

115TH CONGRESS  
2D SESSION

# 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.

---

## IN THE SENATE OF THE UNITED STATES

JANUARY 17, 2018

Mr. ISAKSON (for himself and Mr. CASEY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

## A BILL

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.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

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, an active in-  
15           ingredient, or a combination of active ingredients that  
16           is not subject to section 503(b)(1).

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

4           “(3) SPONSOR.—The term ‘sponsor’ means a  
5 person or group of persons marketing, manufac-  
6 turing, or processing a drug and who has a listing  
7 in effect under section 510(j) for such drug.

8           “(b) MONOGRAPH DRUGS.—

9           “(1) IN GENERAL.—With respect to a non-  
10 prescription drug that, on or after the date of enact-  
11 ment of the Over-the-Counter Drug Safety, Innova-  
12 tion, and Reform Act, is introduced or delivered for  
13 introduction in interstate commerce for which an ap-  
14 proved application under section 505 is not required,  
15 the following shall apply:

16           “(A) A nonprescription drug is deemed to  
17 be generally recognized as safe and effective  
18 within the meaning of section 201(p)(1) and  
19 not a new drug under section 201(p) if—

20           “(i)(I) such drug is—

21                   “(aa)(AA) subject to a final  
22 monograph issued under part  
23 330 of title 21, Code of Federal  
24 Regulations, as of the date of en-  
25 actment of the Over-the-Counter

1 Drug Safety, Innovation, and Re-  
2 form Act;

3 “(BB) in conformity with  
4 the conditions for nonprescription  
5 use of such monograph and the  
6 general requirements specified  
7 for nonprescription drugs, includ-  
8 ing any modifications to those  
9 conditions made under sub-  
10 sections (c), (d), and (j); and

11 “(CC) except as permitted  
12 by an administrative order issued  
13 under subsection (c) or a minor  
14 change in the drug in conformity  
15 with subsection (d), is in a dos-  
16 age form that has been used to a  
17 material extent and for a mate-  
18 rial time within the meaning of  
19 section 201(p)(2); or

20 “(bb)(AA) the subject of a  
21 tentative final monograph that is  
22 the most recently applicable pro-  
23 posal or determination issued  
24 under part 330 of title 21, Code  
25 of Federal Regulations, as of the

1 date of enactment of the Over-  
2 the-Counter Drug Safety, Inno-  
3 vation, and Reform Act;

4 “(BB) classified in category  
5 I for safety and effectiveness  
6 under such tentative final mono-  
7 graph;

8 “(CC) in conformity with  
9 the conditions for nonprescription  
10 use of such tentative final mono-  
11 graph, any subsequent deter-  
12 mination by the Secretary, and  
13 the general conditions for non-  
14 prescription drugs, including any  
15 modifications of those conditions  
16 under subsections (c), (d), and  
17 (j); and

18 “(DD) except as permitted  
19 by an administrative order issued  
20 under subsection (c) or a minor  
21 change in the drug in conformity  
22 with subsection (d), is in a dos-  
23 age form that has been used to a  
24 material extent and for a mate-

1                   rial time within the meaning of  
2                   section 201(p)(2); or

3                   “(II) the active ingredient in such  
4 drug is in conformity with—

5                   “(aa) the requirements of a final  
6 administrative order issued under sub-  
7 section (c) determining that such drug  
8 under the specific conditions of use is  
9 generally recognized as safe and effec-  
10 tive within the meaning of section  
11 201(p)(1); and

12                   “(bb) the general requirements  
13 for nonprescription drugs, including  
14 any modifications of the requirements  
15 under subsections (c), (d), and (j);  
16 and

17                   “(ii) such drug is—

18                   “(I) not classified in Category II  
19 for safety or effectiveness under a ten-  
20 tative final monograph; or

21                   “(II) determined by the Sec-  
22 retary to be not safe and effective, in  
23 a final monograph or preamble to a  
24 rule that is the most recently applica-  
25 ble proposal or determination issued

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

3 “(B) A nonprescription drug may be intro-  
4 duced into interstate commerce if such drug  
5 is—

6 “(i)(I) not classified in Category II  
7 for safety or effectiveness under a tentative  
8 final monograph; or

9 “(II) determined by the Secretary to  
10 be not safe and effective, in a final mono-  
11 graph or preamble to a rule that is the  
12 most recently applicable proposal or deter-  
13 mination issued under part 330 of title 21,  
14 Code of Federal Regulations; and

15 “(ii)(I)(aa) the subject of a tentative  
16 final monograph that is the most recently  
17 applicable proposal or determination issued  
18 under part 330 of title 21, Code of Federal  
19 Regulations;

20 “(bb) classified in category III for  
21 safety or effectiveness in the preamble of a  
22 proposed rule establishing such tentative  
23 final monograph;

24 “(cc) in conformity with the most re-  
25 cently proposed or final rule establishing or

1 proposing conditions of nonprescription use  
2 published in the Federal Register related  
3 to such tentative final monograph and the  
4 general requirements for nonprescription  
5 drugs, including any modifications of those  
6 requirements under subsections (c) and (j);  
7 and

8 “(dd) in a dosage form that has been  
9 used to a material extent and for a mate-  
10 rial time within the meaning of section  
11 201(p)(2); or

12 “(II)(aa) the subject of a proposed  
13 monograph or advance notice of proposed  
14 rulemaking that is the most recently appli-  
15 cable proposal or determination issued  
16 under part 330 of title 21, Code of Federal  
17 Regulations;

18 “(bb) classified in category I for safe-  
19 ty and effectiveness under such proposed  
20 monograph or advance notice of proposed  
21 rulemaking;

22 “(cc) in conformity with the most re-  
23 cently proposed or final rule establishing or  
24 proposing conditions of nonprescription use  
25 published in the Federal Register related

1 to such proposed monograph or advance  
2 notice of proposed rulemaking and the gen-  
3 eral requirements for nonprescription  
4 drugs, including any modifications of those  
5 requirements under subsections (c) and (j);  
6 and

7 “(dd) in a dosage form that has been  
8 used to a material extent and for a mate-  
9 rial time within the meaning of section  
10 201(p)(2).

11 “(C) A nonprescription drug may be intro-  
12 duced into interstate commerce if—

13 “(i) such drug is classified in category  
14 II for safety or effectiveness under a ten-  
15 tative final monograph, or the Secretary  
16 has determined such drug not to be safe  
17 and effective in a final monograph or pre-  
18 amble to a rule that is the most recently  
19 applicable proposal or determination issued  
20 under part 330 of title 21, Code of Federal  
21 Regulations; and

22 “(ii) the Secretary determines within  
23 6 months of the date of enactment of the  
24 Over-the-Counter Drug Safety, Innovation,  
25 and Reform Act, that it is in the interest

1 of public health to extend the period dur-  
2 ing which the drug may be marketed with-  
3 out an approved new drug application  
4 under section 505.

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

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

23 “(A) not described in subparagraph (A),  
24 (B), or (D) of paragraph (1) and not in con-  
25 formity with subsection (d);

1           “(B) not subject to an administrative final  
2 order pursuant to subsection (c); or

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

7           “(3) MONOGRAPH DRUG.—A nonprescription  
8 drug that is in compliance with paragraph (1) shall  
9 be referred to in this section as a ‘monograph drug’.

10          “(4) RULES OF CONSTRUCTION.—

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

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

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

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

1           “(C) NO EFFECT ON OTHER AUTHORI-  
2           TIES.—Nothing in this subsection shall be con-  
3           strued to prohibit the Secretary from issuing an  
4           order under this section finding a drug to be  
5           not generally recognized as safe and effective.

6           “(c) ADMINISTRATIVE ORDERS.—

7           “(1) IN GENERAL.—

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

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

18                   “(ii) generally recognized as safe and  
19                   effective within the meaning of section  
20                   201(p)(1); and

21                   “(iii) not required to be approved  
22                   under section 505.

23           “(B) NOT GENERALLY RECOGNIZED AS  
24           SAFE AND EFFECTIVE.—The Secretary shall  
25           issue an order determining that a drug is not

1 generally recognized as safe and effective within  
2 the meaning of section 201(p)(1) for the speci-  
3 fied requirements if, after substantive review of  
4 evidence, the Secretary determines that—

5 “(i) the evidence shows that the drug  
6 is not generally recognized as safe and ef-  
7 fective within the meaning of section  
8 201(p)(1); or

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

13 “(2) NONAPPLICATION OF CERTAIN REQUIRE-  
14 MENTS.—The requirements of subchapter II of  
15 chapter 5 of title 5, United States Code, shall not  
16 apply with respect to administrative orders issued  
17 under this section.

18 “(3) ADMINISTRATIVE ORDERS INITIATED BY  
19 THE SECRETARY; CITIZEN PETITIONS.—

20 “(A) IN GENERAL.—Except as provided in  
21 paragraph (5), in issuing an administrative  
22 order under paragraph (1) on the initiative of  
23 the Secretary, the Secretary shall—

24 “(i) not later than 2 business days be-  
25 fore issuance of the proposed order, infor-

1 mally communicate the pending issuance of  
2 the order to sponsors of drugs that will be  
3 subject to such order;

4 “(ii) after making any such informal  
5 communication—

6 “(I) issue such a proposed ad-  
7 ministrative order by publishing it on  
8 the internet website of the Food and  
9 Drug Administration and include in  
10 such order the reasons for the  
11 issuance of such order; and

12 “(II) publish notice of availability  
13 of such proposed order in the Federal  
14 Register;

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

19 “(iv) if, after satisfying the require-  
20 ments of clauses (i) through (iii), the Sec-  
21 retary determines that it is appropriate to  
22 issue a final administrative order—

23 “(I) issue the final administrative  
24 order, together with a detailed state-  
25 ment of reasons, but such order shall

1 not take effect until the time for re-  
2 requesting judicial review under para-  
3 graph (4)(D)(ii) has expired;

4 “(II) publish a notice of avail-  
5 ability of such final administrative  
6 order in the Federal Register;

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

18 “(IV) except with respect to  
19 drugs described in paragraph (4)(B),  
20 upon completion of the formal dispute  
21 resolution procedure, inform the per-  
22 son or persons which sought such dis-  
23 pute resolution of their right to re-  
24 quest a hearing.

1           “(B) SPECIAL REQUIREMENTS WITH RE-  
2           SPECT TO CERTAIN MONOGRAPH DRUGS.—  
3           When issuing an administrative order under  
4           paragraph (1) on the initiative of the Secretary  
5           (except as provided under paragraph (5)) pro-  
6           posing to determine that a monograph drug de-  
7           scribed in subsection (b)(1)(B) is not generally  
8           recognized as safe and effective within the  
9           meaning of section 201(p)(1), the Secretary  
10          shall follow the procedures in subparagraph (A)  
11          except that—

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

14                           “(I) the general categories of  
15                           data the Secretary has determined  
16                           necessary to establish that the drug is  
17                           generally recognized as safe and effec-  
18                           tive within the meaning of section  
19                           201(p)(1); and

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

22                           “(ii) the Secretary shall provide for a  
23                           public comment period of not less than 180  
24                           calendar days with respect to such pro-  
25                           posed order, except when the Secretary de-

1 termines, for good cause, that a shorter pe-  
2 riod is in the interest of public health; and

3 “(iii) any person who submits data in  
4 such comment period shall include a cer-  
5 tification that the person has submitted all  
6 evidence created, obtained, or received by  
7 that person that is both within the cat-  
8 egories of data identified in the proposed  
9 order and relevant to a determination as to  
10 whether the drug is generally recognized as  
11 safe and effective within the meaning of  
12 section 201(p)(1).

13 “(C) CITIZEN PETITIONS.—

14 “(i) IN GENERAL.—The Secretary  
15 may issue an administrative order under  
16 paragraph (1) in response to a citizen peti-  
17 tion submitted under section 10.30 of title  
18 21, Code of Federal Regulations (or any  
19 successor regulation), subject to clause (ii).

20 “(ii) EFFECT OF PETITION.—Nothing  
21 in clause (i) shall be construed to provide  
22 an alternative to, or otherwise supplant or  
23 supersede—

24 “(I) the processes through which  
25 a requestor may seek an administra-

1                   tive order pursuant to paragraph (6);

2                   or

3                   “(II) the fee structure under sec-  
4                   tion 744L-1(a)(2).

5                   “(4) HEARINGS; JUDICIAL REVIEW.—

6                   “(A) IN GENERAL.—A person who partici-  
7                   pated in each level of formal dispute resolution  
8                   under paragraph (3)(A)(iv)(III) of an adminis-  
9                   trative order with respect to a drug may re-  
10                  quest a hearing concerning a final administra-  
11                  tive order issued under paragraph (3)(A)(iv)  
12                  with respect to such drug. Such person may  
13                  submit a request for a hearing, which shall be  
14                  based solely on the information in the adminis-  
15                  trative record, to the Secretary not later than  
16                  30 calendar days after receiving notice of the  
17                  final decision of the formal dispute resolution  
18                  procedure.

19                  “(B) NO HEARING REQUIRED WITH RE-  
20                  SPECT TO ORDERS RELATING TO CERTAIN  
21                  DRUGS.—The Secretary is not required to pro-  
22                  vide notice and an opportunity for a hearing  
23                  pursuant to paragraph (3)(A)(iv) if the final  
24                  administrative order involved relates to a  
25                  drug—

1           “(i) that is described in subclause (I)  
2 or (II) of subsection (b)(1)(B)(i); and

3           “(ii) with respect to which no data  
4 relevant to the safety or effectiveness of  
5 such drug have been submitted to the ad-  
6 ministrative record since the issuance of  
7 the most recent tentative final monograph  
8 relating to such drug (or, as applicable,  
9 since the deeming of such tentative final  
10 monograph as a final administrative order  
11 under paragraph (7)).

12           “(C) HEARING PROCEDURES.—

13           “(i) DENIAL OF REQUEST FOR HEAR-  
14 ING.—If the Secretary determines that a  
15 request for a hearing under subparagraph  
16 (A) with respect to a final administrative  
17 order issued under paragraph (3)(A)(iv),  
18 does not establish the existence of a gen-  
19 uine and substantial question of material  
20 fact, the Secretary may deny such request.  
21 In making such a determination, the Sec-  
22 retary may consider only information and  
23 data that are based on relevant and reli-  
24 able scientific principles and methodolo-  
25 gies.

1           “(ii) SINGLE HEARING FOR MULTIPLE  
2 RELATED REQUESTS.—If more than one  
3 request for a hearing is submitted with re-  
4 spect to the same administrative order  
5 under subparagraph (A), the Secretary  
6 may direct that a single hearing be con-  
7 ducted in which all persons whose hearing  
8 requests were granted may participate.

9           “(iii) PRESIDING OFFICER.—The Sec-  
10 retary shall appoint a presiding officer of  
11 a hearing requested under subparagraph  
12 (A) who—

13                 “(I) is not an employee of the  
14 Center for Drug Evaluation and Re-  
15 search; and

16                 “(II) has not previously been in-  
17 volved in the development of the appli-  
18 cable administrative order or in the  
19 proceedings relating to that adminis-  
20 trative order.

21           “(iv) RIGHTS OF PARTIES TO HEAR-  
22 ING.—The parties to a hearing requested  
23 under subparagraph (A) shall have the  
24 right to present testimony, including testi-  
25 mony of expert witnesses, and to cross-ex-

1 amine witnesses presented by other parties.  
2 Where appropriate, the presiding officer  
3 may require that cross-examination by par-  
4 ties representing substantially the same in-  
5 terests be consolidated to promote effi-  
6 ciency and avoid duplication.

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

17 “(D) JUDICIAL REVIEW OF FINAL ADMIN-  
18 ISTRATIVE ORDER.—

19 “(i) IN GENERAL.—The procedures  
20 described in section 505(h) shall apply  
21 with respect to judicial review of final ad-  
22 ministrative orders issued under this sub-  
23 section in the same manner and to the  
24 same extent as such section applies to an  
25 order described in such section except that

1 the judicial review shall be taken by filing  
2 in an appropriate district court of the  
3 United States in lieu of the appellate  
4 courts specified in such section.

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

13 “(I) the date on which notice of  
14 such order is published;

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

18 “(III) the date on which a final  
19 decision is made following any hearing  
20 with respect to such order under sub-  
21 paragraph (C)(v); or

22 “(IV) if no hearing is requested,  
23 the date on which the time for re-  
24 questing a hearing expires.

1           “(5) EXPEDITED PROCEDURE WITH RESPECT  
2 TO ADMINISTRATIVE ORDERS INITIATED BY THE  
3 SECRETARY.—

4           “(A) IMMINENT HAZARD TO THE PUBLIC  
5 HEALTH.—

6           “(i) IN GENERAL.—In the case of a  
7 determination by the Secretary that a  
8 monograph drug poses an imminent hazard  
9 to the public health, the Secretary may,  
10 after informally communicating with any  
11 sponsor that will be the subject of such de-  
12 termination, not later than 48 hours before  
13 issuance of an order under this subpara-  
14 graph—

15           “(I) issue an interim final admin-  
16 istrative order for such drug or com-  
17 bination of drugs under paragraph  
18 (1), together with a detailed state-  
19 ment of the reasons for such order;

20           “(II) publish in the Federal Reg-  
21 ister a notice of availability of such  
22 order; and

23           “(III) provide for a public com-  
24 ment period of at least 45 calendar

1           days after issuance of such interim  
2           final order.

3           “(ii) NONDELEGATION.—The Sec-  
4           retary may not delegate the authority to  
5           issue an interim final administrative order  
6           under this subparagraph.

7           “(B) SAFETY LABELING CHANGES.—

8           “(i) IN GENERAL.—In the case of a  
9           determination by the Secretary that a  
10          change in the labeling of a drug, class of  
11          drugs, or combination of drugs subject to  
12          this section is reasonably expected to miti-  
13          gate a significant or unreasonable risk of  
14          a serious adverse event associated with use  
15          of the drug, the Secretary may, after infor-  
16          mally communicating with any sponsor  
17          that will be the subject of such determina-  
18          tion, not later than 48 hours before  
19          issuance of an order under this subpara-  
20          graph—

21                   “(I) issue an interim final admin-  
22                   istrative order in accordance with  
23                   paragraph (1) to require such change,  
24                   together with a detailed statement of  
25                   the reasons for such order;

1                   “(II) publish in the Federal Reg-  
2                   ister a notice of availability of such  
3                   order; and

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

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

14                  “(C) EFFECTIVE DATE.—An order under  
15                  subparagraph (A) or (B) shall take effect on a  
16                  date specified by the Secretary, which date, in  
17                  the case of an order under subparagraph (B)  
18                  that includes changes to the packaging of the  
19                  drug, shall not be earlier than the day after the  
20                  date on which the comment period described in  
21                  subparagraph (B)(i)(III) ends.

22                  “(D) FINAL ORDER.—After the completion  
23                  of the proceedings in subparagraph (A) or (B),  
24                  the Secretary shall—

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

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

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

15           “(E) HEARINGS.—

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

1           respect to a hearing on an administrative  
2           order issued under paragraph (3)(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 (4)—

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

13                     “(II) to ‘final administrative  
14                     order issued under paragraph  
15                     (3)(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 (4)(D).

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

6 “(6) 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           (3) and (4); 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 (3)(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 subpara-  
9                   graph (D), that there is an inadequate  
10                  basis to find the drug is generally recog-  
11                  nized as safe and effective under para-  
12                  graph (1) and issues a final order an-  
13                  nouncing that determination.

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 shall cease proceedings  
21                  under 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 providing the order requestor (or  
2 the licensees, assignees, or successors in  
3 interest of such requestor with respect to  
4 the subject of such order and listed under  
5 clause (v)) the exclusive right, for a period  
6 of 2 years, to market drugs under this sec-  
7 tion incorporating changes described in  
8 clause (ii), subject to the limitations under  
9 clause (iv), and beginning on the date the  
10 requestor (or any such licensees, assignees,  
11 or successors in interest of such requestor)  
12 may lawfully market such drugs pursuant  
13 to the order.

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

18 “(I) permits a drug to contain an  
19 active ingredient not previously incor-  
20 porated in a marketed drug listed in  
21 clause (iii); or

22 “(II) permits a change in the  
23 conditions of use of a drug, for which  
24 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) MARKETED DRUGS.—The mar-  
5           keted drugs listed in this clause are  
6           drugs—

7                   “(I) marketed in accordance with  
8                   a final monograph issued under part  
9                   330 of title 21, Code of Federal Regu-  
10                  lations (including conditions of use  
11                  thereunder), as in effect on the day  
12                  before the date of enactment of this  
13                  section;

14                   “(II) marketed as category I or  
15                   III in accordance with a tentative  
16                   final monograph issued under such  
17                   part 330 (including conditions of use  
18                   and any applicable subsequent deter-  
19                   minations thereunder), as so in effect;

20                   “(III) marketed as category I in  
21                   accordance with an advance notice of  
22                   proposed rulemaking issued under  
23                   such part 330 (including conditions of  
24                   use and any applicable subsequent de-

1 terminations thereunder), as so in ef-  
2 fect;

3 “(IV) marketed in accordance  
4 with a final order issued under this  
5 section; or

6 “(V) described in subsection  
7 (b)(1)(C), other than drugs subject to  
8 an active enforcement action under  
9 section 303.

10 “(iv) LIMITATIONS ON PRODUCT DIF-  
11 FERENTIATION.—

12 “(I) ONLY ONE PERIOD.—Only  
13 one 2-year period may be granted per  
14 drug under clause (i) with respect to  
15 any change described in clause (ii).

16 “(II) EXCLUSIONS.—No period  
17 of product differentiation under this  
18 subparagraph shall apply to changes  
19 to a drug that are—

20 “(aa) ‘Tier 2’ changes de-  
21 scribed in section 744L(14)(A);

22 “(bb) safety-related changes  
23 described in section 744L-  
24 1(a)(2)(C), required under para-  
25 graph (5), or any other change

1 the Secretary determines nec-  
2 essary to ensure safe use; or

3 “(cc) changes related to  
4 methods of testing safety or effi-  
5 cacy.

6 “(v) LISTING OF LICENSEES, ASSIGN-  
7 EES, OR SUCCESSORS IN INTEREST.—The  
8 requestors of an order described in clause  
9 (i) shall, as applicable, submit to the Sec-  
10 retary, at a time when a finished dosage  
11 form subject to such order is introduced or  
12 delivered for introduction into interstate  
13 commerce, a list of licensees, assignees, or  
14 successors in interest that have the exclu-  
15 sive right described in such clause.

16 “(vi) HUMAN DATA DEFINED.—For  
17 purposes of this subparagraph, the term  
18 ‘human data’ means data from clinical  
19 trials of safety or effectiveness, or phar-  
20 macokinetics or bioavailability studies.

21 “(D) INFORMATION REGARDING SAFE  
22 NONPRESCRIPTION MARKETING AND USE AS A  
23 CONDITION FOR FILING A GRASE REQUEST.—

24 “(i) IN GENERAL.—In response to a  
25 request under this paragraph that a drug

1 described in clause (ii) be generally recog-  
2 nized as safe and effective, the Secretary—

3 “(I) may file such request, if the  
4 request includes information specified  
5 under clause (iii) with respect to safe  
6 nonprescription marketing and use of  
7 such drug; or

8 “(II) if the request fails to in-  
9 clude information specified under  
10 clause (iii), shall refuse to file such re-  
11 quest and may require that non-  
12 prescription marketing of the drug be  
13 pursuant to a new drug application as  
14 described in clause (iv).

15 “(ii) DRUG DESCRIBED.—A drug de-  
16 scribed in this clause is a monograph drug  
17 that contains an active ingredient not pre-  
18 viously incorporated in a drug—

19 “(I) marketed in accordance with  
20 a final monograph issued under part  
21 330 of title 21, Code of Federal Regu-  
22 lations (including conditions of use  
23 under such part), as in effect on the  
24 day before the date of enactment of  
25 this section;

1           “(II) marketed as category I in  
2           accordance with a tentative final  
3           monograph issued under part 330 of  
4           title 21, Code of Federal Regulations  
5           (including conditions of use and any  
6           applicable subsequent determinations  
7           under such part), as in effect on the  
8           day before the date of enactment of  
9           this section; or

10           “(III) marketed in accordance  
11           with a final order issued under this  
12           section.

13           “(iii) SUFFICIENT INFORMATION FOR  
14           A THRESHOLD DEMONSTRATION OF NON-  
15           PRESCRIPTION MARKETING AND USE.—In-  
16           formation specified in this subparagraph,  
17           with respect to a request described in  
18           clause (i)(I), is—

19           “(I) information sufficient for a  
20           threshold demonstration that the drug  
21           subject to such request has a  
22           verifiable history of being marketed  
23           and safely used by consumers in the  
24           United States as a nonprescription

1 drug under comparable conditions of  
2 use;

3 “(II) if the drug has not been  
4 previously marketed in the United  
5 States as a nonprescription drug, in-  
6 formation sufficient for a threshold  
7 demonstration that the drug was mar-  
8 keted and safely used in a foreign  
9 country under conditions of marketing  
10 and use—

11 “(aa) for such period of time  
12 as needed to provide reasonable  
13 assurances concerning the safe  
14 nonprescription use of the drug;  
15 and

16 “(bb) during such period of  
17 time, was subject to sufficient  
18 monitoring by a regulatory body  
19 of any country listed in section  
20 802(b)(1)(A) or any country des-  
21 ignated by the Secretary in ac-  
22 cordance with section  
23 802(b)(1)(B); or

24 “(III) if the Secretary determines  
25 that information described in sub-

1 clause (I) or (II) is not needed to pro-  
2 vide a threshold demonstration that  
3 the drug can be safely marketed and  
4 used as a nonprescription drug, other  
5 information the Secretary determines  
6 sufficient for such purposes.

7 “(iv) MARKETING PURSUANT TO NEW  
8 DRUG APPLICATION.—In the case of a re-  
9 quest described in clause (i)(II), the drug  
10 subject to such request may be re-sub-  
11 mitted for filing only if—

12 “(I) the drug is marketed as a  
13 nonprescription drug, under condi-  
14 tions of use comparable to the re-  
15 quirements specified in the request,  
16 for such period of the time as the Sec-  
17 retary determines appropriate (not to  
18 exceed 5 consecutive years) pursuant  
19 to an application approved under sec-  
20 tion 505; and

21 “(II) during such period of time,  
22 1,000,000 retail packages of the drug,  
23 or an equivalent quantity of the active  
24 ingredient or ingredients of such drug  
25 as determined by the Secretary, were

1 distributed for retail sale, as deter-  
2 mined in such manner as the Sec-  
3 retary may require.

4 “(v) RULE OF APPLICATION.—If the  
5 Secretary refuses to file a request under  
6 this subparagraph, the requestor may not  
7 file over protest under subparagraph  
8 (A)(iii) unless the request involves a drug  
9 described in section 586(9) as in effect on  
10 January 1, 2017.

11 “(7) TREATMENT OF FINAL AND TENTATIVE  
12 FINAL MONOGRAPHS.—A final monograph or ten-  
13 tative final monograph establishing requirements of  
14 use for a drug described in subsection (b)(1) shall  
15 be deemed to be a final administrative order under  
16 this subsection and may be amended, revoked, or  
17 otherwise modified in accordance with the proce-  
18 dures of this subsection.

19 “(8) PACKAGING.—

20 “(A) IN GENERAL.—An administrative  
21 order issued under paragraph (3), (5)(A), or  
22 (6) may include requirements for the packaging  
23 of a drug, such as to promote use in accordance  
24 with labeling, unit dose packaging, or require-  
25 ments to prevent accidental overdose or inges-

1           tion, misuse, or abuse, including by pediatric  
2           populations. The Secretary shall consider, as  
3           appropriate, any such nonprescription drugs  
4           currently available, and the impact of the re-  
5           moval of such drugs without such packaging  
6           and the changing of such packaging on patients  
7           and manufacturers when establishing such re-  
8           quirements.

9           “(B) EFFECTIVE DATE.—Requirements for  
10          packaging in an administrative order under  
11          paragraph (5)(B) shall not take effect earlier  
12          than the day after the date on which the com-  
13          ment period under paragraph (5)(B)(i)(III)  
14          ends.

15          “(C) CLARIFICATION.—This paragraph  
16          does not authorize the Secretary to require spe-  
17          cial packaging or child-resistant packaging  
18          under the Poison Prevention Packaging Act of  
19          1970.

20          “(d) PROCEDURE FOR MINOR CHANGES.—

21          “(1) IN GENERAL.—Minor changes in the dos-  
22          age form of a drug that is described in clause  
23          (i)(I)(aa)(CC) or (ii) of subsection (b)(1)(A) may be  
24          made by a requestor without the issuance of an ad-  
25          ministrative order under subsection (c) if—

1           “(A) the requestor maintains information  
2 necessary to demonstrate that the change—

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

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

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

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

19           “(2) ADDITIONAL INFORMATION.—

20                   “(A) ACCESS TO RECORDS.—The requestor  
21 shall submit to the Secretary, under section  
22 704(a)(4), records requested by the Secretary  
23 related to a minor change within 15 business  
24 days of receiving such request, or such longer  
25 period as the Secretary may provide. Such re-

1           quest shall be specific to a company and limited  
2           to the product and the minor change that  
3           prompted such request. Such request shall be  
4           specific to a company and limited to the prod-  
5           uct and the minor change that prompted such  
6           request.

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

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

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

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

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

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

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

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

1           may take into account special needs of popu-  
2           lations, including children.

3           “(e) INFORMATION SUBMITTED BY REQUESTORS.—

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

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

23                  “(A) the information pertains to pharma-  
24                  ceutical quality, unless such information is nec-  
25                  essary to establish standards under which a

1 drug is generally recognized as safe and effec-  
2 tive within the meaning of section 201(p)(1);

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

9 “(C) the Secretary otherwise obtains the  
10 information under subsection (d).

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 other than a  
6                   change in dosage form, which is in conformity with the  
7                   requirements under subparagraph (A) or (B) of subsection  
8                   (b)(1), shall not be subject to the requirements of sub-  
9                   section (c) or (d) with respect to such change, and shall  
10                  submit updated drug listing information for the drug in  
11                  accordance with the requirements of section 510(j) within  
12                  30 calendar days of the date on which the drug, with the  
13                  change, is first introduced or delivered for introduction  
14                  into interstate commerce.

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

1 needed to support the modification of the drug that is sub-  
2 ject to the determination under this section.

3 “(i) DEVELOPMENT ADVICE TO REQUESTORS OR  
4 SPONSORS.—

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

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

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

1       “(j) EFFECT ON EXISTING REGULATIONS GOV-  
2       ERNING NONPRESCRIPTION DRUGS.—

3               “(1) REGULATIONS OF GENERAL APPLICA-  
4       BILITY TO NONPRESCRIPTION DRUGS.—Except as  
5       provided in this subsection, nothing in this section  
6       supersedes regulations establishing general require-  
7       ments for nonprescription drugs, including regula-  
8       tions of general applicability contained in parts 201,  
9       250, and 330 of title 21, Code of Federal Regula-  
10      tions, or any successor regulations. The Secretary  
11      shall establish or modify such regulations by means  
12      of rulemaking in accordance with section 553 of title  
13      5, United States Code.

14              “(2) REGULATIONS ESTABLISHING REQUIRE-  
15      MENTS FOR SPECIFIC NONPRESCRIPTION DRUGS.—

16                      “(A) IN GENERAL.—Section 310.545 of  
17                      title 21, Code of Federal Regulations, as in ef-  
18                      fect on the date of enactment of this section,  
19                      shall be deemed to be final administrative order  
20                      under subsection (c).

21                      “(B) OTHER REGULATIONS.—Regulations  
22                      establishing requirements for specific non-  
23                      prescription drugs marketed pursuant to this  
24                      section that are in effect on the day before the  
25                      date of enactment of this section (including

1 such requirements in parts 201, 250, and 330  
2 of title 21, Code of Federal Regulations), shall  
3 be deemed to be final administrative orders  
4 under subsection (c) only as such requirements  
5 apply to monograph drugs.

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

13 “(3) WITHDRAWAL OF REGULATIONS.—The  
14 Secretary shall withdraw regulations establishing  
15 final monographs and the procedures governing the  
16 over-the-counter drug review under part 330 and  
17 other relevant parts of title 21, Code of Federal  
18 Regulations (as in effect on the day before the date  
19 of enactment of this Act), or make technical changes  
20 to such regulations to ensure conformity with appro-  
21 priate terminology and cross references, to the ex-  
22 tent needed to effectuate or harmonize the provi-  
23 sions of this section. Notwithstanding subchapter II  
24 of chapter 5 of title 5, United States Code, any such  
25 withdrawal or technical amendments shall be made

1 without public notice and comment and be effective  
2 upon publication through notice in the Federal Reg-  
3 ister (or upon such date as specified in such notice).

4 “(k) GUIDANCE.—

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

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

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

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

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

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

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

1 “(m) INAPPLICABILITY OF PAPERWORK REDUCTION  
 2 ACT.—Chapter 35 of title 44, United States Code, shall  
 3 not apply to collections of information made under this  
 4 section.”.

5 **SEC. 102. MISBRANDING.**

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

9 “(ee) If it is a nonprescription drug that is not the  
 10 subject of an application approved under section 505, and  
 11 does not comply with the requirements under section  
 12 505G.

13 “(ff) If it is a drug for which fees under section  
 14 744L–1 have been assessed but have not been paid.”.

15 **SEC. 103. CONFORMING AMENDMENTS TO THE SUNSCREEN  
 16 INNOVATION ACT.**

17 (a) REVIEW OF NONPRESCRIPTION INGREDIENTS  
 18 SUBJECT TO SUNSCREEN INNOVATION ACT.—

19 (1) PENDING SUNSCREEN INGREDIENTS.—Non-  
 20 prescription sunscreen active ingredients or combina-  
 21 tions of sunscreen active ingredients subject, on the  
 22 date of enactment of this Act, to a proposed sun-  
 23 screen order, as defined in section 586(7) of the  
 24 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
 25 360fff(7)), shall—

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

4 (B) be reviewed under section 505G of  
5 such Act upon notification of the Secretary by  
6 the sponsor that such sponsor elects to have  
7 such ingredient or combination of ingredients  
8 reviewed under such section 505G, and such  
9 proposed sunscreen order under such section  
10 586C shall be considered a proposed adminis-  
11 trative order under section 505G(c)(3)(A)(ii) of  
12 such Act.

13 (2) PENDING NONSUNSCREEN INGREDIENTS.—  
14 The sponsor of any application described in section  
15 586F of the Federal Food, Drug, and Cosmetic Act  
16 (21 U.S.C. 360fff-6) that was submitted to the Sec-  
17 retary of Health and Human Services (referred to in  
18 this section as the “Secretary”) pursuant to section  
19 330.14 of title 21, Code of Federal Regulations (as  
20 in effect on the day before the date of enactment of  
21 this Act), shall—

22 (A) notify the Secretary that the sponsor  
23 elects to withdraw such application; or

24 (B) notify the Secretary that the sponsor  
25 elects for such ingredient to be considered

1 under section 505G of the Federal Food, Drug,  
2 and Cosmetic Act, and any proposed order  
3 under such section 586F shall be considered a  
4 proposed administrative order under section  
5 505G(c)(3)(A)(ii) of that Act.

6 (3) INGREDIENTS SUBMITTED AFTER THE  
7 DATE OF ENACTMENT OF SECTION 506G.—Any in-  
8 gredient that is eligible for review under section  
9 506G of the Federal Food, Drug, and Cosmetic Act  
10 and is submitted after the date of enactment of this  
11 Act shall be considered under that section.

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

16 “(11) MEETINGS WITH SPONSORS.—A sponsor  
17 may request an individual, confidential meeting to  
18 discuss the data requirements to support a general  
19 recognition of safety and effectiveness with respect  
20 to the subject of a pending sunscreen ingredient.  
21 The Secretary shall respond within 14 calendar days  
22 of the request and schedule such meeting within 45  
23 calendar days, or within such timeline as specified in  
24 the letters described in section 201 of the Over-the-  
25 Counter Drug Safety, Innovation, and Reform Act.

1 If a sponsor requests more than one confidential  
2 meeting for the same request, the Secretary may  
3 refuse to grant an additional confidential meeting  
4 request if the Secretary determines such additional  
5 confidential meeting is not reasonably necessary for  
6 the sponsor to advance its request. The Secretary  
7 shall publish a post-meeting summary on the inter-  
8 net website of the Food and Drug Administration of  
9 any confidential meeting that does not disclose con-  
10 fidential business information. Such meetings shall  
11 not be required to comply with guidance issued by  
12 the Secretary addressing formal meetings for spon-  
13 sors of human drug applications, as defined in sec-  
14 tion 735.”.

15 (c) PRODUCT DIFFERENTIATION.—Section 586C of  
16 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
17 360fff–3) is amended by adding at the end the following:

18 “(f) PRODUCT DIFFERENTIATION.—

19 “(1) IN GENERAL.—A final sunscreen order  
20 shall have the effect of providing the order requestor  
21 (or the licensees, assignees, or successors in interest  
22 of such requestor with respect to the subject of such  
23 request and listed under paragraph (5)) the exclu-  
24 sive right, for a period of 2 years, to market a sun-  
25 screen ingredient under this section incorporating

1 changes described in paragraph (2) subject to the  
2 limitations under paragraph (4), beginning on the  
3 date the requestor (or any licensees, assignees, or  
4 successors in interest of such requestor with respect  
5 to the subject of such request and listed under para-  
6 graph (5)) may lawfully market such sunscreen in-  
7 gredient pursuant to the order.

8 “(2) CHANGES DESCRIBED.—A change de-  
9 scribed in this paragraph is a change subject to an  
10 order specified in paragraph (1) that—

11 “(A) permits a sunscreen to contain an ac-  
12 tive ingredient not previously incorporated in a  
13 marketed sunscreen listed in paragraph (3); or

14 “(B) permits a change in the conditions of  
15 use of a sunscreen ingredient, for which human  
16 data studies conducted or sponsored by the re-  
17 questor (or for which the requestor has an ex-  
18 clusive right of reference) were essential to the  
19 issuance of such order.

20 “(3) MARKETED SUNSCREEN.—The marketed  
21 sunscreen ingredients described this paragraph are  
22 sunscreen ingredients—

23 “(A) marketed in accordance with a final  
24 monograph issued under part 330 of title 21,  
25 Code of Federal Regulations (including condi-

1 tions of use thereunder), as in effect on the day  
2 before the date of enactment of this section;

3 “(B) marketed as category I or III in ac-  
4 cordance with a tentative final monograph  
5 issued under such part 330 (including condi-  
6 tions of use and any applicable subsequent de-  
7 terminations thereunder), as so in effect;

8 “(C) marketed as category I in accordance  
9 with an advance notice of proposed rulemaking  
10 issued under such part 330 (including condi-  
11 tions of use and any applicable subsequent de-  
12 terminations thereunder), as so in effect; or

13 “(D) marketed in accordance with a final  
14 order issued under this section.

15 “(4) LIMITATIONS ON PRODUCT DIFFERENTIA-  
16 TION.—

17 “(A) ONLY ONE PERIOD.—Only one 2-year  
18 period may be granted per ingredient under  
19 paragraph (1).

20 “(B) EXCLUSIONS.—No period of product  
21 differentiation under this subparagraph shall  
22 apply to changes to a sunscreen that are—

23 “(i) ‘Tier 2’ changes described in sec-  
24 tion 744L(14)(A);

1           “(ii) safety-related changes described  
2           in section 744L–1(a)(2)(C), required under  
3           section 505G(c)(5), or any other change  
4           the Secretary determines necessary to en-  
5           sure safe use; or

6           “(iii) changes related to methods of  
7           testing safety or efficacy.

8           “(5) LISTING OF LICENSEES, ASSIGNEES, OR  
9           SUCCESSORS IN INTEREST.—Requestors shall submit  
10          to the Secretary at the time when a final dosage  
11          form subject to such request is introduced or deliv-  
12          ered for introduction into interstate commerce, a list  
13          of licensees, assignees, or successors in interest that  
14          have the exclusive right described in paragraph (1).

15          “(6) HUMAN DATA DEFINED.—For purposes of  
16          this subsection, the term ‘human data’ means data  
17          from clinical trials of safety or effectiveness (includ-  
18          ing actual use studies), pharmacokinetics, or bio-  
19          availability.”.

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

24                  “(3) RELATIONSHIP TO ORDERS UNDER SEC-  
25          TION 505G.—A final sunscreen order shall be deemed

1 to be a final administrative order under section  
2 505G and subject to the applicable provisions under  
3 such section 505G, including with respect to amend-  
4 ment of such order.”.

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

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

12 (2) OPTION TO TRANSFER SUBMISSIONS TO OTC  
13 MONOGRAPH ORDER PROCESS.—

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

23 (B) REQUESTS.—A request described in  
24 this subparagraph is—

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

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

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

11 **“SEC. 586E. SUNSCREEN ORDER.**

12 “(a) IN GENERAL.—

13 “(1) REVISION OF FINAL SUNSCREEN ORDER.—

14 Not later than November 26, 2019, the Secretary  
15 shall amend and revise the final administrative order  
16 concerning nonprescription sunscreen (referred to in  
17 this section as the ‘sunscreen order’) for which the  
18 substance, prior to the date of enactment of the  
19 Over-the-Counter Drug Safety, Innovation, and Re-  
20 form Act, was represented by stayed regulations  
21 under part 352 of title 21, Code of Federal Regula-  
22 tions.

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

1                   “(A) effective not later than November 26,  
2                   2019; and

3                   “(B) issued by the Secretary at least 30  
4                   calendar days prior to such date.

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

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

23           **“SEC. 586H. SUNSET.**

24           “‘This subchapter shall no longer be effective upon  
25 the later of—

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

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

8   **SEC. 104. DRUGS EXCLUDED FROM OVER-THE-COUNTER**  
9                           **REVIEW.**

10          (a) IN GENERAL.—Nothing in this Act (or the  
11          amendments made by this Act) shall apply to any non-  
12          prescription drug which was excluded by the Food and  
13          Drug Administration from the Over-the-Counter Drug Re-  
14          view in accordance with the statement set out at page  
15          9466 of volume 37 of the Federal Register, published on  
16          May 11, 1972.

17          (b) RULE OF CONSTRUCTION.—Nothing in this sec-  
18          tion shall be construed to preclude or limit the applica-  
19          tion of any provision of the Federal Food, Drug, and  
20          Cosmetic Act.

21   **SEC. 105. CONFORMING AMENDMENT.**

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

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

1 (A) by striking “final regulation” and in-  
2 serting “final order”; and

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

4 (2) in subparagraph (A), by striking “regula-  
5 tion in effect” and inserting “regulation or order in  
6 effect”.

7 **SEC. 106. ANNUAL UPDATE TO CONGRESS ON APPRO-**  
8 **PRIATE PEDIATRIC INDICATION FOR CER-**  
9 **TAIN COUGH AND COLD MONOGRAPH DRUGS.**

10 (a) IN GENERAL.—Not later than one year after the  
11 date of enactment of this Act and annually thereafter, the  
12 Secretary of Health and Human Services (referred to in  
13 this section as the “Secretary”) shall submit to the Com-  
14 mittee on Health, Education, Labor, and Pensions of the  
15 Senate and the Committee on Energy and Commerce of  
16 the House of Representatives a letter describing the  
17 progress of the Food and Drug Administration—

18 (1) in evaluating the cough and cold monograph  
19 described in subsection (b) with respect to children  
20 under age 6; and

21 (2) as appropriate, revising such cough and cold  
22 monograph to address such children, through the ad-  
23 ministrative order process under section 505G(b) of  
24 the Federal Food, Drug, and Cosmetic Act, as  
25 added by section 101.

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

12 (c) DURATION OF AUTHORITY.—Subsection (a) shall  
13 have no force or effect beginning on the date on which  
14 the Secretary submits a letter under subsection (a) in  
15 which the Secretary indicates that the Food and Drug Ad-  
16 ministration has completed its evaluation and revised, in  
17 a final administrative order, as applicable, the cough and  
18 cold monograph in accordance with this section.

## 19 **TITLE II—FEES RELATING TO** 20 **MONOGRAPH DRUGS**

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

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

24 (b) FINDINGS.—The Congress finds that the fees au-  
25 thorized by the amendments made in this title will be dedi-

1 cated toward the regulation of monograph drugs under  
2 section 505G of the Federal, Food, Drug, and Cosmetic  
3 Act, as set forth in the goals identified for purposes of  
4 such section, in the letters from the Secretary of Health  
5 and Human Services to the Chairman of the Committee  
6 on Health, Education, Labor, and Pensions of the Senate  
7 and the Chairman of the Committee on Energy and Com-  
8 merce of the House of Representatives, as set forth in the  
9 Congressional Record.

10 **SEC. 202. AUTHORITY TO ACCESS AND USE FEES.**

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

14 **“PART 10—FEES RELATING TO MONOGRAPH**  
15 **DRUGS**

16 **“SEC. 744L. DEFINITIONS.**

17 “For purposes of this part:

18 “(1) The term ‘affiliate’ means a business enti-  
19 ty that has a relationship with a second business en-  
20 tity if, directly or indirectly—

21 “(A) one business entity controls, or has  
22 the power to control, the other business entity;  
23 or

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

1           “(2) the term ‘contract manufacturing organi-  
2           zation facility’ means a monograph drug facility  
3           where neither the owner of such manufacturing fa-  
4           cility nor any affiliate of such owner or facility sells  
5           such monograph drug produced at such facility di-  
6           rectly to wholesalers, retailers, or consumers in the  
7           United States.

8           “(3) The term ‘costs of resources allocated for  
9           monograph drug activities’ means the expenses in  
10          connection with monograph drug activities for—

11               “(A) officers and employees of the Food  
12               and Drug Administration, contractors of the  
13               Food and Drug Administration, advisory com-  
14               mittees, and costs related to such officers, em-  
15               ployees, and committees and to contracts with  
16               such contractors;

17               “(B) management of information, and the  
18               acquisition, maintenance, and repair of com-  
19               puter resources;

20               “(C) leasing, maintenance, renovation, and  
21               repair of facilities and acquisition, maintenance,  
22               and repair of fixtures, furniture, scientific  
23               equipment, and other necessary materials and  
24               supplies; and

1           “(D) collecting fees under section 744L-1  
2           and accounting for resources allocated for  
3           monograph drug activities.

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

8           “(5) The term ‘monograph drug’ shall have the  
9           meaning given the term under section 505G.

10          “(6) The term ‘monograph drug activities’  
11          means activities of the Secretary associated with  
12          monograph drug products and inspection of facilities  
13          associated with such products, including—

14               “(A) the activities necessary for review and  
15               evaluation of monograph drugs and monograph  
16               drug order requests, including—

17                       “(i) orders proposing or finalizing ap-  
18                       plicable requirements of use for monograph  
19                       drugs products;

20                       “(ii) orders affecting status regarding  
21                       general recognition of safety and effective-  
22                       ness of a monograph drug ingredient or  
23                       combination of ingredients under specified  
24                       requirements of use;

1           “(iii) all monograph drug development  
2           and review activities, including intra-agen-  
3           cy collaboration;

4           “(iv) regulation and policy develop-  
5           ment activities related to monograph  
6           drugs;

7           “(v) development of product standards  
8           for products subject to review and evalua-  
9           tion;

10          “(vi) meetings regarding monograph  
11          drug activities;

12          “(vii) review of labeling prior to  
13          issuance of orders related to monograph  
14          drugs or conditions of use; and

15          “(viii) regulatory science activities re-  
16          lated to monograph drugs;

17          “(B) inspections related to monograph  
18          drugs;

19          “(C) monitoring of clinical and other re-  
20          search conducted in connection with monograph  
21          drugs;

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

1           “(i) collecting, developing, and review-  
2           ing safety information on monograph  
3           drugs, including adverse event reports;

4           “(ii) developing and using improved  
5           adverse event data-collection systems, in-  
6           cluding information technology systems;  
7           and

8           “(iii) developing and using improved  
9           analytical tools to assess potential safety  
10          risks, including access to external data-  
11          bases; and

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

14          “(7)(A) The term ‘monograph drug facility’  
15          means a foreign or domestic business or other enti-  
16          ty—

17                 “(i) that is under one management, either  
18                 direct or indirect;

19                 “(ii) at one geographic location or address  
20                 engaged in manufacturing or processing a  
21                 monograph drug in finished dosage form;

22                 “(iii) includes a finished dosage form man-  
23                 ufacturer facility or an affiliate thereof in a  
24                 contractual relationship with a monograph drug

1 requestor or requestors to manufacture or proc-  
2 ess monograph drugs; and

3 “(iv) does not include a business or other  
4 entity whose only manufacturing or processing  
5 activities relate to—

6 “(I) production of clinical research  
7 supplies;

8 “(II) testing; or

9 “(III) packaging of packaged final  
10 dosages in a manner that does not affect  
11 the drug.

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

16 “(i) closely related to the same business  
17 enterprise;

18 “(ii) under the supervision of the same  
19 local management; and

20 “(iii) under a single firm establishment  
21 identifier and capable of being inspected by the  
22 Food and Drug Administration during a single  
23 inspection.

24 “(C) If a business or other entity would meet  
25 the definition of a facility under this paragraph but

1 for being under multiple management, the business  
2 or other entity is deemed to constitute multiple fa-  
3 cilities, one per management entity, for purposes of  
4 this paragraph.

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

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

12 “(10) The term ‘monograph drug order request’  
13 means a request for an order under section 505G for  
14 the issuance of an administrative order for a change  
15 to the monograph drug product.

16 “(11) The term ‘monograph drug requestor’  
17 means an entity submitting a monograph drug order  
18 request or a monograph drug meeting request or any  
19 other inquiry relating to a request for an order or  
20 development of a monograph drug order request.

21 “(12) The term ‘person’ includes an affiliate  
22 thereof.

23 “(13) The term ‘Tier 1 monograph drug order  
24 request’ means any monograph drug order request

1 not determined to be a Tier 2 monograph drug order  
2 request.

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

6 “(i) the reordering of existing information  
7 in the drug facts label of a monograph drug  
8 product;

9 “(ii) the addition of information to the  
10 other information section of the drug facts label  
11 of a nonprescription drug product, as limited by  
12 part 201.66(c)(7) of title 21, Code of Federal  
13 Regulations;

14 “(iii) modification to the directions for use  
15 section of the drug facts label of a nonprescrip-  
16 tion drug product, if such changes conform to  
17 changes made pursuant to section 505G(d);

18 “(iv) the standardization of the concentra-  
19 tion or dose of a specific finalized ingredient  
20 within a particular finalized monograph;

21 “(v) a change to ingredient nomenclature  
22 to align with nomenclature of a standards-set-  
23 ting organization; or

1           “(vi) addition of an interchangeable term  
2           in accordance with part 330.1 of title 21, Code  
3           of Federal Regulations.

4           “(B) The Secretary may, based on program im-  
5           plementation experience or other factors found ap-  
6           propriate by the Secretary, characterize any mono-  
7           graph drug order request as a Tier 2 monograph  
8           drug order request (including recategorizing a re-  
9           quest from Tier 1 to Tier 2) and publish such deter-  
10          mination in a proposed order issued pursuant to sec-  
11          tion 505G(c).

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

14          “(a) TYPES OF FEES.—Beginning with fiscal year  
15 2018, the Secretary shall assess and collect fees in accord-  
16 ance with this section as follows:

17           “(1) FACILITY FEE.—

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

25           “(B) EXCEPTION.—

1           “(i) IN GENERAL.—A fee shall not be  
2           assessed under subparagraph (A) if the  
3           identified monograph drug facility has  
4           ceased all activities related to monograph  
5           drug products prior to the publication of  
6           the Notice under subparagraph C and has  
7           updated its registration to reflect such  
8           change under the requirements for drug  
9           establishment registration set forth in sec-  
10          tion 510.

11           “(ii) FEE AMOUNT.—The amount of  
12          the fee for a contract manufacturing orga-  
13          nization facility shall be equal to two-thirds  
14          the amount of the fee for a monograph  
15          drug facility that is not a contract manu-  
16          facturing organization facility.

17           “(C) DUE DATE.—For each fiscal year, the  
18          facility fees required under subparagraph (A)  
19          shall be due on the later of—

20           “(i) the first business day of April of  
21          such year; and

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

1           “(2) MONOGRAPH DRUG ORDER REQUEST  
2 FEE.—

3           “(A) IN GENERAL.—Each person that sub-  
4 mits a monograph drug order request shall be  
5 subject to a fee for a monograph drug order re-  
6 quest. The monograph drug order request fee  
7 under paragraph (2) shall be—

8           “(i) for a Tier 1 monograph drug  
9 order request, \$500,000, adjusted for in-  
10 flation for the fiscal year (as determined  
11 under subsection (c)(1)); and

12           “(ii) for a Tier 2 monograph drug  
13 order request other than a Tier 1 request,  
14 \$100,000 adjusted for inflation for the fis-  
15 cal year (as determined under subsection  
16 (c)(1)).

17           “(B) DUE DATE.—The monograph drug  
18 order request fees required under subparagraph  
19 (A) shall be due on the date of submission of  
20 the monograph drug order request.

21           “(C) EXCEPTION FOR CERTAIN SAFETY  
22 CHANGES.—A person who is named as the re-  
23 questor in a monograph drug order shall not be  
24 subject to a fee under subparagraph (A) if the  
25 Secretary finds that the monograph drug order

1 request seeks to change the Drug Facts labeling  
2 of a monograph drug product in a way that  
3 would add to or strengthen—

4 “(i) a contraindication, warning, or  
5 precaution;

6 “(ii) a statement about risk associated  
7 with misuse or abuse; or

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

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

24 “(E) REFUND OF FEE IF ORDER REQUEST  
25 REFUSED FOR FILING OR WITHDRAWN BEFORE

1           FILING.—The Secretary shall refund 75 percent  
2           of the fee paid under subparagraph (B) for any  
3           order request that is refused for filing.

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

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

23          “(3) REFUNDS.—

24                 “(A) IN GENERAL.—Other than refunds  
25                 under subparagraphs (D) through (G) of para-

1 graph (2), the Secretary shall not refund any  
2 fee paid under this subsection, except as pro-  
3 vided in subparagraph (B).

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

10 “(b) FEE REVENUE AMOUNTS.—

11 “(1) FISCAL YEAR 2018.—For fiscal year 2018,  
12 fees under subsection (a)(1) shall be established to  
13 generate a total facility fee revenue amount equal to  
14 the sum of—

15 “(A) the annual base revenue for fiscal  
16 year 2018 (as determined under paragraph  
17 (3));

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

22 “(C) additional direct cost adjustments (as  
23 determined under subsection (c)(3)).

24 “(2) SUBSEQUENT FISCAL YEARS.—For each of  
25 the fiscal years 2019 through 2022, fees under sub-

1 section (a)(1) shall be established to generate a total  
2 facility fee revenue amount equal to the sum of—

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

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

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

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

14 “(E) additional dollar amounts for each  
15 fiscal year as follows:

16 “(i) \$7,000,000 for fiscal year 2019.

17 “(ii) \$6,000,000 for fiscal year 2020.

18 “(iii) \$7,000,000 for fiscal year 2021.

19 “(iv) \$3,000,000 for fiscal year 2022.

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

24 “(A) for fiscal year 2018, \$8,000,000; and

1           “(B) for fiscal years 2019 through 2022,  
 2           the dollar amount of the total revenue amount  
 3           established under this subsection for the pre-  
 4           vious fiscal year, not including any adjustments  
 5           made under subsection (c)(2) or (c)(3).

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

7           “(1) INFLATION ADJUSTMENT.—

8           “(A) IN GENERAL.—For purposes of sub-  
 9           section (b)(2)(B), the dollar amount of the in-  
 10          flation adjustment to the annual base revenue  
 11          for fiscal year 2019 and each subsequent fiscal  
 12          year shall be equal to the product of—

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

15                   “(ii) the inflation adjustment percent-  
 16                   age under subparagraph (B).

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

21                   “(i) for each of fiscal years 2019  
 22                   through 2020, the average annual percent  
 23                   change that occurred in the Consumer  
 24                   Price Index for urban consumers (Wash-  
 25                   ington-Baltimore, DC–MD–VA–WV; Not

1 Seasonally Adjusted; All items; Annual  
2 Index) for the first 3 years of the pre-  
3 ceding 4 years of available data; and

4 “(ii) for each of fiscal years 2021 and  
5 2022, the sum of—

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

19 “(II) the average annual percent  
20 change that occurred in the Consumer  
21 Price Index for urban consumers  
22 (Washington-Baltimore, DC-MD-VA-  
23 WV; Not Seasonally Adjusted; All  
24 items; Annual Index) for the first 3  
25 years of the preceding 4 years of

1 available data multiplied by the pro-  
2 portion of all costs other than per-  
3 sonnel compensation and benefits  
4 costs to total costs of monograph drug  
5 activities for the first 3 years of the  
6 preceding 4 fiscal years.

7 “(2) OPERATING RESERVE ADJUSTMENT.—

8 “(A) For fiscal year 2018 and subsequent  
9 fiscal years, the Secretary may, in addition to  
10 adjustments under paragraphs (1) and (2), fur-  
11 ther increase the fee revenue and fees if such  
12 an adjustment is necessary to provide operating  
13 reserves of carryover user fees for monograph  
14 drug activities for the number of weeks speci-  
15 fied in subparagraph (B).

16 “(B) For each fiscal year the number of  
17 weeks of operating reserves shall be no more  
18 than—

19 “(i) 3 weeks for fiscal year 2018;

20 “(ii) 7 weeks for fiscal year 2019;

21 “(iii) 10 weeks for fiscal year 2020;

22 “(iv) 10 weeks for fiscal year 2021;

23 and

24 “(v) 10 weeks for fiscal year 2022.

1           “(C) If, for fiscal years 2019 through  
2           2022, the Secretary has carryover balances for  
3           monograph drug activities in excess of the num-  
4           ber of weeks of such operating reserves speci-  
5           fied in subparagraph B, the Secretary shall re-  
6           duce such fee revenue and fees to provide for  
7           not more than the number of weeks of such op-  
8           erating reserves specified in subparagraph  
9           (B)(v).

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

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

21                   “(A) 14,000,000 for fiscal year 2018;

22                   “(B) 7,000,000 for fiscal year 2019;

23                   “(C) 4,000,000 for fiscal year 2020;

24                   “(D) 3,000,000 for fiscal year 2021; and

25                   “(E) 3,000,000 for fiscal year 2022.

1 “(4) ANNUAL FEE SETTING.—

2 “(A) FISCAL YEAR 2018.—The Secretary  
3 shall, not later than January 31, 2018—

4 “(i) establish monograph drug facility  
5 fees for fiscal year 2018 under subsection  
6 (a)(1), based on the revenue amount for  
7 such year under subsection (b) and the ad-  
8 justments provided under this subsection;  
9 and

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

12 “(B) SUBSEQUENT FISCAL YEARS.—The  
13 Secretary shall, not later than January 31 of  
14 each fiscal year that begins after September 30,  
15 2018, establish for each such fiscal year, based  
16 on the revenue amounts under subsection (b)  
17 and the adjustments provided under this sub-  
18 section—

19 “(i) monograph drug facility fees  
20 under subsection (a)(1);

21 “(ii) monograph drug order request  
22 fees under subsection (a)(2); and

23 “(iii) publish such fee revenue, facility  
24 fees, and monograph drug order request  
25 fees in the Federal Register.

1       “(d) IDENTIFICATION OF FACILITIES.—Each person  
2 that owns a monograph drug facility shall submit to the  
3 Secretary the information required under this subsection  
4 each year. Such information shall, for each fiscal year—

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

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

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

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

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

22       “(f) MONOGRAPH DRUG FACILITY FEE.—Failure to  
23 pay the fee under subsection (a)(1) within 20 calendar  
24 days of the due date as specified in subparagraph (D) of  
25 such subsection shall result in the Secretary placing the

1 facility on a publicly available arrears list until such fee  
2 has been paid.

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

4 “(1) IN GENERAL.—Subject to paragraph  
5 (2)(D), fees authorized under subsection (a) shall be  
6 collected and available for obligation only to the ex-  
7 tent and in the amount provided in advance in ap-  
8 propriations Acts. Such fees are authorized to re-  
9 main available until expended. Such sums as may be  
10 necessary may be transferred from the Food and  
11 Drug Administration salaries and expenses appro-  
12 priation account without fiscal year limitation to  
13 such appropriation account for salaries and expenses  
14 with such fiscal year limitation. The sums trans-  
15 ferred shall be available solely for monograph drug  
16 activities.

17 “(2) COLLECTIONS AND APPROPRIATION  
18 ACTS.—

19 “(A) IN GENERAL.—Subject to subpara-  
20 graphs (C) and (D), the fees authorized by this  
21 section shall be collected and available in each  
22 fiscal year in an amount not to exceed the  
23 amount specified in appropriation Acts, or oth-  
24 erwise made available for obligation, for such  
25 fiscal year.

1           “(B) USE OF FEES AND LIMITATION.—

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

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

21          “(D) FEE COLLECTION DURING FIRST  
22          PROGRAM YEAR.—Until the date of enactment  
23          of an Act making appropriations and providing  
24          for the collection and obligation of fees under  
25          this section through September 30, 2018, for

1           the salaries and expenses account of the Food  
2           and Drug Administration, fees authorized by  
3           this section for fiscal year 2018 may be col-  
4           lected and shall be credited to such account and  
5           remain available until expended.

6           “(E) PROVISION FOR EARLY PAYMENTS IN  
7           SUBSEQUENT YEARS.—Payment of fees author-  
8           ized under this section for a fiscal year (after  
9           fiscal year 2018), prior to the due date for such  
10          fees, may be accepted by the Secretary in ac-  
11          cordance with authority provided in advance in  
12          a prior year appropriations Act.

13          “(3) AUTHORIZATION OF APPROPRIATIONS.—  
14          For each of the fiscal years 2018 through 2022,  
15          there is authorized to be appropriated for fees under  
16          this section an amount equal to the total amount of  
17          fees assessed for such fiscal year under this section.

18          “(h) COLLECTION OF UNPAID FEES.—In any case  
19          where the Secretary does not receive payment of a fee as-  
20          sessed under subsection (a) within 30 calendar days after  
21          it is due, such fee shall be treated as a claim of the United  
22          States Government subject to subchapter II of chapter 37  
23          of title 31.

24          “(i) CONSTRUCTION.—This section may not be con-  
25          strued to require that the number of full-time equivalent

1 positions in the Department of Health and Human Serv-  
2 ices, for officers, employers, and advisory committees not  
3 engaged in monograph drug activities, be reduced to offset  
4 the number of officers, employees, and advisory commit-  
5 tees so engaged.

6 **“SEC. 744L-2. REAUTHORIZATION; REPORTING REQUIRE-**  
7 **MENTS.**

8 “(a) PERFORMANCE REPORT.—Beginning with fiscal  
9 year 2018, and not later than 120 calendar days after the  
10 end of each fiscal year thereafter for which fees are col-  
11 lected under this part, the Secretary shall prepare and  
12 submit to the Committee on the Health, Education,  
13 Labor, and Pensions of the Senate and the Committee on  
14 Energy and Commerce of the House of Representatives  
15 a report concerning the progress of the Food and Drug  
16 Administration in achieving the goals identified in the let-  
17 ters described in section 201 of the during such fiscal year  
18 and the future plans of the Food and Drug Administration  
19 for meeting such goals.

20 “(b) FISCAL REPORT.—Not later than 120 calendar  
21 days after the end of fiscal year 2018 and each subsequent  
22 fiscal year for which fees are collected under this part,  
23 the Secretary shall prepare and submit to the Committee  
24 on Health, Education, Labor, and Pensions of the Senate  
25 and the Committee on Energy and Commerce of the

1 House of Representatives a report on the implementation  
2 of the authority for such fees during such fiscal year and  
3 the use, by the Food and Drug Administration, of the fees  
4 collected for such fiscal year.

5 “(c) PUBLIC AVAILABILITY.—The Secretary shall  
6 make the reports required under subsections (a) and (b)  
7 available to the public on the internet website of the Food  
8 and Drug Administration.

9 “(d) REAUTHORIZATION.—

10 “(1) CONSULTATION.—In developing rec-  
11 ommendations to present to Congress with respect to  
12 the goals described in subsection (a), and plans for  
13 meeting the goals, for monograph drug activities for  
14 the first 5 fiscal years after fiscal year 2022, and for  
15 the reauthorization of this part for such fiscal years,  
16 the Secretary shall consult with—

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

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

21 “(C) scientific and academic experts;

22 “(D) health care professionals;

23 “(E) representatives of patient and con-  
24 sumer advocacy groups; and

25 “(F) the regulated industry.

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

4                   “(A) present the recommendations devel-  
5                   oped under paragraph (1) to the congressional  
6                   committees specified in such paragraph;

7                   “(B) publish such recommendations in the  
8                   Federal Register;

9                   “(C) provide for a period of 30 calendar  
10                  days for the public to provide written comments  
11                  on such recommendations;

12                  “(D) hold a meeting at which the public  
13                  may present its views on such recommenda-  
14                  tions; and

15                  “(E) after consideration of such public  
16                  views and comments, revise such recommenda-  
17                  tions as necessary.

18           “(3) TRANSMITTAL OF RECOMMENDATIONS.—  
19           Not later than January 15, 2022, the Secretary  
20           shall transmit to Congress the revised recommenda-  
21           tions under paragraph (2), a summary of the views  
22           and comments received under such paragraph, and  
23           any changes made to the recommendations in re-  
24           sponse to such views and comments.”.

○