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

4 (1) by striking “Beginning with” and inserting
5 the following:

6 “(i) GENERAL REQUIREMENTS.—Be-
7 ginning with”; and

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

9 “(ii) ADDITIONAL INFORMATION.—
10 Beginning with fiscal year 2018, the an-
11 nual report under this subparagraph shall
12 include the progress of the Center for De-
13 vices and Radiological Health in achieving
14 the goals, and future plans for meeting the
15 goals, including, for each review division—

16 “(I) the number of premarket ap-
17 plications filed under section 515 per
18 fiscal year for each review division,
19 and the number of approvable letters,
20 major deficiency letters, not approv-
21 able letters, and denials for such ap-
22 plications;

23 “(II) the number of reports filed
24 under section 510(k) per fiscal year
25 for each review division and the num-

1 ber of devices cleared or not substan-
2 tially equivalent for such reports; and

3 “(III) the number of expedited
4 access pathway designations for a fis-
5 cal year for each review division and
6 the number of cleared or approved de-
7 vices or denials for such applications.

8 “(iii) REAL TIME REPORTING.—

9 “(I) IN GENERAL.—Beginning
10 with fiscal year 2018, the Secretary
11 shall, every 30 calendar days, post the
12 data described in subclause (II) on
13 the Internet website of the Food and
14 Drug Administration and remove du-
15 plicative data from the annual report
16 under this subparagraph.

17 “(II) DATA.—The following data
18 is required to be posted in accordance
19 with subclause (I):

20 “(aa) The number and titles
21 of draft and final guidance issued
22 by the Center for Devices and
23 Radiological Health and the jus-
24 tification for the issuance and fi-
25 nalization of such guidance.

1 “(bb) The number and titles
2 of public meetings held by the
3 Center for Devices and Radio-
4 logical Health each fiscal year.”.

5 (c) GDUFA.—Section 744C(a) of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 379j–43(a)) is amend-
7 ed—

8 (1) by striking “Beginning with” and inserting
9 the following:

10 “(1) GENERAL REQUIREMENTS.—Beginning
11 with”; and

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

13 “(2) ADDITIONAL INFORMATION.—Beginning
14 with fiscal year 2018, the report under this sub-
15 section shall include the progress of the Office of
16 Generic Drugs in achieving the goals, and future
17 plans for meeting the goals, including—

18 “(A) the number of original abbreviated
19 new drug applications filed per fiscal year;

20 “(B) the number of amendments to abbre-
21 viated new drug applications filed per fiscal
22 year; and

23 “(C) the number of actions taken delin-
24 eated by the type of action, including final ap-
25 provals, tentative approvals, complete response

1 letters, and the number of ‘refuse to receive’
2 letters issued by the Food and Drug Adminis-
3 tration per fiscal year.

4 “(3) REAL TIME REPORTING.—

5 “(A) IN GENERAL.—Beginning with fiscal
6 year 2018, the Secretary shall, every 30 cal-
7 endar days, post the data described in subpara-
8 graph (B) on the Internet website of the Food
9 and Drug Administration and remove duplica-
10 tive data from the annual report under this
11 subsection.

12 “(B) DATA.—The following data is re-
13 quired to be posted in accordance with subpara-
14 graph (A):

15 “(i) The number and titles of draft
16 and final guidance issued by the Office of
17 Generic Drugs and the justification for the
18 issuance and finalization of such guidance.

19 “(ii) The number and titles of public
20 meetings held by the Office of Generic
21 Drugs each fiscal year.”.

22 (d) BsUFA.—Section 744I(a) of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C. 379j–53(a)) is amend-
24 ed—

1 (1) by striking “Beginning with” and inserting
2 the following:

3 “(1) GENERAL REQUIREMENTS.—Beginning
4 with”; and

5 (2) by adding at the end the following:

6 “(2) ADDITIONAL INFORMATION.—Beginning
7 with fiscal year 2018, the report under this sub-
8 section shall include the progress of the Center for
9 Biologics Evaluation and Research in achieving the
10 goals, and future plans for meeting the goals, includ-
11 ing—

12 “(A) information on all previous cohorts
13 for which the Secretary has not given a com-
14 plete response on all biosimilar biological prod-
15 uct applications and supplements in the cohort;

16 “(B) the number of original biosimilar bio-
17 logical product applications filed per fiscal year,
18 and the number of approvals or complete re-
19 sponse letters issued by the agency for such ap-
20 plications; and

21 “(C) the number of resubmitted original
22 biosimilar biological product applications filed
23 per fiscal year and the number of approvals or
24 complete response letters issued by the agency
25 for such applications.

1 “(3) REAL TIME REPORTING.—

2 “(A) IN GENERAL.—Beginning with fiscal
3 year 2018, the Secretary shall, every 30 cal-
4 endar days, post the data described in subpara-
5 graph (B) on the Internet website of the Food
6 and Drug Administration and remove duplica-
7 tive data from the annual report under this
8 subsection.

9 “(B) DATA.—The following data is re-
10 quired to be posted in accordance with subpara-
11 graph (A):

12 “(i) The number and titles of draft
13 and final guidance issued by the Center for
14 Drug Evaluation and Research and the
15 Center for Biologics Evaluation and Re-
16 search and the justification for the
17 issuance and finalization of such guidance.

18 “(ii) The number and titles of public
19 meetings held by the Center for Drug
20 Evaluation and Research and the Center
21 for Biologic Evaluation and Research each
22 fiscal year.”.

23 “(4) CAPACITY PLANNING AND TIME REPORT-
24 ING.—Beginning with fiscal year 2020, the Sec-

1 retary shall include in the annual report under para-
2 graph (1)—

3 “(A) the number of full-time equivalents
4 agreed upon in the letters described in section
5 401(b) of the Biosimilar User Fee Amendments
6 of 2017 and the number of appropriated full
7 time equivalents at the Food and Drug Admin-
8 istration by each division within the Center for
9 Drug Evaluation and Research, the Center for
10 Biologics Evaluation and Research, the Office
11 of Regulatory Affairs, and the Office of the
12 Commissioner;

13 “(B) identification by name of all time re-
14 porting categories that the Food and Drug Ad-
15 ministration uses for capacity planning and
16 time reporting under the ‘resource capacity
17 planning and modernized time reporting imple-
18 mentation plan’ in the letters described in sec-
19 tion 401(b) of the Biosimilar User Fee Amend-
20 ments of 2017 for the Center for Drug Evalua-
21 tion and Research, the Center for Biologics
22 Evaluation and Research, the Office of Regu-
23 latory Affairs and the Office of the Commis-
24 sioner;

1 “(C) the process by which the Center for
2 Drug Evaluation and Research, the Center for
3 Biologics Evaluation and Research, the Office
4 of Regulatory Affairs, and the Office of the
5 Commissioner require reporting on the amount
6 of an employee’s time that is dedicated to the
7 review of biosimilar biological product applica-
8 tions, required pursuant to the letters described
9 in section 401(b) of the Biosimilar User Fee
10 Amendments of 2017, including information re-
11 garding both employees dedicated to such ac-
12 tivities on a full-time basis, and employees dedi-
13 cated to such activities on a part-time basis;
14 and

15 “(D) for each of the Center for Drug Eval-
16 uation and Research, the Center for Biologics
17 Evaluation and Research, the Office of Regu-
18 latory Affairs, and the Office of the Commis-
19 sioner, the actual number of employees de-
20 scribed in subparagraph (C) (both full-time
21 equivalents and employees dedicated to such ac-
22 tivities on a part-time basis) for whom time re-
23 porting is required as described in subpara-
24 graph (C), and the number of such employees
25 required to estimate time dedicated to the re-

1 view of biosimilar biological product applica-
2 tions.”.

3 **SEC. 803. ANALYSIS OF USE OF FUNDS.**

4 (a) PDUFA REPORTS.—

5 (1) ANALYSIS IN PDUFA PERFORMANCE RE-
6 PORTS.—Section 736B(a) of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 379h–2(a)), as
8 amended by section 802(a), is further amended by
9 adding at the end the following:

10 “(5) ANALYSIS.—For each fiscal year, the Sec-
11 retary shall include in the report under paragraph
12 (1) an analysis of the following:

13 “(A) The difference between the number of
14 human drug applications filed and the number
15 of approvals or complete response letters issued
16 by the agency, accounting for —

17 “(i) such applications filed during one
18 fiscal year for which a decision is not
19 scheduled to be made until the following
20 fiscal year;

21 “(ii) such applications pending with
22 the Center for Drug Evaluation and Re-
23 search and the Center for Biologics Eval-
24 uation and Research that did not meet the
25 goals identified in the letters described in

1 section 101(b) of the Prescription Drug
2 User Fee Amendments of 2017 for the cor-
3 responding fiscal year and the future plans
4 of the Food and Drug Administration to
5 meet these goals; and

6 “(iii) the most common causes within
7 the agency for missing such goals.

8 “(B) Relevant data to determine whether
9 the Center for Drug Evaluation and Research
10 and the Center for Biologics Evaluation and
11 Research have met performance enhancement
12 goals identified in the letters described in sec-
13 tion 101(b) of the Prescription Drug User Fee
14 Amendments of 2017 for the corresponding fis-
15 cal year.

16 “(C) External or other circumstances im-
17 pacting the Center for Drug Evaluation and
18 Research, the Center for Biologics Evaluation
19 and Research, or the Food and Drug Adminis-
20 tration, that impacted the ability of the agency
21 to meet the review time and performance en-
22 hancement goals identified in the letters de-
23 scribed in section 101(b) of the Prescription
24 Drug User Fee Amendments of 2017.”.

1 (2) ISSUANCE OF CORRECTIVE ACTION RE-
2 PORTS.—Section 736B of the Federal Food, Drug,
3 and Cosmetic Act (21 U.S.C. 379h–2) is amended—

4 (A) by redesignating subsections (e) and
5 (d) as subsections (e) and (f), respectively; and

6 (B) inserting after subsection (b) the fol-
7 lowing:

8 “(c) CORRECTIVE ACTION REPORT.—Beginning with
9 fiscal year 2018, and for each fiscal year for which fees
10 are collected under this part, the Secretary shall prepare
11 and submit a corrective action report to the Committee
12 on Energy and Commerce and the Committee on Appro-
13 priations of the House of Representatives and the Com-
14 mittee on Health, Education, Labor, and Pensions and the
15 Committee on Appropriations of the Senate upon submis-
16 sion of the performance report in subsection (a) for the
17 corresponding fiscal year. The report shall include the fol-
18 lowing information, as applicable:

19 “(1) GOALS MET.—For each fiscal year, if the
20 Secretary determines, based on the analysis under
21 subsection (a)(5), that each of the goals identified in
22 the letters described in section 101(b) of the Pre-
23 scription Drug User Fee Amendments of 2017 for
24 the corresponding fiscal year have been met, the cor-
25 rective action report shall include a summary of

1 goals met, and recommendations on ways in which
2 the Secretary can improve and streamline the
3 human drug application review process.

4 “(2) GOALS MISSED.—For each of the goals
5 identified in the letters described in section 101(b)
6 of the Prescription Drug User Fee Amendments of
7 2017 for the corresponding fiscal year that the Sec-
8 retary determines to not have been met, the correc-
9 tive action report shall include a detailed justifica-
10 tion for such determination and—

11 “(A) a detailed description of the cir-
12 cumstances under which each drug application
13 that missed the review goal time was approved
14 during the first cycle review, as applicable;

15 “(B) aggregate data on the circumstances
16 for all unapproved drug applications for which
17 the review goal time was missed; and

18 “(C) the performance enhancement goals
19 that were not achieved during the previous fis-
20 cal year and a detailed description of efforts the
21 agency has put in place for the current fiscal
22 year to improve the ability of the agency to
23 meet each such goal, while maintaining stand-
24 ards of approval, for the current fiscal year.

25 “(d) ENHANCED COMMUNICATION.—

1 “(1) COMMUNICATIONS WITH CONGRESS.—
2 Each fiscal year, as applicable, representatives from
3 the Center for Drug Evaluation and Research and
4 the Center for Biologics Evaluation and Research
5 shall meet with representatives from the Committee
6 on Health, Education, Labor, and Pensions of the
7 Senate and the Committee on Energy and Com-
8 merce of the House of Representatives to report on
9 the contents described in the reports under this sec-
10 tion.

11 “(2) PARTICIPATION IN CONGRESSIONAL HEAR-
12 ING.—Each fiscal year, as applicable, representatives
13 from the Center for Drug Evaluation and Research
14 and the Center for Biologics Evaluation and Re-
15 search shall participate in a public hearing before
16 the Committee on Health, Education, Labor, and
17 Pensions of the Senate and the Committee on En-
18 ergy and Commerce of the House of Representa-
19 tives, to report on the contents described in the re-
20 ports under this section. Such hearing shall occur
21 not later than 120 days after the end of each fiscal
22 year for which fees are collected under this part.

23 “(3) PUBLICLY AVAILABLE UPDATES.—The
24 Secretary shall provide an update on progress made
25 for the corrective action report during the following

1 fiscal year on the publically available Internet
2 website of the Food and Drug Administration every
3 30 business days.”.

4 (b) MDUFA REPORTS.—

5 (1) ANALYSIS IN MDUFA PERFORMANCE RE-
6 PORTS.—Section 738A(a)(1)(A) of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 379j-
8 1(a)(1)(A)), as amended by section 802(b), is fur-
9 ther amended by adding at the end the following:

10 “(iv) ANALYSIS.—For each fiscal
11 year, the Secretary shall include in the re-
12 port under clause (i) an analysis of the fol-
13 lowing:

14 “(I) The difference between the
15 number of premarket applications
16 filed under section 515 and applica-
17 tions filed under section 510(k) and
18 the number of major deficiency let-
19 ters, not approvable letters, and deni-
20 als for such applications issued by the
21 agency, accounting for—

22 “(aa) such applications filed
23 during one fiscal year for which a
24 decision is not scheduled to be

150

1 made until the following fiscal
2 year;

3 “(bb) such applications
4 pending with the Center for De-
5 vices and Radiological Health
6 that did not meet the goals as
7 identified by the letters described
8 in section 201(b) of the Medical
9 Device User Fee Amendments of
10 2017 for the corresponding fiscal
11 year and the future plans of the
12 Food and Drug Administration
13 to meet these goals; and

14 “(cc) the most common
15 causes within the agency for
16 missing such goals.

17 “(II) Relevant data to determine
18 whether the Center Devices and Radi-
19 ological Health have met performance
20 enhancement goals identified by the
21 letters described in section 201(b) of
22 the Medical Device User Fee Amend-
23 ments of 2017 for the corresponding
24 fiscal year.

1 “(III) External or other cir-
2 cumstances impacting the Center De-
3 vices and Radiological Health or the
4 Food and Drug Administration that
5 impacted the ability of the agency to
6 meet review time and performance en-
7 hancement goals identified by the let-
8 ters described in section 201(b) of the
9 Medical Device User Fee Amendments
10 of 2017.”.

11 (2) ISSUANCE OF CORRECTIVE ACTION RE-
12 PORTS.—Section 738A(a) of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 379j–1(a)) is
14 amended—

15 (A) by redesignating paragraphs (2) and
16 (3) as paragraphs (4) and (5), respectively; and

17 (B) by inserting after paragraph (1) the
18 following:

19 “(2) CORRECTIVE ACTION REPORT.—Beginning
20 with fiscal year 2018, and for each fiscal year for
21 which fees are collected under this part, the Sec-
22 retary shall prepare and submit a corrective action
23 report to the Committee on Energy and Commerce
24 and the Committee on Appropriations of the House
25 of Representatives and the Committee on Health,

1 Education, Labor, and Pensions and the Committee
2 on Appropriations of the Senate upon submission of
3 the performance report in paragraph (1)(A) for the
4 corresponding fiscal year. The report shall include
5 the following information, as applicable:

6 “(A) GOALS MET.—For each fiscal year, if
7 the Secretary determines, based on the analysis
8 under paragraph (1)(A)(iv), that each of the
9 goals identified by the letters described in sec-
10 tion 201(b) of the Medical Device User Fee
11 Amendments of 2017 for the corresponding fis-
12 cal year have been met, the corrective action re-
13 port shall include a summary of goals met, and
14 recommendations on ways in which the Sec-
15 retary can improve and streamline the medical
16 device application review process.

17 “(B) GOALS MISSED.—For each of the
18 goals identified by the letters described in sec-
19 tion 201(b) of the Medical Device User Fee
20 Amendments of 2017 for the corresponding fis-
21 cal year that the Secretary determines to not
22 have been met, the corrective action report shall
23 include a detailed justification for such deter-
24 mination and—

1 “(i) a detailed description of the cir-
2 cumstances under which each application
3 or report submitted under section 515 or
4 section 510(k) missed the review goal time
5 but was approved during the first cycle re-
6 view, as applicable;

7 “(ii) aggregate data on the cir-
8 cumstances for all unapproved medical de-
9 vice applications for which the review goal
10 time was missed; and

11 “(iii) the performance enhancement
12 goals that were not achieved during the
13 previous fiscal year and a detailed descrip-
14 tion of efforts the agency has put in place
15 for the current fiscal year to improve the
16 ability of the agency to meet each such
17 goal, while maintaining standards of ap-
18 proval, for the current fiscal year.

19 “(3) ENHANCED COMMUNICATION.—

20 “(A) COMMUNICATIONS WITH CON-
21 GRESS.—Each fiscal year, as applicable, rep-
22 resentatives from the Center for Devices and
23 Radiological Health shall meet with representa-
24 tives from the Committee on Health, Edu-
25 cation, Labor, and Pensions of the Senate and

1 the Committee on Energy and Commerce of the
2 House of Representatives to report on the con-
3 tents described in the reports under this sec-
4 tion.

5 “(B) PARTICIPATION IN CONGRESSIONAL
6 HEARING.—Each fiscal year, as applicable, rep-
7 resentatives from the Center for Devices and
8 Radiological Health shall participate in a public
9 hearing before the Committee on Health, Edu-
10 cation, Labor, and Pensions of the Senate and
11 the Committee on Energy and Commerce of the
12 House of Representatives, to report on the
13 contents described in the reports under this sec-
14 tion. Such hearing shall occur not later than
15 120 days after the end of each fiscal year for
16 which fees are collected under this part.

17 “(C) PUBLICLY AVAILABLE UPDATES.—
18 The Secretary shall provide an update on
19 progress made for the corrective action report
20 during the following fiscal year on the publically
21 available Internet website of the Food and
22 Drug Administration every 30 business days.”.

23 (c) GDUFA REPORTS.—

24 (1) ANALYSIS IN GDUFA PERFORMANCE RE-
25 PORTS.—Section 744C(a) of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 379j–43(a)), as
2 amended by section 802(c) is further amended by
3 adding at the end the following:

4 “(4) ANALYSIS.—For each fiscal year, the Sec-
5 retary shall include in the report an analysis of the
6 following:

7 “(A) The difference between the number of
8 abbreviated new drug applications filed and the
9 number of approvals or complete response let-
10 ters issued by the agency, accounting for —

11 “(i) such applications filed during one
12 fiscal year for which a decision is not
13 scheduled to be made until the following
14 fiscal year;

15 “(ii) such applications pending with
16 the Office of Generic Drugs that did not
17 meet the goals identified by the letters de-
18 scribed in section 301(b) of the Generic
19 Drug User Fee Amendments of 2017 for
20 the corresponding fiscal year and the fu-
21 ture plans of the Food and Drug Adminis-
22 tration to meet these goals; and

23 “(iii) the most common causes within
24 the agency for missing such goals.

1 “(B) Relevant data to determine whether
2 the Office of Generic Drugs has met the per-
3 formance enhancement goals identified by the
4 letters described in section 301(b) of the Ge-
5 neric Drug User Fee Amendments of 2017 for
6 the corresponding fiscal year.

7 “(C) External or other circumstances im-
8 pacting the Office of Generic Drugs or the
9 Food and Drug Administration that impacted
10 the ability of the agency to meet review time
11 and performance enhancement goals identified
12 by the letters described in section 301(b) of the
13 Generic Drug User Fee Amendments of 2017.”.

14 (2) ISSUANCE OF CORRECTIVE ACTION RE-
15 PORTS.—Section 744C of the Federal Food, Drug,
16 and Cosmetic Act (21 U.S.C. 379j–43) is amend-
17 ed—

18 (A) by redesignating subsections (c) and
19 (d) as subsections (e) and (f), respectively; and

20 (B) inserting after subsection (b) the fol-
21 lowing:

22 “(c) CORRECTIVE ACTION REPORT.—Beginning with
23 fiscal year 2018, and for each fiscal year for which fees
24 are collected under this part, the Secretary shall prepare
25 and submit a corrective action report to the Committee

1 on Energy and Commerce and the Committee on Appro-
2 priations of the House of Representatives and the Com-
3 mittee on Health, Education, Labor, and Pensions and the
4 Committee on Appropriations of the Senate upon submis-
5 sion of the performance report in subsection (a) for the
6 corresponding fiscal year. The report shall include the fol-
7 lowing information, as applicable:

8 “(1) GOALS MET.—For each fiscal year, if the
9 Secretary determines, based on the analysis under
10 subsection (a)(4), that each of the goals identified by
11 the letters described in section 301(b) of the Generic
12 Drug User Fee Amendments of 2017 for the cor-
13 responding fiscal year have been met, the corrective
14 action report shall include a summary of goals met,
15 and recommendations on ways in which the Sec-
16 retary can improve and streamline the abbreviated
17 new drug application review process.

18 “(2) GOALS MISSED.—For each of the goals
19 identified by the letters described in section 301(b)
20 of the Generic Drug User Fee Amendments of 2017
21 for the corresponding fiscal year that the Secretary
22 determines to not have been met, the corrective ac-
23 tion report shall include a detailed justification for
24 such determination and—

1 “(A) a detailed description of the cir-
2 cumstances under which each abbreviated new
3 drug application missed the review goal time
4 but was approved during the first cycle review,
5 as applicable;

6 “(B) aggregate data on the circumstances
7 for all unapproved abbreviated new drug appli-
8 cations for which the review goal time was
9 missed; and

10 “(C) the performance enhancement goals
11 that were not achieved during the previous fis-
12 cal year and a detailed description of efforts the
13 agency has put in place for the current fiscal
14 year to improve the ability of the agency to
15 meet each such goal for the current fiscal year.

16 “(d) ENHANCED COMMUNICATION.—

17 “(1) COMMUNICATIONS WITH CONGRESS.—
18 Each fiscal year, as applicable, representatives from
19 the Office of Generic Drugs shall meet with rep-
20 resentatives from the Committee on Health, Edu-
21 cation, Labor, and Pensions of the Senate and the
22 Committee on Energy and Commerce of the House
23 of Representatives to report on the contents de-
24 scribed in the reports under this section.

1 “(2) PARTICIPATION IN CONGRESSIONAL HEAR-
2 ING.—Each fiscal year, as applicable, representatives
3 from the Center for Drug Evaluation and Research
4 shall participate in a public hearing before the Com-
5 mittee on Health, Education, Labor, and Pensions
6 of the Senate and the Committee on Energy and
7 Commerce of the House of Representatives, to re-
8 port on the contents described in the reports under
9 this section. Such hearing shall occur not later than
10 120 days after the end of each fiscal year for which
11 fees are collected under this part.

12 “(3) PUBLICLY AVAILABLE UPDATES.—The
13 Secretary shall provide an update on progress made
14 for the corrective action report during the following
15 fiscal year on the publically available Internet
16 website of the Food and Drug Administration every
17 30 business days.”.

18 (d) BSUFA REPORTS.—

19 (1) ANALYSIS IN BSUFA PERFORMANCE RE-
20 PORTS.—Section 744I(a) of the Federal Food, Drug,
21 and Cosmetic Act (21 U.S.C. 379j–53(a)) as amend-
22 ed by section 802(d) is further amended by adding
23 at the end the following:

1 “(5) ANALYSIS.—For each fiscal year, the Sec-
2 retary shall include in the report an analysis of the
3 following:

4 “(A) The difference between the number of
5 biosimilar biological product applications and
6 supplements filed and the number of approvals
7 or complete response letters issued by the agen-
8 cy, accounting for—

9 “(i) such applications filed during one
10 fiscal year for which a decision is not
11 scheduled to be made until the following
12 fiscal year;

13 “(ii) such applications pending with
14 the Center for Drug Evaluation and Re-
15 search or the Center for Biologics Evalua-
16 tion and Research that did not meet the
17 goals identified by the letters described in
18 section 401(b) of the Biosimilar User Fee
19 Amendments of 2017 for the cor-
20 responding fiscal year and the future plans
21 of the Food and Drug Administration to
22 meet these goals; and

23 “(iii) the most common causes within
24 the agency for missing such goals.

1 “(B) Relevant data to determine whether
2 the Center for Drug Evaluation and Research
3 and the Center for Biologics Evaluation and
4 Research have met the performance enhance-
5 ment goals identified by the letters described in
6 section 401(b) of the Biosimilar User Fee
7 Amendments of 2017 for the corresponding fis-
8 cal year.

9 “(C) External or other circumstances im-
10 pacting the Center for Drug Evaluation and
11 Research, the Center for Biologics Evaluation
12 and Research, and the Food and Drug Admin-
13 istration that impacted the ability of the agency
14 to meet review time and performance enhance-
15 ment goals identified by the letters described in
16 section 401(b) of the Biosimilar User Fee
17 Amendments of 2017.”.

18 (2) ISSUANCE OF CORRECTIVE ACTION RE-
19 PORTS.—Section 744I of the Federal Food, Drug,
20 and Cosmetic Act (21 U.S.C. 379j–53) is amend-
21 ed—

22 (A) by redesignating subsections (c), (d),
23 and (e) as subsections (e), (f), and (g), respec-
24 tively; and

1 (B) inserting after subsection (b) the fol-
2 lowing:

3 “(c) CORRECTIVE ACTION REPORT.—Beginning with
4 fiscal year 2018, and for each fiscal year for which fees
5 are collected under this part, the Secretary shall prepare
6 and submit a corrective action report to the Committee
7 on Energy and Commerce and Committee on Appropria-
8 tions of the House of Representatives and the Committee
9 on Health, Education, Labor, and Pensions and Com-
10 mittee on Appropriations of the Senate upon submission
11 of the performance report in subsection (a) for the cor-
12 responding fiscal year. The report shall include the fol-
13 lowing information, as applicable:

14 “(1) GOALS MET.—For each fiscal year, if the
15 Secretary determines, based on the analysis under
16 subsection (a)(5), that each of the goals identified by
17 the letters described in section 401(b) of the Bio-
18 similar User Fee Amendments of 2017 for the cor-
19 responding fiscal year have been met, the corrective
20 action report shall include a summary of goals met,
21 and recommendations on ways in which the Sec-
22 retary can improve and streamline the biosimilar bi-
23 ological product application review process.

24 “(2) GOALS MISSED.—For each of the goals
25 identified by the letters described in section 401(b)

1 of the Biosimilar User Fee Amendments of 2017 for
2 the corresponding fiscal year that the Secretary de-
3 termines to not have been met, the corrective action
4 report shall include a detailed justification for such
5 determination and—

6 “(A) a detailed description of the cir-
7 cumstances under which each biosimilar biologi-
8 cal product application missed the review goal
9 time but was approved during the first cycle re-
10 view, as applicable;

11 “(B) aggregate data on the circumstances
12 for all biosimilar biological product applications
13 for which the review goal time was missed; and

14 “(C) the performance enhancement goals
15 that were not achieved during the previous fis-
16 cal year and a detailed description of efforts the
17 agency has put in place for the current fiscal
18 year to improve the ability of the agency to
19 meet each such goal for the current fiscal year.

20 “(d) ENHANCED COMMUNICATION.—

21 “(1) COMMUNICATIONS WITH CONGRESS.—

22 Each fiscal year, as applicable, representatives from
23 the Center for Drug Evaluation and Research and
24 the Center for Biologics Evaluation and Research
25 shall meet with representatives from the Committee

1 on Health, Education, Labor, and Pensions of the
2 Senate and the Committee on Energy and Com-
3 merce of the House of Representatives to report on
4 the contents described in the reports under this sec-
5 tion.

6 “(2) PARTICIPATION IN CONGRESSIONAL HEAR-
7 ING.—Each fiscal year, as applicable, representatives
8 from the Center for Drug Evaluation and Research
9 and the Center for Biologics Evaluation and Re-
10 search shall participate in a public hearing before
11 the Committee on Health, Education, Labor, and
12 Pensions of the Senate and the Committee on En-
13 ergy and Commerce of the House of Representa-
14 tives, to report on the contents described in the re-
15 ports under this section. Such hearing shall occur
16 not later than 120 days after the end of each fiscal
17 year for which fees are collected under this part.

18 “(3) PUBLICLY AVAILABLE UPDATES.—The
19 Secretary shall provide an update on progress made
20 for the corrective action report during the following
21 fiscal year on the publically available Internet
22 website of the Food and Drug Administration every
23 30 business days.”.

1 **SEC. 804. INFORMATION ON TECHNOLOGY CONTRACTING.**

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

4 (1) by striking “report on the” and inserting
5 “report on—

6 “(1) the”;

7 (2) by striking the period at the end and insert-
8 ing “; and”;

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

10 “(2) the amount of the fees collected that are
11 invested in the information technology infrastructure
12 of the Food and Drug Administration, the entities
13 receiving contracts to develop such infrastructure,
14 the length of such contracts (including renewals),
15 and the progress such entities have made toward
16 meeting the goals described in such contracts.”.

17 **SEC. 805. FACILITIES MANAGEMENT.**

18 (a) EVALUATION.—

19 (1) STUDY.—The Comptroller General of the
20 United States shall conduct a study on the expenses
21 incurred by the Food and Drug Administration re-
22 lated to facility maintenance and renovation in fiscal
23 years 2012 through 2019. The study shall include
24 the following:

25 (A) A review of purchases and expenses
26 differentiated by appropriated funds, and re-

1 sources authorized by the Food and Drug Ad-
2 ministration Safety and Innovation Act (Public
3 Law 112–144) and this Act, as applicable, that
4 contributed to—

5 (i) the maintenance of scientific equip-
6 ment and any existing facility plan or
7 plans to maintain previously purchased sci-
8 entific equipment;

9 (ii) the renovation of facilities in the
10 Center for Drug Evaluation and Research,
11 the Center for Biologics Evaluation and
12 Research, and the Center for Devices and
13 Radiological Health, and the purpose of
14 such renovation including the need for the
15 renovation; and

16 (iii) the assets purchased or repaired
17 under the “repair of facilities and acquisi-
18 tion” authority under parts 2, 3, 7, and 8
19 of subchapter C of chapter VII of the Fed-
20 eral Food, Drug, and Cosmetic Act (21
21 U.S.C. 379f et seq.);

22 (iv) the maintenance and repair of fa-
23 cilities and fixtures, including a description
24 of any unanticipated repairs and mainte-
25 nance as well as scheduled repairs mainte-

1 nance, and the budget plan for the sched-
2 uled or anticipated maintenance;

3 (v) the acquisition of furniture, a de-
4 scription of the furniture purchased, and
5 the purpose of the furniture including pur-
6 chases for the Center for Drug Evaluation
7 and Research, the Center for Biologics
8 Evaluation and Research, and the Center
9 for Devices and Radiological Health;

10 (vi) the acquisition of other necessary
11 materials and supplies by product category
12 under the authority under parts 2, 3, 7,
13 and 8 of subchapter C of chapter VII of
14 the Federal Food, Drug, and Cosmetic Act
15 (21 U.S.C. 379f et seq.).

16 (B) An analysis of the Food and Drug Ad-
17 ministration's ability to further its public health
18 mission and review medical products by incur-
19 ring the expenses listed in clauses (i) through
20 (vi) of subparagraph (A). In conducting the
21 analysis, the Comptroller General shall request
22 information from and consult with appropriate
23 employees, including staff and those responsible
24 for the fiscal decisions regarding facility main-
25 tenance and renovation for the agency.

1 (C) RECOMMENDATIONS.—The Comp-
2 troller General may provide recommendations,
3 as applicable, on methods through which the
4 Food and Drug Administration may improve
5 planning for—

6 (i) the maintenance, renovation, and
7 repair of facilities;

8 (ii) the purchase of furniture or other
9 acquisitions; and

10 (iii) ways the agency may allocate the
11 expenses described in clauses (i) and (ii),
12 as informed by the analysis under subpara-
13 graph (B).

14 (2) REPORT.—The Comptroller General shall
15 issue a report to the Committee on Health, Edu-
16 cation, Labor, and Pensions of the Senate and the
17 Committee on Energy and Commerce of the House
18 of Representatives not later than September 30,
19 2020, containing the results of the study under
20 paragraph (1).

21 (b) ADMINISTRATION.—

22 (1) PDUFA.—Section 736(f) of the Federal
23 Food, Drug, and Cosmetic Act (21 U.S.C. 379h(f))
24 is amended by adding at the end the following:

1 “(3) LIMITATION.—Beginning on October 1,
2 2023, the authorities under section 735(7)(C) shall
3 only include expenditures for leasing and necessary
4 scientific equipment.”.

5 (2) MDUFA.—Section 738(h) of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 379j(h))
7 is amended by adding at the end the following:

8 “(3) LIMITATION.—Beginning on October 1,
9 2023, the authorities under section 737(9)(C) shall
10 only include leasing and necessary scientific equip-
11 ment.”.

12 (3) GDUFA.—Section 744B(e) of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 379j-
14 42(e)) is amended—

15 (A) in the subsection heading, by striking
16 “LIMIT” and inserting “LIMITATIONS”;

17 (B) by striking “The total amount” and
18 inserting the following:

19 “(1) IN GENERAL.—The total amount”; and

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

21 “(2) LEASING AND NECESSARY EQUIPMENT.—
22 Beginning on October 1, 2023, the authorities under
23 section 744A(11)(C) shall only include leasing and
24 necessary scientific equipment.”.

1 (4) BSUFA.—Section 744H(e)(2)(B) of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 379j–52(e)(2)(B)) is amended—

4 (A) in the subparagraph heading, by strik-
5 ing “LIMITATION” and inserting “LIMITA-
6 TIONS”;

7 (B) by striking “The fees authorized” and
8 inserting the following:

9 “(i) IN GENERAL.—The fees author-
10 ized”; and

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

12 “(ii) LEASING AND NECESSARY
13 EQUIPMENT.—Beginning on October 1,
14 2023, the authorities under Section
15 744G(9)(C) shall only include leasing and
16 necessary scientific equipment.”.

17 **SEC. 806. TECHNICAL CORRECTIONS.**

18 (a) CROSS-REFERENCE.—Section 3075(a) of the 21st
19 Century Cures Act (Public Law 111–255) is amended—

20 (1) in the matter preceding paragraph (1), by
21 striking “as amended by section 2074” and inserting
22 “as amended by section 3102”; and

23 (2) in paragraph (2), by striking “section
24 2074(1)(C)” and inserting “section 3102(1)(C)”.

1 (b) 506G.—Section 506G(b)(1)(A) of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C. 356g(b)(1)(A))
3 is amended by striking “identity” and inserting “iden-
4 tify”.