

AMENDMENT NO. \_\_\_\_\_ Calendar No. \_\_\_\_\_

Purpose: In the nature of a substitute.

**IN THE SENATE OF THE UNITED STATES—115th Cong., 2d Sess.**

**S. 2315**

To amend the Federal Food, Drug, and Cosmetic Act to clarify the regulatory framework with respect to certain nonprescription drugs that are marketed without an approved new drug application, 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; TABLE OF CONTENTS.**

4 (a) **SHORT TITLE.**—This Act may be cited as the  
5 “Over-the-Counter Drug Safety, Innovation, and Reform  
6 Act”.

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

Sec. 1. Short title; table of contents.

**TITLE I—REGULATION OF NONPRESCRIPTION DRUGS**

Sec. 101. Regulation of certain nonprescription drugs that are marketed without an approved new drug application.

Sec. 102. Misbranding.

Sec. 103. Conforming amendments to the Sunscreen Innovation Act.

Sec. 104. Drugs excluded from over-the-counter review.

Sec. 105. Conforming amendment.

Sec. 106. Annual update to Congress on appropriate pediatric indication for certain cough and cold monograph drugs.

## TITLE II—FEES RELATING TO MONOGRAPH DRUGS

Sec. 201. Short title; findings.

Sec. 202. Authority to access and use fees.

# 1           **TITLE I—REGULATION OF** 2           **NONPRESCRIPTION DRUGS**

## 3   **SEC. 101. REGULATION OF CERTAIN NONPRESCRIPTION** 4                   **DRUGS THAT ARE MARKETED WITHOUT AN** 5                   **APPROVED NEW DRUG APPLICATION.**

6           Chapter V of the Federal Food, Drug, and Cosmetic  
7 Act is amended by inserting after section 505F (21 U.S.C.  
8 355g) the following:

## 9   **“SEC. 505G. REGULATION OF CERTAIN NONPRESCRIPTION** 10                   **DRUGS THAT ARE MARKETED WITHOUT AN** 11                   **APPROVED NEW DRUG APPLICATION.**

12           “(a) DEFINITIONS.—In this section:

13                   “(1) NONPRESCRIPTION DRUG.—The term  
14           ‘nonprescription drug’ means a drug that is not sub-  
15           ject to section 503(b)(1).

16                   “(2) REQUESTOR.—The term ‘requestor’ means  
17           a person or group of persons marketing, manufac-  
18           turing, processing, or developing a drug.

19                   “(3) SPONSOR.—The term ‘sponsor’ means a  
20           person or group of persons marketing, manufac-

1       turing, or processing a drug and who has a listing  
2       in effect under section 510(j) for such drug.

3       “(b) TREATMENT OF MONOGRAPH DRUGS MAR-  
4       KETED WITHOUT AN APPROVED APPLICATION.—

5               “(1) IN GENERAL.—A nonprescription drug  
6       that is marketed without an approved application  
7       under section 505 shall be treated in accordance  
8       with this subsection beginning on the date of enact-  
9       ment of the Over-the-Counter Drug Safety, Innova-  
10      tion, and Reform Act:

11               “(A) A nonprescription drug is deemed to  
12       be generally recognized as safe and effective  
13       within the meaning of section 201(p)(1) and  
14       not a new drug under section 201(p) if such  
15       drug is—

16               “(i)(I)(aa) subject to a final mono-  
17       graph issued under part 330 of title 21,  
18       Code of Federal Regulations, as of the  
19       date of enactment of the Over-the-Counter  
20       Drug Safety, Innovation, and Reform Act;

21               “(bb) in conformity with the require-  
22       ments for nonprescription use of such  
23       monograph, the general requirements spec-  
24       ified for nonprescription drugs, and the re-

1            requirements under subsections (c), (d), and  
2            (j); and

3            “(cc) except as permitted by an ad-  
4            ministrative order issued under subsection  
5            (c) or a minor change in the drug in con-  
6            formity with subsection (d), is in a dosage  
7            form that, on day before the date of enact-  
8            ment of the Over-the-Counter Drug Safety,  
9            Innovation, and Reform Act, has been used  
10           to a material extent and for a material  
11           time within the meaning of section  
12           201(p)(2);

13           “(II)(aa) the subject of a tentative  
14           final monograph that is the most recently  
15           applicable proposal or determination issued  
16           under part 330 of title 21, Code of Federal  
17           Regulations, on the day before the date of  
18           enactment of the Over-the-Counter Drug  
19           Safety, Innovation, and Reform Act;

20           “(bb) classified in category I for safe-  
21           ty and effectiveness under such tentative  
22           final monograph;

23           “(cc) in conformity with the require-  
24           ments for nonprescription use of such ten-  
25           tative final monograph, any subsequent de-

1 termination by the Secretary, the general  
2 requirements for nonprescription drugs,  
3 and the requirements under subsections  
4 (c), (d), and (j); and

5 “(dd) except as permitted by an ad-  
6 ministrative order issued under subsection  
7 (c) or a minor change in the drug in con-  
8 formity with subsection (d), is in a dosage  
9 form that has been used to a material ex-  
10 tent and for a material time within the  
11 meaning of section 201(p)(2); or

12 “(III) in conformity with—

13 “(aa) the requirements of a final  
14 administrative order issued under sub-  
15 section (c) determining that such drug  
16 is generally recognized as safe and ef-  
17 fective within the meaning of section  
18 201(p)(1); and

19 “(bb) the general requirements  
20 for nonprescription drugs and the re-  
21 quirements under subsections (c), (d),  
22 and (j);

23 “(ii) not classified in Category II for  
24 safety or effectiveness under a tentative  
25 final monograph; and

1 “(iii) not determined by the Secretary  
2 to be not generally recognized as safe and  
3 effective, in a final monograph or preamble  
4 to a rule that is the most recently applica-  
5 ble proposal or determination issued under  
6 part 330 of title 21, Code of Federal Regu-  
7 lations.

8 “(B) A nonprescription drug for which  
9 there is not an approved application under sec-  
10 tion 505 may be introduced into interstate com-  
11 merce if such drug is—

12 “(i)(I) not classified in Category II  
13 for safety or effectiveness under a tentative  
14 final monograph; or

15 “(II) not determined by the Secretary  
16 to be not generally recognized as safe and  
17 effective, in a final monograph or preamble  
18 to a rule that is the most recently applica-  
19 ble proposal or determination issued under  
20 part 330 of title 21, Code of Federal Regu-  
21 lations; and

22 “(ii)(I)(aa) the subject of a tentative  
23 final monograph that is the most recently  
24 applicable proposal or determination issued

1 under part 330 of title 21, Code of Federal  
2 Regulations;

3 “(bb) classified in category III for  
4 safety or effectiveness in the preamble of a  
5 proposed rule establishing such tentative  
6 final monograph;

7 “(cc) in conformity with the most re-  
8 cently proposed or final rule establishing or  
9 proposing conditions of nonprescription use  
10 published in the Federal Register related  
11 to such tentative final monograph, the gen-  
12 eral requirements for nonprescription  
13 drugs, and the requirements under sub-  
14 sections (c) and (j); and

15 “(dd) in a dosage form that, as of the  
16 day before the date of enactment of the  
17 Over-the-Counter Drug Safety, Innovation,  
18 and Reform Act, has been used to a mate-  
19 rial extent and for a material time within  
20 the meaning of section 201(p)(2); or

21 “(II)(aa) the subject of a proposed  
22 monograph or advance notice of proposed  
23 rulemaking that is the most recently appli-  
24 cable proposal or determination issued

1 under part 330 of title 21, Code of Federal  
2 Regulations;

3 “(bb) classified in category I for safe-  
4 ty and effectiveness under such proposed  
5 monograph or advance notice of proposed  
6 rulemaking;

7 “(cc) in conformity with the most re-  
8 cently proposed or final rule establishing or  
9 proposing conditions of nonprescription use  
10 published in the Federal Register related  
11 to such proposed monograph or advance  
12 notice of proposed rulemaking, the general  
13 requirements for nonprescription drugs,  
14 and the requirements under subsections (c)  
15 and (j); and

16 “(dd) in a dosage form that, as of the  
17 day before the date of enactment of the  
18 Over-the-Counter Drug Safety, Innovation,  
19 and Reform Act has been used to a mate-  
20 rial extent and for a material time within  
21 the meaning of section 201(p)(2).

22 “(C)(i) Subject to clause (iii), beginning on  
23 the date that is 180 calendar days after the  
24 date of enactment of the Over-the-Counter  
25 Drug Safety, Innovation, and Reform Act, a



1 nonprescription drug is deemed to be not gen-  
2 erally recognized as safe and effective within  
3 the meaning of section 201(p)(1), a new drug  
4 under section 201(p), and misbranded under  
5 section 502(ee), if such drug—

6 “(I) is classified in category II for  
7 safety or effectiveness under a tentative  
8 final monograph; or

9 “(II) is subject to a determination to  
10 be not generally recognized as safe and ef-  
11 fective under a proposed rule that is the  
12 most recently applicable proposal issued  
13 under part 330 of title 21, Code of Federal  
14 Regulations.

15 “(ii) A nonprescription drug that the Sec-  
16 retary has determined to be not generally recog-  
17 nized as safe and effective under a final deter-  
18 mination issued under part 330 of title 21,  
19 Code of Federal Regulations is deemed to be  
20 not generally recognized as safe and effective  
21 within the meaning of section 201(p)(1), a new  
22 drug under section 201(p), and misbranded  
23 under section 502(ee).

24 “(iii) A 180-day period described in clause  
25 (i) may be extended with respect to a drug by

1 the Secretary if the Secretary determines that  
2 such extension is in the interest of the public  
3 health.

4 “(D) A drug that is subject to the final  
5 monograph for sunscreen drug products set  
6 forth at part 352 of title 21, Code of Federal  
7 Regulations (as published at volume 64 page  
8 27687 of the Federal Register), shall comply  
9 with the requirements of that monograph, ex-  
10 cept that the testing requirements for effective-  
11 ness and the provisions governing labeling shall  
12 be in accordance with section 201.327 of title  
13 21, Code of Federal Regulations (as in effect on  
14 the date of enactment of the Over-the-Counter  
15 Drug Safety, Innovation, and Reform Act), or  
16 such changes to those requirements as may be  
17 made under subsections (c), (d), and (j).

18 “(2) NEW DRUGS.—A nonprescription drug is a  
19 new drug within the meaning of section 201(p) and  
20 subject to the requirements of section 505 if the  
21 drug is—

22 “(A) not described in subparagraph (A),  
23 (B), (C), or (D) of paragraph (1) and not in  
24 conformity with subsection (d), as applicable; or

1 “(B) not a nonprescription sunscreen ac-  
2 tive ingredient or combination of ingredients  
3 subject to a final sunscreen order, as defined in  
4 section 586(2).

5 “(3) MONOGRAPH DRUG.—In this section, the  
6 term ‘monograph drug’ has the meaning given such  
7 term in section 744L.

8 “(4) RULES OF CONSTRUCTION.—

9 “(A) IN GENERAL.—This section shall not  
10 affect the treatment or status of a nonprescrip-  
11 tion drug subject to section 505—

12 “(i) that, on the date of enactment of  
13 the Over-the-Counter Drug Safety, Innova-  
14 tion, and Reform Act, is marketed without  
15 an application approved under section 505;  
16 and

17 “(ii) to which subparagraphs (A), (B),  
18 (C), and (D) of paragraph (1) do not  
19 apply.

20 “(B) APPLICABILITY OF OTHER PROVI-  
21 SIONS.—Nothing in this paragraph shall be  
22 construed to preclude or limit the applicability  
23 of any other provision of this Act.

24 “(C) NO EFFECT ON OTHER AUTHORI-  
25 TIES.—Nothing in this subsection shall be con-

1           strued to prohibit the Secretary from issuing an  
2           order under this section finding a drug to be  
3           not generally recognized as safe and effective.

4           “(c) ADMINISTRATIVE ORDERS.—

5           “(1) IN GENERAL.—

6                   “(A) GENERALLY RECOGNIZED AS SAFE  
7           AND EFFECTIVE.—The Secretary may, on the  
8           initiative of the Secretary or at the request of  
9           one or more requestors, issue an administrative  
10          order determining whether there are require-  
11          ments under which a specific drug, class of  
12          such drugs, or combination of such drugs is de-  
13          termined to be—

14                   “(i) not subject to section 503(b)(1);

15                   “(ii) generally recognized as safe and  
16           effective within the meaning of section  
17           201(p)(1); and

18                   “(iii) not required to be approved  
19           under section 505.

20                   “(B) NOT GENERALLY RECOGNIZED AS  
21           SAFE AND EFFECTIVE.—The Secretary shall  
22           issue an order determining that a drug is not  
23           generally recognized as safe and effective within  
24           the meaning of section 201(p)(1) for the speci-

1           fied requirements if the Secretary determines  
2           that—

3                   “(i) the evidence shows that the drug  
4                   is not generally recognized as safe and ef-  
5                   fective within the meaning of section  
6                   201(p)(1); or

7                   “(ii) the evidence is inadequate to  
8                   show that the drug is generally recognized  
9                   as safe and effective within the meaning of  
10                  section 201(p)(1).

11           “(2) ADMINISTRATIVE ORDERS INITIATED BY  
12           THE SECRETARY; CITIZEN PETITIONS.—

13                   “(A) IN GENERAL.—Except as provided in  
14                   paragraph (5), in issuing an administrative  
15                   order under paragraph (1) on the initiative of  
16                   the Secretary, the Secretary shall—

17                   “(i) not later than 2 business days be-  
18                   fore issuance of the proposed order, infor-  
19                   mally communicate the pending issuance of  
20                   the order to sponsors of drugs that have a  
21                   listing in effect under section 510(j) for  
22                   drugs will be subject to such order;

23                   “(ii) after making any such informal  
24                   communication—

1 “(I) issue such a proposed ad-  
2 ministrative order by publishing it on  
3 the internet website of the Food and  
4 Drug Administration and include in  
5 such order the reasons for the  
6 issuance of such order; and

7 “(II) publish notice of availability  
8 of such proposed order in the Federal  
9 Register;

10 “(iii) except as provided in subpara-  
11 graph (B), provide for a public comment  
12 period with respect to such proposed order  
13 of not less than 45 calendar days; and

14 “(iv) if, after satisfying the require-  
15 ments of clauses (i) through (iii), the Sec-  
16 retary determines that it is appropriate to  
17 issue a final administrative order—

18 “(I) issue the final administrative  
19 order, together with a detailed state-  
20 ment of reasons, but such order shall  
21 not take effect until the time for re-  
22 questing judicial review under para-  
23 graph (4)(D)(ii) has expired;

1 “(II) publish a notice of avail-  
2 ability of such final administrative  
3 order in the Federal Register;

4 “(III) afford requestors of prod-  
5 ucts that will be subject to such order  
6 the opportunity for formal dispute  
7 resolution up to the level of the Direc-  
8 tor of the Center for Drug Evaluation  
9 and Research, which initially shall be  
10 requested within 45 calendar days of  
11 the issuance of the order, and, for  
12 subsequent levels of appeal, within 30  
13 calendar days of the prior decision;  
14 and

15 “(IV) except with respect to  
16 drugs described in paragraph (3)(B),  
17 upon completion of the formal dispute  
18 resolution procedure, inform the per-  
19 son or persons which sought such dis-  
20 pute resolution of their right to re-  
21 quest a hearing.

22 “(B) SPECIAL REQUIREMENTS WITH RE-  
23 SPECT TO CERTAIN MONOGRAPH DRUGS.—  
24 When issuing an administrative order under  
25 paragraph (1) on the initiative of the Secretary

(except as provided under paragraph (4)) proposing to determine that a monograph drug described in subsection (b)(1)(B) is not generally recognized as safe and effective within the meaning of section 201(p)(1), the Secretary shall follow the procedures in subparagraph (A) except that—

“(i) the proposed order shall include notice of—

“(I) the general categories of data the Secretary has determined necessary to establish that the drug is generally recognized as safe and effective within the meaning of section 201(p)(1); and

“(II) the format for submissions by interested persons;

“(ii) the Secretary shall provide for a public comment period of not less than 180 calendar days with respect to such proposed order, except when the Secretary determines, for good cause, that a shorter period is in the interest of public health; and

“(iii) any person who submits data in such comment period shall include a cer-



1           tification that the person has submitted all  
2           evidence created, obtained, or received by  
3           that person that is both within the cat-  
4           egories of data identified in the proposed  
5           order and relevant to a determination as to  
6           whether the drug is generally recognized as  
7           safe and effective within the meaning of  
8           section 201(p)(1).

9           “(C) CITIZEN PETITIONS.—

10                 “(i) IN GENERAL.—The Secretary  
11           may issue an administrative order under  
12           paragraph (1) in response to a citizen peti-  
13           tion submitted under section 10.30 of title  
14           21, Code of Federal Regulations (or any  
15           successor regulation), subject to clause (ii).

16                 “(ii) EFFECT OF PETITION.—Nothing  
17           in clause (i) shall be construed to provide  
18           an alternative to, or otherwise supplant or  
19           supersede—

20                         “(I) the processes through which  
21           a requestor may seek an administra-  
22           tive order pursuant to paragraph (5);  
23           or

24                         “(II) the fee structure under sec-  
25           tion 744L–1(a)(2).

1 “(3) HEARINGS; JUDICIAL REVIEW.—

2 “(A) IN GENERAL.—A person who partici-  
3 pated in each level of formal dispute resolution  
4 under paragraph (2)(A)(iv)(III) of an adminis-  
5 trative order with respect to a drug may re-  
6 quest a hearing concerning a final administra-  
7 tive order issued under paragraph (2)(A)(iv)  
8 with respect to such drug. Such person may  
9 submit a request for a hearing, which shall be  
10 based solely on the information in the adminis-  
11 trative record, to the Secretary not later than  
12 30 calendar days after receiving notice of the  
13 final decision of the formal dispute resolution  
14 procedure.

15 “(B) NO HEARING REQUIRED WITH RE-  
16 SPECT TO ORDERS RELATING TO CERTAIN  
17 DRUGS.—The Secretary is not required to pro-  
18 vide notice and an opportunity for a hearing  
19 pursuant to paragraph (2)(A)(iv) if the final  
20 administrative order involved relates to a  
21 drug—

22 “(i) that is described in subsection  
23 (b)(1)(B)(ii)(I); and

24 “(ii) with respect to which no data  
25 relevant to the safety or effectiveness of

1 such drug have been submitted to the ad-  
2 ministrative record since the issuance of  
3 the most recent tentative final monograph  
4 relating to such drug (or, as applicable,  
5 since the deeming of such tentative final  
6 monograph as a final administrative order  
7 under paragraph (6)).

8 “(C) HEARING PROCEDURES.—

9 “(i) DENIAL OF REQUEST FOR HEAR-  
10 ING.—If the Secretary determines that a  
11 request for a hearing under subparagraph  
12 (A) with respect to a final administrative  
13 order issued under paragraph (2)(A)(iv),  
14 does not establish the existence of a gen-  
15 uine and substantial question of material  
16 fact, the Secretary may deny such request.  
17 In making such a determination, the Sec-  
18 retary may consider only information and  
19 data that are based on relevant and reli-  
20 able scientific principles and methodolo-  
21 gies.

22 “(ii) SINGLE HEARING FOR MULTIPLE  
23 RELATED REQUESTS.—If more than one  
24 request for a hearing is submitted with re-  
25 spect to the same administrative order

1 under subparagraph (A), the Secretary  
2 may direct that a single hearing be con-  
3 ducted in which all persons whose hearing  
4 requests were granted may participate.

5 “(iii) PRESIDING OFFICER.—The Sec-  
6 retary shall designate a presiding officer of  
7 a hearing requested under subparagraph  
8 (A) who—

9 “(I) is not an employee of the  
10 Center for Drug Evaluation and Re-  
11 search; and

12 “(II) has not previously been in-  
13 volved in the development of the appli-  
14 cable administrative order or in the  
15 proceedings relating to that adminis-  
16 trative order.

17 “(iv) RIGHTS OF PARTIES TO HEAR-  
18 ING.—The parties to a hearing requested  
19 under subparagraph (A) shall have the  
20 right to present testimony, including testi-  
21 mony of expert witnesses, and to cross-ex-  
22 amine witnesses presented by other parties.  
23 Where appropriate, the presiding officer  
24 may require that cross-examination by par-  
25 ties representing substantially the same in-

1           terests be consolidated to promote effi-  
2           ciency and avoid duplication.

3           “(v) FINAL DECISION.—At the conclu-  
4           sion of a hearing requested under subpara-  
5           graph (A), the presiding officer of the  
6           hearing shall issue a decision containing  
7           findings of fact and conclusions of law.  
8           The decision of the presiding officer shall  
9           be final. The final decision may not take  
10          effect until the period under subparagraph  
11          (D)(ii) for submitting a request for judicial  
12          review of such decision expires.

13          “(D) JUDICIAL REVIEW OF FINAL ADMIN-  
14          ISTRATIVE ORDER.—

15          “(i) IN GENERAL.—The procedures  
16          described in section 505(h) shall apply  
17          with respect to judicial review of final ad-  
18          ministrative orders issued under this sub-  
19          section in the same manner and to the  
20          same extent as such section applies to an  
21          order described in such section except that  
22          the judicial review shall be taken by filing  
23          in an appropriate district court of the  
24          United States in lieu of the appellate  
25          courts specified in such section.

1                   “(ii) TIME TO SUBMIT A REQUEST  
2                   FOR JUDICIAL REVIEW.—A person eligible  
3                   to request a hearing under this paragraph  
4                   and seeking judicial review of a final ad-  
5                   ministrative order issued under this sub-  
6                   section shall file a request for such review  
7                   not later than 60 calendar days after the  
8                   latest of—

9                   “(I) the date on which notice of  
10                  such order is published;

11                  “(II) the date on which any hear-  
12                  ing with respect to such order is de-  
13                  nied under subparagraph (C)(i);

14                  “(III) the date on which a final  
15                  decision is made following any hearing  
16                  with respect to such order under sub-  
17                  paragraph (C)(v); or

18                  “(IV) if no hearing is requested,  
19                  the date on which the time for re-  
20                  questing a hearing expires.

21                  “(4) EXPEDITED PROCEDURE WITH RESPECT  
22                  TO ADMINISTRATIVE ORDERS INITIATED BY THE  
23                  SECRETARY.—

24                  “(A) IMMINENT HAZARD TO THE PUBLIC  
25                  HEALTH.—

1                   “(i) IN GENERAL.—In the case of a  
2                   determination by the Secretary that a  
3                   monograph drug poses an imminent hazard  
4                   to the public health, the Secretary, after  
5                   informally communicating with any spon-  
6                   sor that has a listing in effect under sec-  
7                   tion 510(j) for such drug not later than 48  
8                   hours before issuance of an order under  
9                   this subparagraph, may—

10                   “(I) issue an interim final admin-  
11                   istrative order for such drug or com-  
12                   bination of drugs under paragraph  
13                   (1), together with a detailed state-  
14                   ment of the reasons for such order;

15                   “(II) publish in the Federal Reg-  
16                   ister a notice of availability of such  
17                   order; and

18                   “(III) provide for a public com-  
19                   ment period of at least 45 calendar  
20                   days after issuance of such interim  
21                   final order.

22                   “(ii) NONDELEGATION.—The Sec-  
23                   retary may not delegate the authority to  
24                   issue an interim final administrative order  
25                   under this subparagraph.

1 “(B) SAFETY LABELING CHANGES.—

2 “(i) IN GENERAL.—In the case of a  
3 determination by the Secretary that a  
4 change in the labeling of a drug, class of  
5 drugs, or combination of drugs subject to  
6 this section is reasonably expected to miti-  
7 gate a significant or unreasonable risk of  
8 a serious adverse event associated with use  
9 of the drug, the Secretary may—

10 “(I) informally communicate, not  
11 later than 48 hours before issuance of  
12 an interim final order under this sub-  
13 paragraph any sponsors of a drug who  
14 has a listing in effect under section  
15 510(j) for such drug or combination  
16 of drugs;

17 “(II) after informally commu-  
18 nicating with the sponsors under sub-  
19 clause (I), issue an interim final ad-  
20 ministrative order under paragraph  
21 (1) to require such change, together  
22 with a detailed statement of the rea-  
23 sons for such order and, in the case of  
24 a required change to the packaging, a  
25 brief description of the factors consid-



## 25

1                   ered in accordance with paragraph  
2                   (7)(B)(i);

3                   “(III) publish in the Federal  
4                   Register a notice of availability of  
5                   such order; and

6                   “(IV) provide for a public com-  
7                   ment period of at least 45 calendar  
8                   days after issuance of such interim  
9                   final order.

10                  “(ii) CONTENT OF ORDER.—An in-  
11                  terim final order issued under this sub-  
12                  paragraph with respect to the labeling of a  
13                  drug may provide for new warnings and  
14                  other information required for safe use of  
15                  the drug.

16                  “(C) EFFECTIVE DATE.—An order under  
17                  subparagraph (A) or (B) shall take effect on a  
18                  date specified by the Secretary.

19                  “(D) FINAL ORDER.—After the completion  
20                  of the proceedings in subparagraph (A) or (B),  
21                  the Secretary shall—

22                         “(i) issue a final order in accordance  
23                         with paragraph (1);

1 “(ii) publish a notice of availability of  
2 such final administrative order in the Fed-  
3 eral Register; and

4 “(iii) afford sponsors of drugs that  
5 will be subject to such an order the oppor-  
6 tunity for formal dispute resolution up to  
7 the level of the Director of the Center for  
8 Drug Evaluation and Research, which ini-  
9 tially shall be within 45 calendar days of  
10 the issuance of the order; and, for subse-  
11 quent levels of appeal, within 30 calendar  
12 days of the prior decision.

13 “(E) HEARINGS.—

14 “(i) IN GENERAL.—A sponsor of a  
15 drug subject to a final order issued under  
16 subparagraph (D) who participated in each  
17 level of formal dispute resolution under  
18 subparagraph (D)(iii) may request a hear-  
19 ing on such order. The provisions of sub-  
20 paragraphs (A) and (B), and (C) of para-  
21 graph (3) (except for clause (v)), of such  
22 subparagraph (C)) shall apply with respect  
23 to a hearing on such order in the same  
24 manner and to the same extent as such  
25 provisions apply with respect to a hearing

1 on an administrative order issued under  
2 paragraph (2)(A)(iv).

3 “(ii) REFERENCES.—For purposes of  
4 a hearing under this subparagraph, the  
5 references in subparagraphs (A), (B), and  
6 (C) of paragraph (3)—

7 “(I) to ‘each level of dispute reso-  
8 lution under paragraph  
9 (2)(A)(iv)(III)’ shall be deemed to  
10 mean ‘each level of formal dispute res-  
11 olution under subparagraph (D)(iii)’;  
12 and

13 “(II) to ‘final administrative  
14 order issued under paragraph  
15 (2)(A)(iv)’ shall be deemed to mean  
16 ‘final order under subparagraph  
17 (D)(i)’.

18 “(F) FINAL ORDER.—Not later than 1  
19 year after the date on which an interim final  
20 order is issued under subparagraph (A) or (B),  
21 the Secretary shall issue a final order in accord-  
22 ance with paragraph (1) and complete any re-  
23 quired hearing.

24 “(G) JUDICIAL REVIEW.—A final order  
25 issued pursuant to subparagraph (F) shall be

1 subject to judicial review in accordance with  
2 paragraph (3)(D).

3 “(H) CLARIFICATION.—Paragraph (2)  
4 shall not apply to the orders issued under this  
5 paragraph.

6 “(5) ADMINISTRATIVE ORDER INITIATED BY  
7 REQUEST.—

8 “(A) IN GENERAL.—In issuing an adminis-  
9 trative order under paragraph (1) at the re-  
10 quest of a requestor or a group of requestors  
11 with respect to certain drugs, classes of drugs,  
12 or combinations of drugs—

13 “(i) the Secretary shall, after receiv-  
14 ing a request under this subparagraph, de-  
15 termine whether the request is sufficiently  
16 complete and formatted to permit a sub-  
17 stantive review;

18 “(ii) subject to subparagraph (D), if  
19 the Secretary determines that the request  
20 is sufficiently complete and formatted to  
21 permit a substantive review, the Secretary  
22 shall—

23 “(I) file the request; and

24 “(II) initiate proceedings with re-  
25 spect to issuing an administrative

1 order in accordance with paragraphs  
2 (2) and (3); and

3 “(iii) except as provided in subpara-  
4 graph (D)(v), if the Secretary determines  
5 that a request does not meet the require-  
6 ments for filing or is not sufficiently com-  
7 plete or formatted to permit a substantive  
8 review, the requestor may elect that the  
9 Secretary file the request over protest, and  
10 the Secretary shall initiate proceedings to  
11 review the request in accordance with  
12 paragraph (2)(A).

13 “(B) REQUEST TO INITIATE PRO-  
14 CEEDINGS.—

15 “(i) IN GENERAL.—A requestor seek-  
16 ing an administrative order with respect to  
17 certain drugs, classes of drugs, or com-  
18 binations of drugs, shall submit to the Sec-  
19 retary a request to initiate proceedings for  
20 such order in the form and manner as  
21 specified by the Secretary. Such requestor  
22 may submit a request under this subpara-  
23 graph for the issuance of an administrative  
24 order—

1                   “(I) determining whether a drug  
2                   is generally recognized as safe and ef-  
3                   fective within the meaning of section  
4                   201(p)(1), exempt from section  
5                   503(b)(1), and not required to be the  
6                   subject of an approved application  
7                   under section 505; or

8                   “(II) determining whether a  
9                   change to a condition of use or a new  
10                  condition of use of a drug is generally  
11                  recognized as safe and effective within  
12                  the meaning of section 201(p)(1), ex-  
13                  empt from section 503(b)(1), and not  
14                  required to be the subject of an ap-  
15                  proved application under section 505,  
16                  if such drug is—

17                       “(aa) described in sub-  
18                       section (b)(1)(A); or

19                       “(bb) described in sub-  
20                       section (b)(1)(B), but only if  
21                       such requestor initiates such re-  
22                       quest in conjunction with a re-  
23                       quest for the Secretary to deter-  
24                       mine whether such drug is gen-  
25                       erally recognized as safe and ef-

1                   fective within the meaning of sec-  
2                   tion 201(p)(1), which is filed by  
3                   the Secretary under subpara-  
4                   graph (A)(ii)(I).

5                   The Secretary is not required to complete  
6                   review of the request for a change de-  
7                   scribed in subclause (II) if the Secretary  
8                   determines, in accordance with paragraph  
9                   (1)(B), that there is an inadequate basis to  
10                  find the drug is generally recognized as  
11                  safe and effective under paragraph (1) and  
12                  issues a final order announcing that deter-  
13                  mination.

14                 “(ii) WITHDRAWAL OF REQUEST.—  
15                 The requestor may withdraw a request  
16                 under this paragraph, according to the  
17                 procedures established by the Secretary.  
18                 Notwithstanding any other provision of  
19                 this section, if such request is withdrawn,  
20                 the Secretary may cease proceedings under  
21                 this subparagraph.

22                 “(C) PRODUCT DIFFERENTIATION.—

23                 “(i) IN GENERAL.—A final adminis-  
24                 trative order issued in response to a re-  
25                 quest under this paragraph shall have the

1 effect of authorizing solely the order re-  
2 questor (or the licensees, assignees, or suc-  
3 cessors in interest of such requestor with  
4 respect to the subject of such order and  
5 listed under clause (v)), for a 2-year period  
6 beginning on the effective date of such  
7 order, to market drugs under this sec-  
8 tion—

9 “(I) incorporating changes de-  
10 scribed in clause (ii); and

11 “(II) subject to the limitations  
12 under clause (iv).

13 “(ii) CHANGES DESCRIBED.—A  
14 change described in this clause is a change  
15 subject to an order specified in clause (i),  
16 which—

17 “(I) provides for a drug to con-  
18 tain an active ingredient (including  
19 any ester or salt of the active ingre-  
20 dient) not previously incorporated in a  
21 drug described in clause (iii); or

22 “(II) provides for a change in the  
23 conditions of use of a drug, for which  
24 new human data studies conducted or  
25 sponsored by the requestor (or for



1 which the requestor has an exclusive  
2 right of reference) were essential to  
3 the issuance of such order.

4 “(iii) DRUGS DESCRIBED.—The drugs  
5 described in this clause are drugs—

6 “(I) specified in subparagraphs  
7 (A), (B), and (D) of subsection (b)(1);

8 “(II) subject to a final order  
9 issued under this section;

10 “(III) subject to a final sun-  
11 screen order (as defined in section  
12 586(2)(A)); or

13 “(IV) described in subsection  
14 (b)(4)(A), other than drugs subject to  
15 an active enforcement action under  
16 chapter III.

17 “(iv) LIMITATIONS ON PRODUCT DIF-  
18 FERENTIATION.—

19 “(I) ONLY ONE PERIOD.—Only  
20 one 2-year period under this subpara-  
21 graph shall be granted for each order  
22 described in clause (i) with respect to  
23 changes (to the drug subject to such  
24 order) that are—

1 “(aa) changes described in  
2 clause (ii)(I), relating to active  
3 ingredients; or

4 “(bb) changes described in  
5 clause (ii)(II), relating to condi-  
6 tions of use.

7 “(II) EXCLUSIONS.—No 2-year  
8 period under this subparagraph shall  
9 apply to changes to a drug that are—

10 “(aa) the subject of a ‘Tier  
11 2’ monograph drug order re-  
12 quested as described in section  
13 744L(14)(A);

14 “(bb) safety-related changes  
15 described in section 744L–  
16 1(a)(2)(C), required under this  
17 paragraph, or any other change  
18 the Secretary determines nec-  
19 essary to ensure safe use; or

20 “(cc) changes related to  
21 methods of testing safety or effi-  
22 cacy.

23 “(v) LISTING OF LICENSEES, ASSIGN-  
24 EES, OR SUCCESSORS IN INTEREST.—The  
25 requestors of an order described in clause

1 (i) shall, as applicable, submit to the Sec-  
2 retary, at a time when a drug subject to  
3 such order is introduced or delivered for  
4 introduction into interstate commerce, a  
5 list of licensees, assignees, or successors in  
6 interest under such clause.

7 “(vi) NEW HUMAN DATA STUDIES DE-  
8 FINED.—For purposes of this subpara-  
9 graph, the term ‘new human data studies’  
10 means studies from clinical trials of safety  
11 or effectiveness, pharmacokinetics studies,  
12 or bioavailability studies, the results of  
13 which—

14 “(I) the Secretary has not relied  
15 on to support—

16 “(aa) a proposed or final de-  
17 termination that a drug described  
18 in subclauses (I), (II), or (III) of  
19 clause (iii) is generally recognized  
20 as safe and effective within the  
21 meaning of section 201(p)(1); or

22 “(bb) approval of a drug  
23 under section 505; and

1 “(II) do not duplicate the results  
2 of another study that the Secretary  
3 relied on to support—

4 “(aa) a proposed or final de-  
5 termination that a drug described  
6 in subclause (I), (II), or (III) of  
7 clause (iii) is generally recognized  
8 as safe and effective within the  
9 meaning of section 201(p)(1); or

10 “(bb) approval of a drug  
11 that was approved under section  
12 505.

13 “(D) INFORMATION REGARDING SAFE  
14 NONPRESCRIPTION MARKETING AND USE AS A  
15 CONDITION FOR FILING A GRASE REQUEST.—

16 “(i) IN GENERAL.—In response to a  
17 request under this paragraph that a drug  
18 described in clause (ii) be generally recog-  
19 nized as safe and effective, the Secretary—

20 “(I) may file such request, if the  
21 request includes information specified  
22 under clause (iii) with respect to safe  
23 nonprescription marketing and use of  
24 such drug; or

1 “(II) if the request fails to in-  
2 clude information specified under  
3 clause (iii), shall refuse to file such re-  
4 quest and may require that non-  
5 prescription marketing of the drug be  
6 pursuant to a new drug application as  
7 described in clause (iv).

8 “(ii) DRUG DESCRIBED.—A drug de-  
9 scribed in this clause is a monograph drug  
10 that contains an active ingredient not pre-  
11 viously incorporated in a drug—

12 “(I) described in subparagraph  
13 (A), (B), or (D) of subsection (b)(1);

14 “(II) subject to a final order  
15 under this section; or

16 “(III) subject to a final sun-  
17 screen order (as defined in section  
18 586(2)(A)).

19 “(iii) SUFFICIENT INFORMATION FOR  
20 A THRESHOLD DEMONSTRATION OF NON-  
21 PRESCRIPTION MARKETING AND USE.—In-  
22 formation specified in this subparagraph,  
23 with respect to a request described in  
24 clause (i)(I), is—

1                   “(I) information sufficient for a  
2 threshold demonstration that the drug  
3 subject to such request has a  
4 verifiable history of being marketed  
5 and safely used by consumers in the  
6 United States as a nonprescription  
7 drug under comparable conditions of  
8 use;

9                   “(II) if the drug has not been  
10 previously marketed in the United  
11 States as a nonprescription drug, in-  
12 formation sufficient for a threshold  
13 demonstration that the drug was mar-  
14 keted and safely used in a foreign  
15 country under conditions of marketing  
16 and use—

17                   “(aa) for such period of time  
18 as needed to provide reasonable  
19 assurances concerning the safe  
20 nonprescription use of the drug;  
21 and

22                   “(bb) during such period of  
23 time, was subject to sufficient  
24 monitoring by a regulatory body  
25 of any country listed in section

1 802(b)(1)(A) or any country des-  
2 igned by the Secretary in ac-  
3 cordance with section  
4 802(b)(1)(B); or

5 “(III) if the Secretary determines  
6 that information described in sub-  
7 clause (I) or (II) is not needed to pro-  
8 vide a threshold demonstration that  
9 the drug can be safely marketed and  
10 used as a nonprescription drug, other  
11 information the Secretary determines  
12 sufficient for such purposes.

13 “(iv) MARKETING PURSUANT TO NEW  
14 DRUG APPLICATION.—In the case of a re-  
15 quest described in clause (i)(II), the drug  
16 subject to such request may be re-sub-  
17 mitted for filing only if—

18 “(I) the drug is marketed as a  
19 nonprescription drug, under condi-  
20 tions of use comparable to the re-  
21 quirements specified in the request,  
22 for such period of time as the Sec-  
23 retary determines appropriate (not to  
24 exceed 5 consecutive years) pursuant

1 to an application approved under sec-  
2 tion 505; and

3 “(II) during such period of time,  
4 1,000,000 retail packages of the drug,  
5 or an equivalent quantity of the active  
6 ingredient or ingredients of such drug  
7 as determined by the Secretary, were  
8 distributed for retail sale, as deter-  
9 mined in such manner as the Sec-  
10 retary may require.

11 “(v) RULE OF APPLICATION.—If the  
12 Secretary refuses to file a request under  
13 this subparagraph, the requestor may not  
14 file over protest under subparagraph  
15 (A)(iii) unless the request involves a drug  
16 described in section 586(9) as in effect on  
17 January 1, 2017.

18 “(6) TREATMENT OF FINAL AND TENTATIVE  
19 FINAL MONOGRAPHS.—

20 “(A) IN GENERAL.—A final monograph or  
21 tentative final monograph described in subpara-  
22 graph (B) shall be deemed to be a final admin-  
23 istrative order under this subsection and may  
24 be amended, revoked, or otherwise modified in



1           accordance with the procedures of this sub-  
2           section.

3           “(B) MONOGRAPHS DESCRIBED.—For pur-  
4           poses of subparagraph (A), a final monograph  
5           or tentative final monograph, as applicable, is  
6           described in this subparagraph if such mono-  
7           graph—

8                   “(i) establishes requirements of use  
9                   for a drug described in subclause (I) or  
10                  (II) of subsection (b)(1)(A)(i); and

11                   “(ii) represents the most recently pro-  
12                   mulgated version of such requirements, in-  
13                   cluding as modified, in whole or in part, by  
14                   any proposed or final rule.

15           “(7) PACKAGING.—

16                   “(A) IN GENERAL.—An administrative  
17                   order issued under paragraph (2), (4), or (5)  
18                   may include requirements for the packaging of  
19                   a drug, such as to promote use in accordance  
20                   with labeling, unit dose packaging, or require-  
21                   ments to prevent overdose or accidental inges-  
22                   tion, including by pediatric populations.

23                   “(B) SAFETY LABELING CHANGES.—An  
24                   administrative order issued under paragraph

1           (4)(B) that includes requirements for the pack-  
2           aging of a drug may be issued only after—

3                   “(i) consideration of—

4                           “(I) whether labeling changes  
5                           alone would mitigate a significant or  
6                           unreasonable risk of a serious adverse  
7                           event; and

8                           “(II) as appropriate, any of the  
9                           applicable nonprescription drugs cur-  
10                          rently available; and

11                          “(ii) consultation with sponsors on the  
12                          impact of the removal of such drugs with-  
13                          out such packaging and the change of such  
14                          packaging on patients and manufacturers  
15                          when establishing such requirements.

16                          “(C) CLARIFICATION.—This paragraph  
17                          does not authorize the Secretary to require  
18                          standards or testing procedures as described in  
19                          part 1700 of title 16, Code of Federal Regula-  
20                          tions.

21           “(d) PROCEDURE FOR MINOR CHANGES.—

22                          “(1) IN GENERAL.—Minor changes in the dos-  
23                          age form of a drug that is described in subpara-  
24                          graph (A) or (B) of subsection (b)(1) may be made

1 by a requestor without the issuance of an adminis-  
2 trative order under subsection (c) if—

3 “(A) the requestor maintains information  
4 necessary to demonstrate that the change—

5 “(i) will not affect the safety or effec-  
6 tiveness of the drug; and

7 “(ii) will not materially affect the ex-  
8 tent of absorption or other exposure to the  
9 active ingredient in comparison to a suit-  
10 able reference product;

11 “(B) the requestor submits updated drug  
12 listing information for the drug in accordance  
13 with the requirements of section 510(j) within  
14 30 calendar days of the date on which the drug  
15 is first introduced into interstate commerce  
16 with the change; and

17 “(C) the change is in conformity with the  
18 requirements of an applicable administrative  
19 order issued by the Secretary under paragraph  
20 (3).

21 “(2) ADDITIONAL INFORMATION.—

22 “(A) ACCESS TO RECORDS.—If the Sec-  
23 retary requests records under section 704(a)(4)  
24 with respect to a minor change made to a drug  
25 by a requestor under this subsection, any such

1 records pertinent to such drug, such minor  
2 change, and the requestor shall be provided to  
3 the Secretary by the requestor within 15 busi-  
4 ness days of receiving such request, or such  
5 longer period as the Secretary may provide.

6 “(B) INSUFFICIENT INFORMATION.—If the  
7 Secretary determines that the information con-  
8 tained in such records is not sufficient to dem-  
9 onstrate that the change does not affect the  
10 safety or effectiveness of the drug or materially  
11 affect the extent of absorption or other expo-  
12 sure to the active ingredient, the Secretary—

13 “(i) may so inform the requestor of  
14 the drug in writing; and

15 “(ii) provide the requestor of the drug  
16 with a reasonable opportunity to provide  
17 additional information.

18 “(C) FAILURE TO SUBMIT SUFFICIENT IN-  
19 FORMATION.—If the requestor fails to provide  
20 such additional information within the pre-  
21 scribed time, or if the Secretary determines that  
22 such additional information does not dem-  
23 onstrate that the change does not affect the  
24 safety or effectiveness of the drug or materially  
25 affect the extent of absorption or other expo-

1           sure to the active ingredient, the drug as modi-  
2           fied is a new drug within the meaning of sec-  
3           tion 201(p) and shall be deemed to be mis-  
4           branded under section 502(ee).

5           “(3) DETERMINING WHETHER CHANGE WILL  
6           AFFECT SAFETY OR EFFECTIVENESS.—

7                   “(A) IN GENERAL.—The Secretary shall  
8           issue one or more administrative orders under  
9           this subsection specifying requirements for de-  
10          termining whether a minor change made by a  
11          requestor pursuant to this subsection will affect  
12          the safety or effectiveness of a drug or materi-  
13          ally affect the extent of absorption or other ex-  
14          posure to an active ingredient in the drug in  
15          comparison to a suitable reference product, to-  
16          gether with guidance for applying those orders  
17          to specific dosage forms.

18                   “(B) STANDARD PRACTICES AND SPECIAL  
19          NEEDS OF POPULATIONS.—The orders and  
20          guidance issued by the Secretary under sub-  
21          paragraph (A) shall take into account relevant  
22          public standards and standard practices for  
23          evaluating the quality of drug products and  
24          may take into account special needs of popu-  
25          lations, including children.

1 “(e) INFORMATION SUBMITTED BY REQUESTORS.—

2 “(1) CONFIDENTIAL INFORMATION.—Subject to  
3 paragraph (2), any information, including reports of  
4 testing conducted on the drug or drugs involved,  
5 that is submitted by a requestor in connection with  
6 proceedings on an administrative order under this  
7 section (or any minor change under subsection (d))  
8 and is a trade secret or confidential information sub-  
9 ject to section 552(b)(4) of title 5, United States  
10 Code, or section 1905 of title 18, United States  
11 Code, shall not be disclosed to the public unless the  
12 requestor consents to that disclosure.

13 “(2) PUBLIC AVAILABILITY LIMITATIONS.—The  
14 Secretary shall make available to the public any in-  
15 formation (other than information contained in sub-  
16 ject-level data sets, such as those derived from indi-  
17 vidual case report forms) submitted by a requestor  
18 in support of a request under subsection (c)(6)(A)  
19 as of the date on which the proposed order is issued  
20 unless—

21 “(A) the information pertains to pharma-  
22 ceutical quality, unless such information is nec-  
23 essary to establish standards under which a  
24 drug is generally recognized as safe and effec-  
25 tive within the meaning of section 201(p)(1);

1           “(B) the information is submitted in a re-  
2           questor-initiated request, but the requestor  
3           withdraws such request before the Secretary  
4           issues the proposed order in accordance with  
5           withdrawal procedures established by the Sec-  
6           retary; or

7           “(C) the Secretary requests and obtains  
8           the information under subsection (d) and such  
9           information is not submitted in relation to an  
10          order under subsection (c).

11          “(f) PUBLIC AVAILABILITY OF ADMINISTRATIVE OR-  
12          DERS.—The Secretary shall establish, maintain, update  
13          (as the Secretary determines necessary, but not less fre-  
14          quently than annually), and make available on the internet  
15          website of the Food and Drug Administration—

16               “(1) a repository of each final administrative  
17          order and interim final order issued under sub-  
18          section (c) that is in effect, including the complete  
19          text of the administrative order; and

20               “(2) a listing of all administrative orders pro-  
21          posed and under development on the initiative of the  
22          Secretary under this section, including—

23                       “(A) a brief description of the administra-  
24          tive order; and

1                   “(B) the expectations of the Secretary, for  
2                   issuance of proposed administrative orders over  
3                   a 3-year period.

4           “(g) UPDATES TO DRUG LISTING INFORMATION.—  
5   A sponsor who makes a change to a drug subject in ac-  
6   cordance with subsection (c) shall submit updated drug  
7   listing information for the drug in accordance with the re-  
8   quirements of section 510(j) not later than the date on  
9   which the drug is first introduced or delivered for intro-  
10   duction into interstate commerce with the change.

11          “(h) APPROVALS UNDER SECTION 505.—This sec-  
12   tion shall not be construed to preclude a sponsor of a drug  
13   or requestor from seeking or maintaining the approval of  
14   an application for such drug under subsection (b)(1),  
15   (b)(2), or (j) of section 505. A determination under this  
16   section that a drug is not subject to section 503(b)(1),  
17   is generally recognized as safe and effective within the  
18   meaning of section 201(p)(1), and is not a new drug under  
19   section 201(p), shall constitute a finding of safety and ef-  
20   fectiveness for purposes of section 505(b)(2) so that the  
21   applicant shall be required to submit only that information  
22   needed to support the modification of the drug that is sub-  
23   ject to the determination under this section.

24          “(i) DEVELOPMENT ADVICE TO REQUESTORS OR  
25   SPONSORS.—



1           “(1) IN GENERAL.—The Secretary shall estab-  
2           lish procedures under which requestors may meet  
3           with appropriate officials of the Food and Drug Ad-  
4           ministration to obtain advice on the studies and  
5           other information necessary to support requests  
6           under this section and other matters relevant to the  
7           regulation and development of monograph drugs  
8           under this section.

9           “(2) PARTICIPATION OF MULTIPLE SPON-  
10          SORS.—The Secretary shall establish procedures to  
11          facilitate efficient participation by multiple reques-  
12          tors in proceedings under this section, including pro-  
13          vision for joint meetings with multiple requestors or  
14          with organizations nominated by requestors to rep-  
15          resent their interests in a proceeding.

16          “(3) PRIVATE MEETINGS WITH REQUESTORS.—  
17          The procedures established under this subsection  
18          shall include appropriate provision for confidential  
19          meetings with requestors with respect to discussion  
20          of matters involving confidential commercial infor-  
21          mation or trade secrets.

22          “(j) EFFECT ON EXISTING REGULATIONS GOV-  
23          ERNING NONPRESCRIPTION DRUGS.—

24                 “(1) REGULATIONS OF GENERAL APPLICA-  
25                 BILITY TO NONPRESCRIPTION DRUGS.—Except as

1 provided in this subsection, nothing in this section  
2 supersedes regulations establishing general require-  
3 ments for nonprescription drugs, including regula-  
4 tions of general applicability contained in parts 201,  
5 250, and 330 of title 21, Code of Federal Regula-  
6 tions, or any successor regulations. The Secretary  
7 shall establish or modify such regulations by means  
8 of rulemaking in accordance with section 553 of title  
9 5, United States Code.

10 “(2) REGULATIONS ESTABLISHING REQUIRE-  
11 MENTS FOR SPECIFIC NONPRESCRIPTION DRUGS.—

12 “(A) IN GENERAL.—Section 310.545 of  
13 title 21, Code of Federal Regulations, as in ef-  
14 fect on the day before the date of enactment of  
15 this section, shall be deemed to be final admin-  
16 istrative order under subsection (c).

17 “(B) OTHER REGULATIONS.—Regulations  
18 establishing requirements for specific non-  
19 prescription drugs marketed pursuant to this  
20 section that are in effect on the day before the  
21 date of enactment of this section (including  
22 such requirements in parts 201, 250, and 330  
23 of title 21, Code of Federal Regulations), shall  
24 be deemed to be final administrative orders  
25 under subsection (c) only as such requirements

1           apply to monograph drugs subject to this sec-  
2           tion.

3                   “(C) EFFECTIVE DATE PERIOD.—Unless  
4           withdrawn or revised by the Secretary, the reg-  
5           ulations under title 21 of the Code of Federal  
6           Regulations that are described in subparagraph  
7           (B) shall remain in effect with respect to drugs  
8           not subject to subparagraph (A), (B), (C), or  
9           (D) of subsection (b)(1).

10                   “(3) WITHDRAWAL OF REGULATIONS.—The  
11       Secretary shall withdraw regulations establishing  
12       final monographs and the procedures governing the  
13       over-the-counter drug review under part 330 and  
14       other relevant parts of title 21, Code of Federal  
15       Regulations (as in effect on the day before the date  
16       of enactment of the Over-the-Counter Drug Safety,  
17       Innovation, and Reform Act), or make technical  
18       changes to such regulations to ensure conformity  
19       with appropriate terminology and cross references,  
20       to the extent needed to effectuate or harmonize the  
21       provisions of this section. Notwithstanding sub-  
22       chapter II of chapter 5 of title 5, United States  
23       Code, any such withdrawal or technical amendments  
24       shall be made without public notice and comment  
25       and be effective upon publication through notice in

1 the Federal Register (or upon such date as specified  
2 in such notice).

3 “(k) GUIDANCE.—

4 “(1) ISSUANCE.—The Secretary shall issue  
5 guidance that provides—

6 “(A) the procedures and principles for for-  
7 mal meetings between the Secretary and spon-  
8 sors or requestors for drugs subject to this sec-  
9 tion;

10 “(B) the format and content of data sub-  
11 missions to the Secretary under this section;

12 “(C) the format of electronic submissions  
13 to the Secretary under this section;

14 “(D) consolidated proceedings and the pro-  
15 ceedures for such proceedings where appropriate;  
16 and

17 “(E) for minor changes in drugs, rec-  
18 ommendations on how to comply with the re-  
19 quirements in administrative orders issued  
20 under subsection (d)(3)(A).

21 “(l) ELECTRONIC FORMAT.—All submissions under  
22 this section shall be in an electronic format specified by  
23 the Secretary after providing a period for public comment.

24 “(m) INAPPLICABILITY OF PAPERWORK REDUCTION  
25 ACT.—Chapter 35 of title 44, United States Code, shall

1 not apply to collections of information made under this  
2 section.

3 “(n) NONAPPLICATION OF CERTAIN REQUIRE-  
4 MENTS.—The requirements of subchapter II of chapter 5  
5 of title 5, United States Code, shall not apply with respect  
6 to administrative orders issued under this section.

7 “(o) INVESTIGATIONAL NEW DRUGS.—A drug for  
8 which an exemption under section 505(i) is in effect is  
9 not subject to this section.”.

10 **SEC. 102. MISBRANDING.**

11 Section 502 of the Federal Food, Drug, and Cosmetic  
12 Act (21 U.S.C. 352) is amended by inserting after sub-  
13 section (dd) the following:

14 “(ee) If it is a nonprescription drug that is not the  
15 subject of an application approved under section 505, and  
16 does not comply with the requirements under section  
17 505G.

18 “(ff) If it is a drug for which fees under section  
19 744L–1 have been assessed but have not been paid.”.

20 **SEC. 103. CONFORMING AMENDMENTS TO THE SUNSCREEN**  
21 **INNOVATION ACT.**

22 (a) REVIEW OF NONPRESCRIPTION INGREDIENTS  
23 SUBJECT TO SUNSCREEN INNOVATION ACT.—

24 (1) PENDING SUNSCREEN INGREDIENTS.—Non-  
25 prescription sunscreen active ingredients or combina-

1 tions of sunscreen active ingredients for use under  
2 specified conditions subject, on the date of enact-  
3 ment of this Act, to a proposed sunscreen order, as  
4 defined in section 586(7) of the Federal Food, Drug,  
5 and Cosmetic Act (21 U.S.C. 360fff(7)), shall—

6 (A) continue to be reviewed in accordance  
7 with section 586C of the Federal Food, Drug,  
8 and Cosmetic Act (21 U.S.C. 360fff–3); or

9 (B) be reviewed under section 505G of  
10 such Act upon written notification of the Sec-  
11 retary by the sponsor within 180 calendar days  
12 after the date of enactment of the Over-the-  
13 Counter Drug Safety, Innovation, and Reform  
14 Act that such sponsor elects to have such ingre-  
15 dient or combination of ingredients reviewed  
16 under such section 505G, and, upon notifica-  
17 tion, such proposed sunscreen order under such  
18 section 586C shall be considered to be a request  
19 for an administrative order that has been ac-  
20 cepted for filing under section 505G(c)(6)(A)(ii)  
21 of such Act.

22 (2) PENDING NONSUNSCREEN INGREDIENTS.—

23 (A) IN GENERAL.—Any application de-  
24 scribed in section 586F of the Federal Food,  
25 Drug, and Cosmetic Act (21 U.S.C. 360fff–6)

1           that was submitted to the Secretary of Health  
2           and Human Services pursuant to section  
3           330.14 of title 21, Code of Federal Regulations  
4           (as such provisions were in effect on the day be-  
5           fore the date of enactment of this Act), shall be  
6           voided as of such date of enactment, subject to  
7           subparagraph (B).

8           (B) ORDER REQUEST.—Nothing in sub-  
9           paragraph (A) precludes the submission of an  
10          order request under section 505G(b) of the  
11          Federal Food, Drug, and Cosmetic Act, as  
12          added by section 101 of this Act, with respect  
13          to a drug that was the subject of an application  
14          voided under subparagraph (A).

15          (C) INGREDIENTS SUBMITTED AFTER THE  
16          DATE OF ENACTMENT OF SECTION 506G.—Any  
17          ingredient that is eligible for review under sec-  
18          tion 505G of the Federal Food, Drug, and Cos-  
19          metic Act and is submitted after the date of en-  
20          actment of this Act shall be considered under  
21          that section.

22          (b) MEETINGS REGARDING SUNSCREEN INGREDI-  
23          ENTS.—Section 586C(b) of the Federal Food, Drug, and  
24          Cosmetic Act (21 U.S.C. 360fff–3(b)) is amended by add-  
25          ing at the end the following:

1           “(11) MEETINGS WITH SPONSORS.—A sponsor  
2           may request an individual, confidential meeting to  
3           discuss the data requirements to support a general  
4           recognition of safety and effectiveness with respect  
5           to the subject of a pending sunscreen ingredient.  
6           The Secretary shall respond within 14 calendar days  
7           of the request and schedule such meeting within 45  
8           calendar days, or within such timeline as specified in  
9           the letters described in section 201 of the Over-the-  
10          Counter Drug Safety, Innovation, and Reform Act.  
11          If a sponsor requests more than one confidential  
12          meeting for the same proposed sunscreen order, the  
13          Secretary may refuse to grant an additional con-  
14          fidential meeting request if the Secretary determines  
15          such additional confidential meeting is not reason-  
16          ably necessary for the sponsor to advance the pro-  
17          posed sunscreen order, or if the sponsor does not  
18          provide sufficient information upon which to base a  
19          substantive discussion. The Secretary shall publish a  
20          post-meeting summary on the internet website of the  
21          Food and Drug Administration of any confidential  
22          meeting that does not disclose confidential business  
23          information.”.



1 (c) PRODUCT DIFFERENTIATION.—Section 586C of  
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
3 360fff–3) is amended by adding at the end the following:

4 “(f) PRODUCT DIFFERENTIATION.—

5 “(1) IN GENERAL.—A final sunscreen order  
6 shall have the effect of authorizing solely the order  
7 requestor (or the licensees, assignees, or successors  
8 in interest of such requestor with respect to the sub-  
9 ject of such request and listed under paragraph (5))  
10 for a period of 2 years, to market a sunscreen ingre-  
11 dient under this section incorporating changes de-  
12 scribed in paragraph (2) subject to the limitations  
13 under paragraph (4), beginning on the date the re-  
14 questor (or any licensees, assignees, or successors in  
15 interest of such requestor with respect to the subject  
16 of such request and listed under paragraph (5)) may  
17 lawfully market such sunscreen ingredient pursuant  
18 to the order.

19 “(2) CHANGES DESCRIBED.—A change de-  
20 scribed in this paragraph is a change subject to an  
21 order specified in paragraph (1) that permits a sun-  
22 screen to contain an active sunscreen ingredient not  
23 previously incorporated in a marketed sunscreen list-  
24 ed in paragraph (3).

1           “(3) MARKETED SUNSCREEN.—The marketed  
2        sunscreen ingredients described this paragraph are  
3        sunscreen ingredients—

4           “(A) marketed in accordance with a final  
5        monograph for sunscreen drug products set  
6        forth at part 352 of title 21, Code of Federal  
7        Regulations (as published at 64 Fed. Reg.  
8        27687); or

9           “(B) marketed in accordance with a final  
10       order issued under this section.

11          “(4) LIMITATIONS ON PRODUCT DIFFERENTIA-  
12       TION.—Only one 2-year period may be granted per  
13       ingredient under paragraph (1).

14          “(5) LISTING OF LICENSEES, ASSIGNEES, OR  
15       SUCCESSORS IN INTEREST.—Requestors shall submit  
16       to the Secretary at the time when a drug subject to  
17       such request is introduced or delivered for introduc-  
18       tion into interstate commerce, a list of licensees, as-  
19       signees, or successors in interest under paragraph  
20       (1).”.

21       (d) SUNSCREEN INNOVATION ACT AMENDMENTS.—  
22       Section 586C(e) of the Federal Food, Drug, and Cosmetic  
23       Act (21 U.S.C. 360fff–3(e)) is amended by striking para-  
24       graph (3) and inserting the following:

1           “(3) RELATIONSHIP TO ORDERS UNDER SEC-  
2           TION 505G.—A final sunscreen order shall be deemed  
3           to be a final administrative order under section  
4           505G and subject to the applicable provisions under  
5           such section 505G, including with respect to amend-  
6           ment of such order.”.

7           (e) PRECLUSION OF NEW SUNSCREEN SUBMISSIONS;  
8           OPTION TO TRANSFER SUBMISSIONS TO OTC MONO-  
9           GRAPH ORDER PROCESS.—

10           (1) SUNSET.—Beginning on the date of enact-  
11           ment of this Act, section 586A of the Federal Food,  
12           Drug, and Cosmetic Act (21 U.S.C. 360fff–1) shall  
13           have no force or effect.

14           (2) OPTION TO TRANSFER SUBMISSIONS TO OTC  
15           MONOGRAPH ORDER PROCESS.—

16           (A) IN GENERAL.—Any person who sub-  
17           mitted a request described in subparagraph (B)  
18           may, at any time prior to the sunset of sub-  
19           chapter I of chapter V of the Federal Food,  
20           Drug, and Cosmetic Act (21 U.S.C. 360fff et  
21           seq.) under section 586H of such Act, withdraw  
22           such request from the process under such sub-  
23           chapter and resubmit such request as an order  
24           request under section 505G of such Act.

1 (B) REQUESTS.—A request described in  
2 this subparagraph is—

3 (i) a request under section 586A of  
4 the Federal Food, Drug, and Cosmetic Act  
5 submitted before the date of enactment of  
6 this Act; or

7 (ii) a pending request described in  
8 section 586(6).

9 (f) TREATMENT OF AUTHORITY REGARDING FINAL-  
10 IZATION OF SUNSCREEN MONOGRAPH.—Section 586E of  
11 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
12 360fff–5) is amended to read as follows:

13 **“SEC. 586E. SUNSCREEN ORDER.**

14 **“(a) IN GENERAL.—**

15 **“(1) REVISION OF FINAL SUNSCREEN ORDER.—**

16 Not later than November 26, 2019, the Secretary  
17 shall amend and revise the final administrative order  
18 concerning nonprescription sunscreen (referred to in  
19 this section as the ‘sunscreen order’) for which the  
20 substance, prior to the date of enactment of the  
21 Over-the-Counter Drug Safety, Innovation, and Re-  
22 form Act, was marketed in accordance with a final  
23 monograph for sunscreen drug products set forth in  
24 part 352 of title 21, Code of Federal Regulations (as  
25 published at 64 Fed. Reg. 27687)

1           “(2) ISSUANCE OF REVISED SUNSCREEN  
2           ORDER; EFFECTIVE DATE.—A revised sunscreen  
3           order described in paragraph (1) shall be—

4                   “(A) issued in accordance with the proce-  
5                   dures described in section 505G(c)(2);

6                   “(B) issued in proposed form not later  
7                   than May 28, 2019;

8                   “(C) effective not later than November 26,  
9                   2020; and

10                   “(D) issued by the Secretary at least 1  
11                   year prior to such effective date.

12           “(b) REPORTS.—If a revised sunscreen order issued  
13           under subsection (a) does not include provisions related  
14           to the effectiveness of various sun protection factor levels,  
15           and does not address all dosage forms known to the Sec-  
16           retary to be used in sunscreens marketed in the United  
17           States without a new drug application approved under sec-  
18           tion 505, the Secretary shall submit a report to the Com-  
19           mittee on Health, Education, Labor, and Pensions of the  
20           Senate and the Committee on Energy and Commerce of  
21           the House of Representatives on the rationale for omission  
22           of such provisions from such order, and a plan and  
23           timeline to compile any information necessary to address  
24           such provisions through such order.”.

1 (g) SUNSET OF PROCESS UNDER SUNSCREEN INNO-  
2 VATION ACT.—Subchapter I of chapter V of the Federal  
3 Food, Drug, and Cosmetic Act (21 U.S.C. 360fff et seq.),  
4 as amended by subsection (f), is further amended by in-  
5 serting at the end the following new section:

6 **“SEC. 586H. SUNSET.**

7 “This subchapter shall no longer be effective upon  
8 the later of—

9 “(1) a final determination by the Secretary  
10 under this subchapter with respect to every request  
11 described in section 586A(b)(2) (other than any  
12 withdrawn requests and requests resubmitted as  
13 order requests under section 505G); or

14 “(2) the effective date of the revised sunscreen  
15 order described in section 586E(a)(2).”.

16 **SEC. 104. DRUGS EXCLUDED FROM OVER-THE-COUNTER**  
17 **REVIEW.**

18 (a) IN GENERAL.—Nothing in this Act (or the  
19 amendments made by this Act) shall apply to any non-  
20 prescription drug which was excluded by the Food and  
21 Drug Administration from the Over-the-Counter Drug Re-  
22 view in accordance with the statement set out at page  
23 9466 of volume 37 of the Federal Register, published on  
24 May 11, 1972.

1 (b) RULE OF CONSTRUCTION.—Nothing in this sec-  
2 tion shall be construed to preclude or limit the applica-  
3 bility of any provision of the Federal Food, Drug, and  
4 Cosmetic Act.

5 **SEC. 105. CONFORMING AMENDMENT.**

6 Section 751(d)(1) of the Federal Food, Drug, and  
7 Cosmetic Act (21 U.S.C. 379r(d)(1)) is amended—

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

9 (A) by striking “final regulation promul-  
10 gated” and inserting “final order issued under  
11 section 505G”; and

12 (B) by striking “and not misbranded”; and

13 (2) in subparagraph (A), by striking “regula-  
14 tion in effect” and inserting “regulation or order in  
15 effect”.

16 **SEC. 106. ANNUAL UPDATE TO CONGRESS ON APPRO-**  
17 **PRIATE PEDIATRIC INDICATION FOR CER-**  
18 **TAIN COUGH AND COLD MONOGRAPH DRUGS.**

19 (a) IN GENERAL.—Not later than one year after the  
20 date of enactment of this Act and annually thereafter, the  
21 Secretary of Health and Human Services (referred to in  
22 this section as the “Secretary”) shall submit to the Com-  
23 mittee on Health, Education, Labor, and Pensions of the  
24 Senate and the Committee on Energy and Commerce of

1 the House of Representatives a letter describing the  
2 progress of the Food and Drug Administration—

3 (1) in evaluating the cough and cold monograph  
4 described in subsection (b) with respect to children  
5 under age 6; and

6 (2) as appropriate, revising such cough and cold  
7 monograph to address such children, through the ad-  
8 ministrative order process under section 505G(c) of  
9 the Federal Food, Drug, and Cosmetic Act, as  
10 added by section 101.

11 (b) COUGH AND COLD MONOGRAPH DESCRIBED.—  
12 The cough and cold monograph described in this sub-  
13 section consists of the conditions under which nonprescrip-  
14 tion drug products containing antitussive, expectorant,  
15 nasal decongestant, or antihistamine active ingredients (or  
16 combinations thereof) are generally recognized as safe and  
17 effective, as specified in part 341 of title 21, Code of Fed-  
18 eral Regulations (as in effect on the day before the date  
19 of enactment of this Act), and included in an administra-  
20 tive order deemed established under such section 505G(c)  
21 of the Federal Food, Drug, and Cosmetic Act.

22 (c) DURATION OF AUTHORITY.—Subsection (a) shall  
23 have no force or effect beginning on the date on which  
24 the Secretary submits a letter under subsection (a) in  
25 which the Secretary indicates that the Food and Drug Ad-



1 ministration has completed its evaluation and revised, in  
2 a final administrative order, as applicable, the cough and  
3 cold monograph in accordance with this section.

## 4 **TITLE II—FEES RELATING TO** 5 **MONOGRAPH DRUGS**

### 6 **SEC. 201. SHORT TITLE; FINDINGS.**

7 (a) SHORT TITLE.—This title may be cited as the  
8 “Over-the-Counter Monograph User Fee Act of 2018”.

9 (b) FINDINGS.—The Congress finds that the fees au-  
10 thorized by the amendments made in this title will be dedi-  
11 cated toward the regulation of monograph drugs under  
12 section 505G of the Federal, Food, Drug, and Cosmetic  
13 Act, as set forth in the goals identified for purposes of  
14 such section, in the letters from the Secretary of Health  
15 and Human Services to the Chairman of the Committee  
16 on Health, Education, Labor, and Pensions of the Senate  
17 and the Chairman of the Committee on Energy and Com-  
18 merce of the House of Representatives, as set forth in the  
19 Congressional Record.

### 20 **SEC. 202. AUTHORITY TO ASSESS AND USE FEES.**

21 Subchapter C of chapter VII of the Federal Food,  
22 Drug, and Cosmetic Act (21 U.S.C. 379f et seq.) is  
23 amended by adding at the end the following:

1       **“PART 10—FEES RELATING TO MONOGRAPH**  
2                   **DRUGS**

### 3 “SEC. 744L. DEFINITIONS.

4 “For purposes of this part:

“(1) The term ‘affiliate’ means a business entity that has a relationship with a second business entity if, directly or indirectly—

8                   “(A) one business entity controls, or has  
9                   the power to control, the other business entity;  
10                  or

11                   “(B) a third party controls, or has power  
12                   to control, both of the business entities.

“(2) the term ‘contract manufacturing organization facility’ means a monograph drug facility where neither the owner of such manufacturing facility nor any affiliate of such owner or facility sells such monograph drug produced at such facility directly to wholesalers, retailers, or consumers in the United States.

20 “(3) The term ‘costs of resources allocated for  
21 monograph drug activities’ means the expenses in  
22 connection with monograph drug activities for—

“(A) officers and employees of the Food  
and Drug Administration, contractors of the  
Food and Drug Administration, advisory com-  
mittees, and costs related to such officers, em-

1            ployees, and committees and to contracts with  
2            such contractors;

3            “(B) management of information, and the  
4            acquisition, maintenance, and repair of com-  
5            puter resources;

6            “(C) leasing, maintenance, renovation, and  
7            repair of facilities and acquisition, maintenance,  
8            and repair of fixtures, furniture, scientific  
9            equipment, and other necessary materials and  
10          supplies; and

11          “(D) collecting fees under section 744L–1  
12          and accounting for resources allocated for  
13          monograph drug activities.

14          “(4) The term ‘firm establishment identifier’ is  
15          the unique number automatically generated by the  
16          Field Accomplishments and Compliance Tracking  
17          System of the Food and Drug Administration.

18          “(5) The term ‘monograph drug’ means a drug  
19          subject to section 505G.

20          “(6) The term ‘monograph drug activities’  
21          means activities of the Secretary associated with  
22          monograph drugs and inspection of facilities associ-  
23          ated with such drugs, including—

1           “(A) the activities necessary for review and  
2           evaluation of monograph drugs and monograph  
3           drug order requests, including—

4                   “(i) orders proposing or finalizing ap-  
5                   plicable requirements for monograph  
6                   drugs;

7                   “(ii) orders affecting status regarding  
8                   general recognition of safety and effective-  
9                   ness of a monograph drug ingredient or  
10                  combination of ingredients under specified  
11                  requirements;

12                  “(iii) all monograph drug development  
13                  and review activities, including intra-agen-  
14                  cy collaboration;

15                  “(iv) regulation and policy develop-  
16                  ment activities related to monograph  
17                  drugs;

18                  “(v) development of product standards  
19                  for drugs subject to review and evaluation;

20                  “(vi) meetings regarding monograph  
21                  drug activities;

22                  “(vii) review of labeling prior to  
23                  issuance of orders related to monograph  
24                  drugs or conditions of use; and

1 “(viii) regulatory science activities re-  
2 lated to monograph drugs;

3 “(B) inspections related to monograph  
4 drugs;

5 “(C) monitoring of clinical and other re-  
6 search conducted in connection with monograph  
7 drugs;

8 “(D) safety activities with respect to mono-  
9 graph drugs, including—

10 “(i) collecting, developing, and review-  
11 ing safety information on monograph  
12 drugs, including adverse event reports;

13 “(ii) developing and using improved  
14 adverse event data-collection systems, in-  
15 cluding information technology systems;  
16 and

17 “(iii) developing and using improved  
18 analytical tools to assess potential safety  
19 risks, including access to external data-  
20 bases; and

21 “(E) other activities necessary for imple-  
22 mentation of section 505G.

23 “(7)(A) The term ‘monograph drug facility’  
24 means a foreign or domestic business or other enti-  
25 ty—

1           “(i) that is under one management, either  
2           direct or indirect;

3           “(ii) at one geographic location or address  
4           engaged in manufacturing or processing a  
5           monograph drug in finished dosage form;

6           “(iii) includes a finished dosage form man-  
7           ufacturer facility or an affiliate thereof in a  
8           contractual relationship with a monograph drug  
9           requestor or requestors to manufacture or proc-  
10          ess monograph drugs; and

11          “(iv) does not include a business or other  
12          entity whose only manufacturing or processing  
13          activities relate to—

14               “(I) production of clinical research  
15               supplies;

16               “(II) testing; or

17               “(III) placement of outer overpack-  
18               aging on packages containing multiple  
19               products, for such purposes as creating  
20               multipacks, when each monograph drug  
21               product contained within the overpack-  
22               aging is already in a final packaged form  
23               prior to placement in the outer overpack-  
24               aging.

1           “(B) For purposes of subparagraph (A), sepa-  
2           rate buildings or locations within close proximity are  
3           considered to be at 1 geographic location or address  
4           if the activities conducted in them are—

5                   “(i) closely related to the same business  
6           enterprise;

7                   “(ii) under the supervision of the same  
8           local management; and

9                   “(iii) under a single firm establishment  
10          identifier and capable of being inspected by the  
11          Food and Drug Administration during a single  
12          inspection.

13          “(C) If a business or other entity would meet  
14          the definition of a facility under this paragraph but  
15          for being under multiple management, the business  
16          or other entity is deemed to constitute multiple fa-  
17          cilities, one per management entity, for purposes of  
18          this paragraph.

19          “(8) The term ‘monograph drug meeting’  
20          means any meeting regarding the content of a pro-  
21          posed monograph drug order request.

22          “(9) The term ‘monograph drug product’  
23          means a monograph drug product that is marketed  
24          without an approved new drug application in accord-  
25          ance with section 505G.

1           “(10) The term ‘monograph drug order request’  
2           means a request for an order under section 505G for  
3           the issuance of an administrative order for a change  
4           to the monograph drug product.

5           “(11) The term ‘monograph drug requestor’  
6           means an entity submitting a monograph drug order  
7           request or a monograph drug meeting request or any  
8           other inquiry relating to a request for an order or  
9           development of a monograph drug order request.

10          “(12) The term ‘person’ includes an affiliate  
11          thereof.

12          “(13) The term ‘Tier 1 monograph drug order  
13          request’ means any monograph drug order request  
14          not determined to be a Tier 2 monograph drug order  
15          request.

16          “(14)(A) The term ‘Tier 2 monograph drug  
17          order request’ means, subject to subparagraph (B),  
18          a monograph drug order request for—

19               “(i) the reordering of existing information  
20               in the drug facts label of a monograph drug  
21               product;

22               “(ii) the addition of information to the  
23               other information section of the drug facts label  
24               of a nonprescription drug product, as limited by



1 part 201.66(c)(7) of title 21, Code of Federal  
2 Regulations;

3 “(iii) modification to the directions for use  
4 section of the drug facts label of a nonprescrip-  
5 tion drug product, if such changes conform to  
6 changes made pursuant to section 505G(d);

7 “(iv) the standardization of the concentra-  
8 tion or dose of a specific finalized ingredient  
9 within a particular finalized monograph;

10 “(v) a change to ingredient nomenclature  
11 to align with nomenclature of a standards-set-  
12 ting organization; or

13 “(vi) addition of an interchangeable term  
14 in accordance with part 330.1 of title 21, Code  
15 of Federal Regulations (or any successor regu-  
16 lation).

17 “(B) The Secretary may, based on program im-  
18 plementation experience or other factors found ap-  
19 propriate by the Secretary, characterize any mono-  
20 graph drug order request as a Tier 2 monograph  
21 drug order request (including recategorizing a re-  
22 quest from Tier 1 to Tier 2) and publish such deter-  
23 mination in a proposed order issued pursuant to sec-  
24 tion 505G(c).

1 **“SEC. 744L-1. AUTHORITY TO ASSESS AND USE MONO-**  
2 **GRAPH DRUG FEES.**

3 “(a) TYPES OF FEES.—Beginning with fiscal year  
4 2019, the Secretary shall assess and collect fees in accord-  
5 ance with this section as follows:

6 “(1) FACILITY FEE.—

7 “(A) IN GENERAL.—Except as provided in  
8 subparagraph (B), each person that owns a fa-  
9 cility identified as a monograph drug facility on  
10 December 31 of the fiscal year or at any time  
11 during the preceding 12-month period shall be  
12 assessed an annual fee for each such facility as  
13 determined under subsection (c).

14 “(B) EXCEPTION.—

15 “(i) IN GENERAL.—A fee shall not be  
16 assessed under subparagraph (A) if the  
17 identified monograph drug facility has  
18 ceased all activities related to monograph  
19 drugs prior to the publication of the Notice  
20 under subparagraph C and has updated its  
21 registration to reflect such change under  
22 the requirements for drug establishment  
23 registration set forth in section 510.

24 “(ii) FEE AMOUNT.—The amount of  
25 the fee for a contract manufacturing orga-  
26 nization facility shall be equal to two-thirds

1 the amount of the fee for a monograph  
2 drug facility that is not a contract manu-  
3 facturing organization facility.

4 “(C) DUE DATE.—

5 “(i) FOR FIRST PROGRAM YEAR.—For  
6 fiscal year 2019, the facility fees required  
7 under subparagraph (A) shall be due 45  
8 calendar days after publication of the Fed-  
9 eral Register notice provided for under  
10 subsection (c)(4)(A).

11 “(ii) SUBSEQUENT FISCAL YEARS.—  
12 For each fiscal year after fiscal year 2019,  
13 the facility fees required under subpara-  
14 graph (A) shall be due on the later of—

15 “(I) the first business day of  
16 June of such year; or

17 “(II) the first business day after  
18 the date of enactment of an appro-  
19 priations Act providing for the collec-  
20 tion and obligation of fees under this  
21 section for such year.

22 “(2) MONOGRAPH DRUG ORDER REQUEST  
23 FEE.—

24 “(A) IN GENERAL.—Each person that sub-  
25 mits a monograph drug order request shall be

1 subject to a fee for a monograph drug order re-  
2 quest. The monograph drug order request fee  
3 under paragraph (2) shall be—

4 “(i) for a Tier 1 monograph drug  
5 order request, \$500,000, adjusted for in-  
6 flation for the fiscal year (as determined  
7 under subsection (c)(1)); and

8 “(ii) for a Tier 2 monograph drug  
9 order request other than a Tier 1 request,  
10 \$100,000 adjusted for inflation for the fis-  
11 cal year (as determined under subsection  
12 (c)(1)).

13 “(B) DUE DATE.—The monograph drug  
14 order request fees required under subparagraph  
15 (A) shall be due on the date of submission of  
16 the monograph drug order request.

17 “(C) EXCEPTION FOR CERTAIN SAFETY  
18 CHANGES.—A person who is named as the re-  
19 questor in a monograph drug order shall not be  
20 subject to a fee under subparagraph (A) if the  
21 Secretary finds that the monograph drug order  
22 request seeks to change the Drug Facts labeling  
23 of a monograph drug product in a way that  
24 would add to or strengthen—

1 “(i) a contraindication, warning, or  
2 precaution;

3 “(ii) a statement about risk associated  
4 with misuse or abuse; or

5 “(iii) an instruction about dosage and  
6 administration that is intended to increase  
7 the safe use of the monograph drug prod-  
8 uct.

9 “(D) REFUND OF FEE IF ORDER REQUEST  
10 IS RECATEGORIZED AS A TIER 2 MONOGRAPH  
11 DRUG ORDER REQUEST.—If the Secretary de-  
12 termines that a monograph drug request ini-  
13 tially characterized as Tier 1 should be re-char-  
14 acterized as a Tier 2 monograph drug order re-  
15 quest, and the requestor has paid a Tier 1 fee  
16 in accordance with subparagraph (A)(i), the  
17 Secretary shall refund the requestor the dif-  
18 ference between the Tier 1 and Tier 2 fees de-  
19 termined under subparagraphs (A)(i) and  
20 (A)(ii), respectively.

21 “(E) REFUND OF FEE IF ORDER REQUEST  
22 REFUSED FOR FILING OR WITHDRAWN BEFORE  
23 FILING.—The Secretary shall refund 75 percent  
24 of the fee paid under subparagraph (B) for any  
25 order request that is refused for filing.

1           “(F) FEES FOR ORDER REQUESTS PRE-  
2           VIOUSLY REFUSED FOR FILING OR WITHDRAWN  
3           BEFORE FILING.—A monograph drug order re-  
4           quest that was submitted but was refused for  
5           filing, or was withdrawn before being accepted  
6           or refused for filing, shall be subject to the full  
7           fee under subparagraph (A) upon being resub-  
8           mitted or filed over protest.

9           “(G) REFUND OF FEE IF ORDER REQUEST  
10          WITHDRAWN.—If an order request is withdrawn  
11          after the order request was filed, the Secretary  
12          may refund the fee or a portion of the fee if no  
13          substantial work was performed on the order  
14          request after the application was filed. The Sec-  
15          retary shall have the sole discretion to refund a  
16          fee or a portion of the fee under this subpara-  
17          graph. A determination by the Secretary con-  
18          cerning a refund under this paragraph shall not  
19          be reviewable.

20          “(3) REFUNDS.—

21               “(A) IN GENERAL.—Other than refunds  
22               under subparagraphs (D) through (G) of para-  
23               graph (2), the Secretary shall not refund any  
24               fee paid under this subsection, except as pro-  
25               vided in subparagraph (B).

1           “(B) DISPUTES CONCERNING FEES.—To  
2           qualify for the return of a fee claimed to have  
3           been paid in error under this paragraph, a per-  
4           son shall submit to the Secretary a written re-  
5           quest justifying such return within 180 cal-  
6           endar days after such fee was paid.

7           “(b) FEE REVENUE AMOUNTS.—

8           “(1) FISCAL YEAR 2019.—For fiscal year 2019,  
9           fees under subsection (a)(1) shall be established to  
10          generate a total facility fee revenue amount equal to  
11          the sum of—

12           “(A) the annual base revenue for fiscal  
13          year 2019 (as determined under paragraph  
14          (3));

15           “(B) the dollar amount equal to the oper-  
16          ating reserve adjustment for the fiscal year, if  
17          applicable (as determined under subsection  
18          (c)(2)); and

19           “(C) additional direct cost adjustments (as  
20          determined under subsection (c)(3)).

21           “(2) SUBSEQUENT FISCAL YEARS.—For each of  
22          the fiscal years 2020 through 2023, fees under sub-  
23          section (a)(1) shall be established to generate a total  
24          facility fee revenue amount equal to the sum of—

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

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

6 “(C) the dollar amount equal to the oper-  
7 ating reserve adjustment for the fiscal year, if  
8 applicable (as determined under subsection  
9 (c)(2));

10 “(D) additional direct cost adjustments (as  
11 determined under subsection (c)(3)); and

12 “(E) additional dollar amounts for each  
13 fiscal year as follows:

14 “(i) \$7,000,000 for fiscal year 2020.

15 “(ii) \$6,000,000 for fiscal year 2021.

16 “(iii) \$7,000,000 for fiscal year 2022.

17 “(iv) \$3,000,000 for fiscal year 2023.

18 “(3) ANNUAL BASE REVENUE.—For purposes  
19 of paragraphs (1)(A) and (2)(A), the dollar amount  
20 of the annual base revenue for a fiscal year shall  
21 be—

22 “(A) for fiscal year 2019, \$8,000,000; and

23 “(B) for fiscal years 2020 through 2023,  
24 the dollar amount of the total revenue amount  
25 established under this subsection for the pre-



1           vious fiscal year, not including any adjustments  
2           made under subsection (c)(2) or (c)(3).

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

4           “(1) INFLATION ADJUSTMENT.—

5                 “(A) IN GENERAL.—For purposes of sub-  
6           section (b)(2)(B), the dollar amount of the in-  
7           flation adjustment to the annual base revenue  
8           for fiscal year 2020 and each subsequent fiscal  
9           year shall be equal to the product of—

10                   “(i) such annual base revenue for the  
11                   fiscal year under subsection (b)(2); and

12                   “(ii) the inflation adjustment percent-  
13                   age under subparagraph (B).

14           “(B) INFLATION ADJUSTMENT PERCENT-  
15           AGE.—The inflation adjustment percentage  
16           under this subparagraph for a fiscal year is  
17           equal to—

18                   “(i) for each of fiscal years 2020  
19                   through 2021, the average annual percent  
20                   change that occurred in the Consumer  
21                   Price Index for urban consumers (Wash-  
22                   ington-Baltimore, DC–MD–VA–WV; Not  
23                   Seasonally Adjusted; All items; Annual  
24                   Index) for the first 3 years of the pre-  
25                   ceding 4 years of available data; and

1 “(ii) for each of fiscal years 2022 and  
2 2023, the sum of—

3 “(I) the average annual percent  
4 change in the cost, per full-time equiv-  
5 alent position of the Food and Drug  
6 Administration, of all personnel com-  
7 pensation and benefits paid with re-  
8 spect to such positions for the first 3  
9 years of the preceding 4 fiscal years,  
10 multiplied by the proportion of per-  
11 sonnel compensation and benefits  
12 costs to total costs of monograph drug  
13 activities (as defined in subsection  
14 (a)) for the first 3 years of the pre-  
15 ceding 4 fiscal years; and

16 “(II) the average annual percent  
17 change that occurred in the Consumer  
18 Price Index for urban consumers  
19 (Washington-Baltimore, DC–MD–VA–  
20 WV; Not Seasonally Adjusted; All  
21 items; Annual Index) for the first 3  
22 years of the preceding 4 years of  
23 available data multiplied by the pro-  
24 portion of all costs other than per-  
25 sonnel compensation and benefits

1 costs to total costs of monograph drug  
2 activities for the first 3 years of the  
3 preceding 4 fiscal years.

4 “(2) OPERATING RESERVE ADJUSTMENT.—

5 “(A) For fiscal year 2019 and subsequent  
6 fiscal years, the Secretary may, in addition to  
7 adjustments under paragraphs (1) and (2), fur-  
8 ther increase the fee revenue and fees if such  
9 an adjustment is necessary to provide operating  
10 reserves of carryover user fees for monograph  
11 drug activities for the number of weeks speci-  
12 fied in subparagraph (B).

13 “(B) For each fiscal year the number of  
14 weeks of operating reserves shall be no more  
15 than—

16 “(i) 3 weeks for fiscal year 2019;

17 “(ii) 7 weeks for fiscal year 2020;

18 “(iii) 10 weeks for fiscal year 2021;

19 “(iv) 10 weeks for fiscal year 2022;

20 and

21 “(v) 10 weeks for fiscal year 2023.

22 “(C) If, for fiscal years 2020 through  
23 2023, the Secretary has carryover balances for  
24 monograph drug activities in excess of the num-  
25 ber of weeks of such operating reserves speci-

1           fied in subparagraph B, the Secretary shall re-  
2           duce such fee revenue and fees to provide for  
3           not more than the number of weeks of such op-  
4           erating reserves specified in subparagraph  
5           (B)(v).

6           “(D) If an adjustment under this para-  
7           graph is made, the rationale for the amount of  
8           the increase or decrease (as applicable) in fee  
9           revenue and fees shall be contained in the an-  
10          nual Federal Register notice under paragraph  
11          (5) establishing fee revenue and fees for the fis-  
12          cal year involved.

13          “(3) ADDITIONAL DIRECT COST ADJUST-  
14          MENT.—The Secretary shall, in addition to adjust-  
15          ments under paragraphs (1) and (2), further in-  
16          crease the fee revenue by an amount equal to—

17               “(A) 14,000,000 for fiscal year 2019;

18               “(B) 7,000,000 for fiscal year 2020;

19               “(C) 4,000,000 for fiscal year 2021;

20               “(D) 3,000,000 for fiscal year 2022; and

21               “(E) 3,000,000 for fiscal year 2023.

22          “(4) ANNUAL FEE SETTING.—

23               “(A) FISCAL YEAR 2019.—The Secretary  
24          shall, not later than January 31, 2019—

1 “(i) establish monograph drug facility  
2 fees for fiscal year 2019 under subsection  
3 (a)(1), based on the revenue amount for  
4 such year under subsection (b) and the ad-  
5 justments provided under this subsection;  
6 and

7 “(ii) publish such fee revenue and fa-  
8 cility fees in the Federal Register.

9 “(B) SUBSEQUENT FISCAL YEARS.—The  
10 Secretary shall, not later than January 31 of  
11 each fiscal year that begins after September 30,  
12 2019, establish for each such fiscal year, based  
13 on the revenue amounts under subsection (b)  
14 and the adjustments provided under this sub-  
15 section—

16 “(i) monograph drug facility fees  
17 under subsection (a)(1);

18 “(ii) monograph drug order request  
19 fees under subsection (a)(2); and

20 “(iii) publish such fee revenue, facility  
21 fees, and monograph drug order request  
22 fees in the Federal Register.

23 “(d) IDENTIFICATION OF FACILITIES.—Each person  
24 that owns a monograph drug facility shall submit to the

1 Secretary the information required under this subsection  
2 each year. Such information shall, for each fiscal year—

3 “(1) be submitted as part of the requirements  
4 for drug establishment registration set forth in sec-  
5 tion 510; and

6 “(2) include for each such facility, at a min-  
7 imum, identification of the facility’s business oper-  
8 ation as that of a monograph drug facility.

9 “(e) EFFECT OF FAILURE TO PAY FEES.—

10 “(1) IN GENERAL.—A monograph drug order  
11 request submitted by a person subject to fees under  
12 subsection (a) shall be considered incomplete and  
13 shall not be accepted for filing by the Secretary until  
14 all fees owed by such person have been paid.

15 “(2) EFFECT ON ELIGIBILITY FOR MEET-  
16 INGS.—If a monograph drug requestor fails to pay  
17 a fee assessed under subsection (a), the requestor  
18 shall be considered ineligible for monograph drug  
19 meetings.

20 “(f) MONOGRAPH DRUG FACILITY FEE.—Failure to  
21 pay the fee under subsection (a)(1) within 20 calendar  
22 days of the due date as specified in subparagraph (D) of  
23 such subsection shall result in the Secretary placing the  
24 facility on a publicly available arrears list until such fee  
25 has been paid.

1 “(g) CREDITING AND AVAILABILITY OF FEES.—

2 “(1) IN GENERAL.—Fees authorized under sub-  
3 section (a) shall be collected and available for obliga-  
4 tion only to the extent and in the amount provided  
5 in advance in appropriations Acts. Such fees are au-  
6 thorized to remain available until expended. Such  
7 sums as may be necessary may be transferred from  
8 the Food and Drug Administration salaries and ex-  
9 penses appropriation account without fiscal year lim-  
10 itation to such appropriation account for salaries  
11 and expenses with such fiscal year limitation. The  
12 sums transferred shall be available solely for mono-  
13 graph drug activities.

14 “(2) COLLECTIONS AND APPROPRIATION  
15 ACTS.—

16 “(A) IN GENERAL.—Subject to subpara-  
17 graph (C), the fees authorized by this section  
18 shall be collected and available in each fiscal  
19 year in an amount not to exceed the amount  
20 specified in appropriation Acts, or otherwise  
21 made available for obligation, for such fiscal  
22 year.

23 “(B) USE OF FEES AND LIMITATION.—  
24 The fees authorized by this section shall be  
25 available to defray increases in the costs of the

1 resources allocated for monograph drug activi-  
2 ties (including increases in such costs for an ad-  
3 ditional number of full-time equivalent positions  
4 in the Department of Health and Human Serv-  
5 ices to be engaged in such activities), only if the  
6 Secretary allocates for such purpose an amount  
7 for such fiscal year (excluding amounts from  
8 fees collecting under this section) no less than  
9 \$12,000,000, multiplied by the adjustment fac-  
10 tor applicable to the fiscal year involved.

11 “(C) COMPLIANCE.—The Secretary shall  
12 be considered to have met the requirements of  
13 subparagraph (B) in any fiscal year if the costs  
14 funded by appropriations and allocated for the  
15 monograph drug activities are not more than 15  
16 percent below the level specified in such sub-  
17 paragraph.

18 “(D) PROVISION FOR EARLY PAYMENTS IN  
19 SUBSEQUENT YEARS.—Payment of fees author-  
20 ized under this section for a fiscal year (after  
21 fiscal year 2019), prior to the due date for such  
22 fees, may be accepted by the Secretary in ac-  
23 cordance with authority provided in advance in  
24 a prior year appropriations Act.



1 “(3) AUTHORIZATION OF APPROPRIATIONS.—

2 For each of the fiscal years 2019 through 2023,

3 there is authorized to be appropriated for fees under

4      this section an amount equal to the total amount of

5 fees assessed for such fiscal year under this section.

6 “(h) COLLECTION OF UNPAID FEES.—In any case

7 where the Secretary does not receive payment of a fee as-

8 sessed under subsection (a) within 30 calendar days after

9 it is due, such fee shall be treated as a claim of the United

10 States Government subject to subchapter II of chapter 37

11 of title 31.

12      “(i) CONSTRUCTION.—This section may not be con-

13 strued to require that the number of full-time equivalent

14 positions in the Department of Health and Human Serv-

15 ices, for officers, employers, and advisory committees not

16 engaged in monograph drug activities, be reduced to offset

17 the number of officers, employees, and advisory commit-

18    tees so engaged.

19 **“SEC. 744L-2. REAUTHORIZATION; REPORTING REQUIRE-**

20                      MENTS.

21 “(a) PERFORMANCE REPORT.—Beginning with fiscal

22 year 2019, and not later than 120 calendar days after the

23 end of each fiscal year thereafter for which fees are col-

24 lected under this part, the Secretary shall prepare and

25 submit to the Committee on the Health, Education,

1 Labor, and Pensions of the Senate and the Committee on  
2 Energy and Commerce of the House of Representatives  
3 a report concerning the progress of the Food and Drug  
4 Administration in achieving the goals identified in the let-  
5 ters described in section 201 of the Over-the-Counter  
6 Drug Safety, Innovation, and Reform Act during such fis-  
7 cal year and the future plans of the Food and Drug Ad-  
8 ministration for meeting such goals.

9 “(b) FISCAL REPORT.—Not later than 120 calendar  
10 days after the end of fiscal year 2019 and each subsequent  
11 fiscal year for which fees are collected under this part,  
12 the Secretary shall prepare and submit to the Committee  
13 on Health, Education, Labor, and Pensions of the Senate  
14 and the Committee on Energy and Commerce of the  
15 House of Representatives a report on the implementation  
16 of the authority for such fees during such fiscal year and  
17 the use, by the Food and Drug Administration, of the fees  
18 collected for such fiscal year.

19 “(c) PUBLIC AVAILABILITY.—The Secretary shall  
20 make the reports required under subsections (a) and (b)  
21 available to the public on the internet website of the Food  
22 and Drug Administration.

23 “(d) REAUTHORIZATION.—

24 “(1) CONSULTATION.—In developing rec-  
25 ommendations to present to Congress with respect to

1 the goals described in subsection (a), and plans for  
2 meeting the goals, for monograph drug activities for  
3 the first 5 fiscal years after fiscal year 2023, and for  
4 the reauthorization of this part for such fiscal years,  
5 the Secretary shall consult with—

6 “(A) the Committee on Health, Education,  
7 Labor, and Pensions of the Senate;

8 “(B) the Committee on Energy and Com-  
9 merce of the House of Representatives;

10 “(C) scientific and academic experts;

11 “(D) health care professionals;

12 “(E) representatives of patient and con-  
13 sumer advocacy groups; and

14 “(F) the regulated industry.

15 “(2) PUBLIC REVIEW OF RECOMMENDA-  
16 TIONS.—After negotiations with the regulated indus-  
17 try, the Secretary shall—

18 “(A) present the recommendations devel-  
19 oped under paragraph (1) to the congressional  
20 committees specified in such paragraph;

21 “(B) publish such recommendations in the  
22 Federal Register;

23 “(C) provide for a period of 30 calendar  
24 days for the public to provide written comments  
25 on such recommendations;

1           “(D) hold a meeting at which the public  
2           may present its views on such recommenda-  
3           tions; and

4           “(E) after consideration of such public  
5           views and comments, revise such recommenda-  
6           tions as necessary.

7           “(3) TRANSMITTAL OF RECOMMENDATIONS.—  
8           Not later than January 15, 2023, the Secretary  
9           shall transmit to Congress the revised recommenda-  
10          tions under paragraph (2), a summary of the views  
11          and comments received under such paragraph, and  
12          any changes made to the recommendations in re-  
13          sponse to such views and comments.”.