

**Calendar No. 413**115<sup>TH</sup> CONGRESS  
2<sup>D</sup> 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.

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**IN THE SENATE OF THE UNITED STATES**

JANUARY 17, 2018

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

MAY 14, 2018

Reported by Mr. ALEXANDER, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

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**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,*

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

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

5 (b) **TABLE OF CONTENTS.**—The table of contents for  
 6 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 with-  
 out 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.

7 **TITLE I—REGULATION OF**  
 8 **NONPRESCRIPTION DRUGS**

9 **SEC. 101. REGULATION OF CERTAIN NONPRESCRIPTION**  
 10 **DRUGS THAT ARE MARKETED WITHOUT AN**  
 11 **APPROVED NEW DRUG APPLICATION.**

12 Chapter V of the Federal Food, Drug, and Cosmetic  
 13 Act is amended by inserting after section 505F (21 U.S.C.  
 14 355g) the following:

15 **“SEC. 505G. REGULATION OF CERTAIN NONPRESCRIPTION**  
 16 **DRUGS THAT ARE MARKETED WITHOUT AN**  
 17 **APPROVED NEW DRUG APPLICATION.**

18 **“(a) DEFINITIONS.**—In this section:

1           “(1) NONPRESCRIPTION DRUG.—The term  
2           ‘nonprescription drug’ means a drug, an active in-  
3           gredient, or a combination of active ingredients that  
4           is not subject to section 503(b)(1).

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

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

12          “(b) MONOGRAPH DRUGS.—

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

20           “(A) A nonprescription drug is deemed to  
21           be generally recognized as safe and effective  
22           within the meaning of section 201(p)(1) and  
23           not a new drug under section 201(p) if—

24           “(i)(I) such drug is—

1           “(aa)(AA) subject to a final  
2 monograph issued under part  
3 330 of title 21, Code of Federal  
4 Regulations, as of the date of en-  
5 actment of the Over-the-Counter  
6 Drug Safety, Innovation, and Re-  
7 form Act;

8           “(BB) in conformity with  
9 the conditions for nonprescription  
10 use of such monograph and the  
11 general requirements specified  
12 for nonprescription drugs, includ-  
13 ing any modifications to those  
14 conditions made under sub-  
15 sections (c), (d), and (j); and

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

1           “(bb)(AA) the subject of a  
2 tentative final monograph that is  
3 the most recently applicable pro-  
4 posal or determination issued  
5 under part 330 of title 21, Code  
6 of Federal Regulations, as of the  
7 date of enactment of the Over-  
8 the-Counter Drug Safety, Inno-  
9 vation, and Reform Act;

10           “(BB) classified in category  
11 I for safety and effectiveness  
12 under such tentative final mono-  
13 graph;

14           “(CC) in conformity with  
15 the conditions for nonprescription  
16 use of such tentative final mono-  
17 graph; any subsequent deter-  
18 mination by the Secretary; and  
19 the general conditions for non-  
20 prescription drugs, including any  
21 modifications of those conditions  
22 under subsections (c), (d), and  
23 (j); and

24           “(DD) except as permitted  
25 by an administrative order issued

1 under subsection (e) or a minor  
2 change in the drug in conformity  
3 with subsection (d), is in a dos-  
4 age form that has been used to a  
5 material extent and for a mate-  
6 rial time within the meaning of  
7 section 201(p)(2); or

8 “(H) the active ingredient in such  
9 drug is in conformity with—

10 “(aa) the requirements of a final  
11 administrative order issued under sub-  
12 section (e) determining that such drug  
13 under the specific conditions of use is  
14 generally recognized as safe and effec-  
15 tive within the meaning of section  
16 201(p)(1); and

17 “(bb) the general requirements  
18 for nonprescription drugs, including  
19 any modifications of the requirements  
20 under subsections (e), (d), and (j);  
21 and

22 “(ii) such drug is—

23 “(I) not classified in Category II  
24 for safety or effectiveness under a ten-  
25 tative final monograph; or

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

8                   “(B) A nonprescription drug may be intro-  
9                   duced into interstate commerce if such drug  
10                  is—

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

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

20                   “(ii)(I)(aa) the subject of a tentative  
21                   final monograph that is the most recently  
22                   applicable proposal or determination issued  
23                   under part 330 of title 21, Code of Federal  
24                   Regulations;

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

5           “(cc) in conformity with the most re-  
6 cently proposed or final rule establishing or  
7 proposing conditions of nonprescription use  
8 published in the Federal Register related  
9 to such tentative final monograph and the  
10 general requirements for nonprescription  
11 drugs, including any modifications of those  
12 requirements under subsections (e) and (j);  
13 and

14           “(dd) in a dosage form that has been  
15 used to a material extent and for a mate-  
16 rial time within the meaning of section  
17 201(p)(2); or

18           “(H)(aa) the subject of a proposed  
19 monograph or advance notice of proposed  
20 rulemaking that is the most recently appli-  
21 cable proposal or determination issued  
22 under part 330 of title 21, Code of Federal  
23 Regulations;

24           “(bb) classified in category I for safe-  
25 ty and effectiveness under such proposed



1 monograph or advance notice of proposed  
2 rulemaking;

3 “(cc) in conformity with the most re-  
4 cently proposed or final rule establishing or  
5 proposing conditions of nonprescription use  
6 published in the Federal Register related  
7 to such proposed monograph or advance  
8 notice of proposed rulemaking and the gen-  
9 eral requirements for nonprescription  
10 drugs, including any modifications of those  
11 requirements under subsections (e) and (j);  
12 and

13 “(dd) in a dosage form that has been  
14 used to a material extent and for a mate-  
15 rial time within the meaning of section  
16 201(p)(2).

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

19 “(i) such drug is classified in category  
20 II for safety or effectiveness under a ten-  
21 tative final monograph, or the Secretary  
22 has determined such drug not to be safe  
23 and effective in a final monograph or pre-  
24 amble to a rule that is the most recently  
25 applicable proposal or determination issued

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

3 “(ii) the Secretary determines within  
4 6 months of the date of enactment of the  
5 Over-the-Counter Drug Safety, Innovation,  
6 and Reform Act, that it is in the interest  
7 of public health to extend the period dur-  
8 ing which the drug may be marketed with-  
9 out an approved new drug application  
10 under section ~~505~~.

11 “(D) A drug that is subject to the final  
12 monograph for sunscreen drug products set  
13 forth at part ~~352~~ of title 21, Code of Federal  
14 Regulations (as published at volume 64 page  
15 ~~27687~~ of the Federal Register), shall comply  
16 with the requirements of that monograph, ex-  
17 cept that the testing requirements for effective-  
18 ness and the provisions governing labeling shall  
19 be in accordance with section ~~201.327~~ of title  
20 21, Code of Federal Regulations (as in effect on  
21 the date of enactment of the Over-the-Counter  
22 Drug Safety, Innovation, and Reform Act), or  
23 such changes to those requirements as may be  
24 made under subsections (c), (d), and (j).

1           “(2) NEW DRUGS.—A nonprescription drug is a  
2 new drug within the meaning of section 201(p) and  
3 subject to the requirements of section 505 if the  
4 drug is—

5           “(A) not described in subparagraph (A),  
6 (B), or (D) of paragraph (1) and not in con-  
7 formity with subsection (d);

8           “(B) not subject to an administrative final  
9 order pursuant to subsection (e); or

10           “(C) not a nonprescription sunscreen ac-  
11 tive ingredient or combination of ingredients  
12 subject to a final sunscreen order, as defined in  
13 section 586(2).

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

17           “(4) RULES OF CONSTRUCTION.—

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

21           “(i) that, on the date of enactment of  
22 the Over-the-Counter Drug Safety, Innova-  
23 tion, and Reform Act, is marketed without  
24 an application approved under section 505;  
25 and

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

4           “(B) APPLICABILITY OF OTHER PROVI-  
5           SIONS.—Nothing in this paragraph shall be  
6           construed to preclude or limit the applicability  
7           of any other provision of this Act.

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

13          “(e) ADMINISTRATIVE ORDERS.—

14           “(1) IN GENERAL.—

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

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

1           “(ii) generally recognized as safe and  
2           effective within the meaning of section  
3           201(p)(1); and

4           “(iii) not required to be approved  
5           under section 505.

6           “(B) NOT GENERALLY RECOGNIZED AS  
7           SAFE AND EFFECTIVE.—The Secretary shall  
8           issue an order determining that a drug is not  
9           generally recognized as safe and effective within  
10          the meaning of section 201(p)(1) for the speci-  
11          fied requirements if, after substantive review of  
12          evidence, the Secretary determines that—

13           “(i) the evidence shows that the drug  
14           is not generally recognized as safe and ef-  
15           fective within the meaning of section  
16           201(p)(1); or

17           “(ii) the evidence is inadequate to  
18           show that the drug is generally recognized  
19           as safe and effective within the meaning of  
20           section 201(p)(1).

21           “(2) NONAPPLICATION OF CERTAIN REQUIRE-  
22          MENTS.—The requirements of subchapter H of  
23          chapter 5 of title 5, United States Code, shall not  
24          apply with respect to administrative orders issued  
25          under this section.

1           ~~“(3) ADMINISTRATIVE ORDERS INITIATED BY~~  
2           ~~THE SECRETARY; CITIZEN PETITIONS.—~~

3           ~~“(A) IN GENERAL.—Except as provided in~~  
4           ~~paragraph (5), in issuing an administrative~~  
5           ~~order under paragraph (1) on the initiative of~~  
6           ~~the Secretary, the Secretary shall—~~

7           ~~“(i) not later than 2 business days be-~~  
8           ~~fore issuance of the proposed order, infor-~~  
9           ~~mally communicate the pending issuance of~~  
10          ~~the order to sponsors of drugs that will be~~  
11          ~~subject to such order;~~

12          ~~“(ii) after making any such informal~~  
13          ~~communication—~~

14          ~~“(I) issue such a proposed ad-~~  
15          ~~ministrative order by publishing it on~~  
16          ~~the internet website of the Food and~~  
17          ~~Drug Administration and include in~~  
18          ~~such order the reasons for the~~  
19          ~~issuance of such order; and~~

20          ~~“(II) publish notice of availability~~  
21          ~~of such proposed order in the Federal~~  
22          ~~Register;~~

23          ~~“(iii) except as provided in subpara-~~  
24          ~~graph (B), provide for a public comment~~

1 period with respect to such proposed order  
2 of not less than 45 calendar days; and

3 “(iv) if, after satisfying the require-  
4 ments of clauses (i) through (iii), the Sec-  
5 retary determines that it is appropriate to  
6 issue a final administrative order—

7 “(I) issue the final administrative  
8 order, together with a detailed state-  
9 ment of reasons, but such order shall  
10 not take effect until the time for re-  
11 questing judicial review under para-  
12 graph (4)(D)(ii) has expired;

13 “(II) publish a notice of avail-  
14 ability of such final administrative  
15 order in the Federal Register;

16 “(III) afford requestors of prod-  
17 ucts that will be subject to such order  
18 the opportunity for formal dispute  
19 resolution up to the level of the Direc-  
20 tor of the Center for Drug Evaluation  
21 and Research, which initially shall be  
22 requested within 45 calendar days of  
23 the issuance of the order, and, for  
24 subsequent levels of appeal, within 30

1 calendar days of the prior decision;  
2 and

3 “(IV) except with respect to  
4 drugs described in paragraph (4)(B);  
5 upon completion of the formal dispute  
6 resolution procedure, inform the per-  
7 son or persons which sought such dis-  
8 pute resolution of their right to re-  
9 quest a hearing.

10 “(B) SPECIAL REQUIREMENTS WITH RE-  
11 SPECT TO CERTAIN MONOGRAPH DRUGS.—

12 When issuing an administrative order under  
13 paragraph (1) on the initiative of the Secretary  
14 (except as provided under paragraph (5)) pro-  
15 posing to determine that a monograph drug de-  
16 scribed in subsection (b)(1)(B) is not generally  
17 recognized as safe and effective within the  
18 meaning of section 201(p)(1), the Secretary  
19 shall follow the procedures in subparagraph (A)  
20 except that—

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

23 “(I) the general categories of  
24 data the Secretary has determined  
25 necessary to establish that the drug is



1 generally recognized as safe and effec-  
2 tive within the meaning of section  
3 201(p)(1); and

4 “(H) the format for submissions  
5 by interested persons;

6 “(ii) the Secretary shall provide for a  
7 public comment period of not less than 180  
8 calendar days with respect to such pro-  
9 posed order, except when the Secretary de-  
10 termines, for good cause, that a shorter pe-  
11 riod is in the interest of public health; and

12 “(iii) any person who submits data in  
13 such comment period shall include a cer-  
14 tification that the person has submitted all  
15 evidence created, obtained, or received by  
16 that person that is both within the cat-  
17 egories of data identified in the proposed  
18 order and relevant to a determination as to  
19 whether the drug is generally recognized as  
20 safe and effective within the meaning of  
21 section 201(p)(1).

22 “(C) CITIZEN PETITIONS.—

23 “(i) IN GENERAL.—The Secretary  
24 may issue an administrative order under  
25 paragraph (1) in response to a citizen peti-

1           tion submitted under section ~~10.30~~ of title  
 2           ~~21~~, Code of Federal Regulations (or any  
 3           successor regulation); subject to clause (ii).

4           “(ii) EFFECT OF PETITION.—Nothing  
 5           in clause (i) shall be construed to provide  
 6           an alternative to, or otherwise supplant or  
 7           supersede—

8                   “(I) the processes through which  
 9                   a requestor may seek an administra-  
 10                  tive order pursuant to paragraph (6);  
 11                  or

12                   “(II) the fee structure under sec-  
 13                  tion ~~744L-1(a)(2)~~.

14           “(4) HEARINGS; JUDICIAL REVIEW.—

15                   “(A) IN GENERAL.—A person who partici-  
 16                  pated in each level of formal dispute resolution  
 17                  under paragraph (3)(A)(iv)(III) of an adminis-  
 18                  trative order with respect to a drug may re-  
 19                  quest a hearing concerning a final administra-  
 20                  tive order issued under paragraph (3)(A)(iv)  
 21                  with respect to such drug. Such person may  
 22                  submit a request for a hearing, which shall be  
 23                  based solely on the information in the adminis-  
 24                  trative record, to the Secretary not later than  
 25                  30 calendar days after receiving notice of the

1 final decision of the formal dispute resolution  
2 procedure.

3 “(B) NO HEARING REQUIRED WITH RE-  
4 SPECT TO ORDERS RELATING TO CERTAIN  
5 DRUGS.—The Secretary is not required to pro-  
6 vide notice and an opportunity for a hearing  
7 pursuant to paragraph (3)(A)(iv) if the final  
8 administrative order involved relates to a  
9 drug—

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

12 “(ii) with respect to which no data  
13 relevant to the safety or effectiveness of  
14 such drug have been submitted to the ad-  
15 ministrative record since the issuance of  
16 the most recent tentative final monograph  
17 relating to such drug (or, as applicable,  
18 since the deeming of such tentative final  
19 monograph as a final administrative order  
20 under paragraph (7)).

21 “(C) HEARING PROCEDURES.—

22 “(i) DENIAL OF REQUEST FOR HEAR-  
23 ING.—If the Secretary determines that a  
24 request for a hearing under subparagraph  
25 (A) with respect to a final administrative

1 order issued under paragraph (3)(A)(iv),  
2 does not establish the existence of a gen-  
3 uine and substantial question of material  
4 fact, the Secretary may deny such request.  
5 In making such a determination, the Sec-  
6 retary may consider only information and  
7 data that are based on relevant and reli-  
8 able scientific principles and methodolo-  
9 gies.

10 “(ii) SINGLE HEARING FOR MULTIPLE  
11 RELATED REQUESTS.—If more than one  
12 request for a hearing is submitted with re-  
13 spect to the same administrative order  
14 under subparagraph (A), the Secretary  
15 may direct that a single hearing be con-  
16 ducted in which all persons whose hearing  
17 requests were granted may participate.

18 “(iii) PRESIDING OFFICER.—The Sec-  
19 retary shall appoint a presiding officer of  
20 a hearing requested under subparagraph  
21 (A) who—

22 “(I) is not an employee of the  
23 Center for Drug Evaluation and Re-  
24 search; and

1           “(H) has not previously been in-  
2           volved in the development of the appli-  
3           cable administrative order or in the  
4           proceedings relating to that adminis-  
5           trative order.

6           “(iv) RIGHTS OF PARTIES TO HEAR-  
7           ING.—The parties to a hearing requested  
8           under subparagraph (A) shall have the  
9           right to present testimony, including testi-  
10          mony of expert witnesses, and to cross-ex-  
11          amine witnesses presented by other parties.  
12          Where appropriate, the presiding officer  
13          may require that cross-examination by par-  
14          ties representing substantially the same in-  
15          terests be consolidated to promote effi-  
16          ciency and avoid duplication.

17          “(v) FINAL DECISION.—At the conclu-  
18          sion of a hearing requested under subpara-  
19          graph (A), the presiding officer of the  
20          hearing shall issue a decision containing  
21          findings of fact and conclusions of law.  
22          The decision of the presiding officer shall  
23          be final. The final decision may not take  
24          effect until the period under subparagraph

1           (D)(ii) for submitting a request for judicial  
2           review of such decision expires.

3           “(D) JUDICIAL REVIEW OF FINAL ADMIN-  
4           ISTRATIVE ORDER.—

5           “(i) IN GENERAL.—The procedures  
6           described in section 505(h) shall apply  
7           with respect to judicial review of final ad-  
8           ministrative orders issued under this sub-  
9           section in the same manner and to the  
10          same extent as such section applies to an  
11          order described in such section except that  
12          the judicial review shall be taken by filing  
13          in an appropriate district court of the  
14          United States in lieu of the appellate  
15          courts specified in such section.

16          “(ii) TIME TO SUBMIT A REQUEST  
17          FOR JUDICIAL REVIEW.—A person eligible  
18          to request a hearing under this paragraph  
19          and seeking judicial review of a final ad-  
20          ministrative order issued under this sub-  
21          section shall file a request for such review  
22          not later than 60 calendar days after the  
23          latest of—

24                       “(I) the date on which notice of  
25                       such order is published;

1                   “~~(II)~~ the date on which any hear-  
2                   ing with respect to such order is de-  
3                   nied under subparagraph ~~(C)~~(i);

4                   “~~(III)~~ the date on which a final  
5                   decision is made following any hearing  
6                   with respect to such order under sub-  
7                   paragraph ~~(C)~~(v); or

8                   “~~(IV)~~ if no hearing is requested,  
9                   the date on which the time for re-  
10                  questing a hearing expires.

11                  “~~(5)~~ EXPEDITED PROCEDURE WITH RESPECT  
12                  TO ADMINISTRATIVE ORDERS INITIATED BY THE  
13                  SECRETARY.—

14                  “~~(A)~~ IMMINENT HAZARD TO THE PUBLIC  
15                  HEALTH.—

16                  “~~(i)~~ IN GENERAL.—In the case of a  
17                  determination by the Secretary that a  
18                  monograph drug poses an imminent hazard  
19                  to the public health, the Secretary may,  
20                  after informally communicating with any  
21                  sponsor that will be the subject of such de-  
22                  termination, not later than 48 hours before  
23                  issuance of an order under this subpara-  
24                  graph—

1           “(I) issue an interim final admin-  
2           istrative order for such drug or com-  
3           bination of drugs under paragraph  
4           (1), together with a detailed state-  
5           ment of the reasons for such order;

6           “(II) publish in the Federal Reg-  
7           ister a notice of availability of such  
8           order; and

9           “(III) provide for a public com-  
10          ment period of at least 45 calendar  
11          days after issuance of such interim  
12          final order.

13          “(ii) NONDELEGATION.—The Sec-  
14          retary may not delegate the authority to  
15          issue an interim final administrative order  
16          under this subparagraph.

17          “(B) SAFETY LABELING CHANGES.—

18          “(i) IN GENERAL.—In the case of a  
19          determination by the Secretary that a  
20          change in the labeling of a drug, class of  
21          drugs, or combination of drugs subject to  
22          this section is reasonably expected to miti-  
23          gate a significant or unreasonable risk of  
24          a serious adverse event associated with use  
25          of the drug, the Secretary may, after infor-



1 mally communicating with any sponsor  
2 that will be the subject of such determina-  
3 tion, not later than 48 hours before  
4 issuance of an order under this subpara-  
5 graph—

6 “(I) issue an interim final admin-  
7 istrative order in accordance with  
8 paragraph (1) to require such change,  
9 together with a detailed statement of  
10 the reasons for such order;

11 “(II) publish in the Federal Reg-  
12 ister a notice of availability of such  
13 order; and

14 “(III) provide for a public com-  
15 ment period of at least 45 calendar  
16 days after issuance of such interim  
17 final order.

18 “(ii) CONTENT OF ORDER.—An in-  
19 terim final order issued under this sub-  
20 paragraph with respect to the labeling of a  
21 drug may provide for new warnings and  
22 other information required for safe use of  
23 the drug.

24 “(C) EFFECTIVE DATE.—An order under  
25 subparagraph (A) or (B) shall take effect on a

1 date specified by the Secretary, which date, in  
2 the case of an order under subparagraph (B)  
3 that includes changes to the packaging of the  
4 drug, shall not be earlier than the day after the  
5 date on which the comment period described in  
6 subparagraph (B)(i)(III) ends.

7 “(D) FINAL ORDER.—After the completion  
8 of the proceedings in subparagraph (A) or (B),  
9 the Secretary shall—

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

12 “(ii) publish a notice of availability of  
13 such final administrative order in the Fed-  
14 eral Register; and

15 “(iii) afford sponsors of drugs that  
16 will be subject to such an order the oppor-  
17 tunity for formal dispute resolution up to  
18 the level of the Director of the Center for  
19 Drug Evaluation and Research, which ini-  
20 tially shall be within 45 calendar days of  
21 the issuance of the order; and, for subse-  
22 quent levels of appeal, within 30 calendar  
23 days of the prior decision.

24 “(E) HEARINGS.—

1           “(i) IN GENERAL.—A sponsor of a  
2 drug subject to a final order issued under  
3 subparagraph (D) who participated in each  
4 level of formal dispute resolution under  
5 subparagraph (D)(iii) may request a hear-  
6 ing on such order. The provisions of sub-  
7 paragraphs (A), (B), and (C) of paragraph  
8 (4) shall apply with respect to a hearing on  
9 such order in the same manner and to the  
10 same extent as such provisions apply with  
11 respect to a hearing on an administrative  
12 order issued under paragraph (3)(A)(iv).

13           “(ii) REFERENCES.—For purposes of  
14 a hearing under this subparagraph, the  
15 references in subparagraphs (A), (B), and  
16 (C) of paragraph (4)—

17                   “(I) to ‘each level of dispute reso-  
18 lution under paragraph  
19 (3)(A)(iv)(III)’ shall be deemed to  
20 mean ‘each level of formal dispute res-  
21 olution under subparagraph (D)(iii)’;  
22 and

23                   “(II) to ‘final administrative  
24 order issued under paragraph  
25 (3)(A)(iv)’ shall be deemed to mean

1                   ‘final order under subparagraph  
2                   (D)(i)’.

3                   “(F) FINAL ORDER.—Not later than 1  
4                   year after the date on which an interim final  
5                   order is issued under subparagraph (A) or (B),  
6                   the Secretary shall issue a final order in accord-  
7                   ance with paragraph (1) and complete any re-  
8                   quired hearing.

9                   “(G) JUDICIAL REVIEW.—A final order  
10                  issued pursuant to subparagraph (F) shall be  
11                  subject to judicial review in accordance with  
12                  paragraph (4)(D).

13                  “(H) CLARIFICATION.—Paragraph (3)  
14                  shall not apply to the orders issued under this  
15                  paragraph.

16                  “(6) ADMINISTRATIVE ORDER INITIATED BY  
17                  REQUEST.—

18                  “(A) IN GENERAL.—In issuing an adminis-  
19                  trative order under paragraph (1) at the re-  
20                  quest of a requestor or a group of requestors  
21                  with respect to certain drugs, classes of drugs,  
22                  or combinations of drugs—

23                         “(i) the Secretary shall, after receiv-  
24                         ing a request under this subparagraph, de-  
25                         termine whether the request is sufficiently

1 complete and formatted to permit a sub-  
 2 stantive review;

3 “(ii) subject to subparagraph (D), if  
 4 the Secretary determines that the request  
 5 is sufficiently complete and formatted to  
 6 permit a substantive review, the Secretary  
 7 shall—

8 “(I) file the request; and

9 “(II) initiate proceedings with re-  
 10 spect to issuing an administrative  
 11 order in accordance with paragraphs  
 12 (3) and (4); and

13 “(iii) except as provided in subpara-  
 14 graph (D)(v), if the Secretary determines  
 15 that a request does not meet the require-  
 16 ments for filing or is not sufficiently com-  
 17 plete or formatted to permit a substantive  
 18 review, the requestor may elect that the  
 19 Secretary file the request over protest, and  
 20 the Secretary shall initiate proceedings to  
 21 review the request in accordance with  
 22 paragraph (3)(A).

23 “(B) REQUEST TO INITIATE PRO-  
 24 CEEDINGS.—

1           “(i) IN GENERAL.—A requestor seek-  
2           ing an administrative order with respect to  
3           certain drugs, classes of drugs, or com-  
4           binations of drugs, shall submit to the Sec-  
5           retary a request to initiate proceedings for  
6           such order in the form and manner as  
7           specified by the Secretary. Such requestor  
8           may submit a request under this subpara-  
9           graph for the issuance of an administrative  
10          order—

11                   “(I) determining whether a drug  
12                   is generally recognized as safe and ef-  
13                   fective within the meaning of section  
14                   201(p)(1), exempt from section  
15                   503(b)(1), and not required to be the  
16                   subject of an approved application  
17                   under section 505; or

18                   “(II) determining whether a  
19                   change to a condition of use or a new  
20                   condition of use of a drug is generally  
21                   recognized as safe and effective within  
22                   the meaning of section 201(p)(1), ex-  
23                   empt from section 503(b)(1), and not  
24                   required to be the subject of an ap-

1 proved application under section 505,  
2 if such drug is—

3 “(aa) described in sub-  
4 section (b)(1)(A); or

5 “(bb) described in sub-  
6 section (b)(1)(B), but only if  
7 such requestor initiates such re-  
8 quest in conjunction with a re-  
9 quest for the Secretary to deter-  
10 mine whether such drug is gen-  
11 erally recognized as safe and ef-  
12 fective within the meaning of sec-  
13 tion 201(p)(1), which is filed by  
14 the Secretary under subpara-  
15 graph (A)(ii)(I).

16 The Secretary is not required to complete  
17 review of the request for a change de-  
18 scribed in subclause (II) if the Secretary  
19 determines, in accordance with subpara-  
20 graph (D), that there is an inadequate  
21 basis to find the drug is generally recog-  
22 nized as safe and effective under para-  
23 graph (1) and issues a final order an-  
24 nouncing that determination.

1           “(ii) WITHDRAWAL OF REQUEST.—

2           The requestor may withdraw a request  
3           under this paragraph, according to the  
4           procedures established by the Secretary.  
5           Notwithstanding any other provision of  
6           this section, if such request is withdrawn,  
7           the Secretary shall cease proceedings  
8           under this subparagraph.

9           “(C) PRODUCT DIFFERENTIATION.—

10           “(i) IN GENERAL.—A final adminis-  
11           trative order issued in response to a re-  
12           quest under this paragraph shall have the  
13           effect of providing the order requestor (or  
14           the licensees, assignees, or successors in  
15           interest of such requestor with respect to  
16           the subject of such order and listed under  
17           clause (v)) the exclusive right, for a period  
18           of 2 years, to market drugs under this sec-  
19           tion incorporating changes described in  
20           clause (ii), subject to the limitations under  
21           clause (iv), and beginning on the date the  
22           requestor (or any such licensees, assignees,  
23           or successors in interest of such requestor)  
24           may lawfully market such drugs pursuant  
25           to the order.



1           “(ii) CHANGES DESCRIBED.—A  
2 change described in this clause is a change  
3 subject to an order specified in clause (i),  
4 which—

5           “(I) permits a drug to contain an  
6 active ingredient not previously incor-  
7 porated in a marketed drug listed in  
8 clause (iii); or

9           “(II) permits a change in the  
10 conditions of use of a drug, for which  
11 human data studies conducted or  
12 sponsored by the requestor (or for  
13 which the requestor has an exclusive  
14 right of reference) were essential to  
15 the issuance of such order.

16           “(iii) MARKETED DRUGS.—The mar-  
17 keted drugs listed in this clause are  
18 drugs—

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 thereunder), as in effect on the day  
24 before the date of enactment of this  
25 section;

1           “(II) marketed as category I or  
2           III in accordance with a tentative  
3           final monograph issued under such  
4           part 320 (including conditions of use  
5           and any applicable subsequent deter-  
6           minations thereunder); as so in effect;

7           “(III) marketed as category I in  
8           accordance with an advance notice of  
9           proposed rulemaking issued under  
10          such part 320 (including conditions of  
11          use and any applicable subsequent de-  
12          terminations thereunder); as so in ef-  
13          fect;

14          “(IV) marketed in accordance  
15          with a final order issued under this  
16          section; or

17          “(V) described in subsection  
18          (b)(1)(C), other than drugs subject to  
19          an active enforcement action under  
20          section 303.

21          “(iv) LIMITATIONS ON PRODUCT DIFF-  
22          FERENTIATION.—

23                 “(I) ONLY ONE PERIOD.—Only  
24                 one 2-year period may be granted per

1 drug under clause (i) with respect to  
2 any change described in clause (ii).

3 “(H) EXCLUSIONS.—No period  
4 of product differentiation under this  
5 subparagraph shall apply to changes  
6 to a drug that are—

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

9 “(bb) safety-related changes  
10 described in section 744L-  
11 1(a)(2)(C), required under para-  
12 graph (5), or any other change  
13 the Secretary determines nec-  
14 essary to ensure safe use; or

15 “(cc) changes related to  
16 methods of testing safety or effi-  
17 eacy.

18 “(v) LISTING OF LICENSEES, ASSIGN-  
19 EES, OR SUCCESSORS IN INTEREST.—The  
20 requestors of an order described in clause  
21 (i) shall, as applicable, submit to the Sec-  
22 retary, at a time when a finished dosage  
23 form subject to such order is introduced or  
24 delivered for introduction into interstate  
25 commerce, a list of licensees, assignees, or

1 successors in interest that have the exclu-  
2 sive right described in such clause.

3 “(vi) HUMAN DATA DEFINED.—For  
4 purposes of this subparagraph, the term  
5 ‘human data’ means data from clinical  
6 trials of safety or effectiveness, or phar-  
7 macokinetics or bioavailability studies.

8 “(D) INFORMATION REGARDING SAFE  
9 NONPRESCRIPTION MARKETING AND USE AS A  
10 CONDITION FOR FILING A GRASE REQUEST.—

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

15 “(I) may file such request, if the  
16 request includes information specified  
17 under clause (iii) with respect to safe  
18 nonprescription marketing and use of  
19 such drug; or

20 “(II) if the request fails to in-  
21 clude information specified under  
22 clause (iii), shall refuse to file such re-  
23 quest and may require that non-  
24 prescription marketing of the drug be

1           pursuant to a new drug application as  
2           described in clause (iv).

3           “(ii) DRUG DESCRIBED.—A drug de-  
4           scribed in this clause is a monograph drug  
5           that contains an active ingredient not pre-  
6           viously incorporated in a drug—

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                  under such part), as in effect on the  
12                  day before the date of enactment of  
13                  this section;

14                  “(II) marketed as category I in  
15                  accordance with a tentative final  
16                  monograph issued under part 330 of  
17                  title 21, Code of Federal Regulations  
18                  (including conditions of use and any  
19                  applicable subsequent determinations  
20                  under such part), as in effect on the  
21                  day before the date of enactment of  
22                  this section; or

23                  “(III) marketed in accordance  
24                  with a final order issued under this  
25                  section.

1           “(iii) SUFFICIENT INFORMATION FOR  
2           A THRESHOLD DEMONSTRATION OF NON-  
3           PRESCRIPTION MARKETING AND USE.—In-  
4           formation specified in this subparagraph,  
5           with respect to a request described in  
6           clause (i)(I), is—

7                   “(I) information sufficient for a  
8                   threshold demonstration that the drug  
9                   subject to such request has a  
10                  verifiable history of being marketed  
11                  and safely used by consumers in the  
12                  United States as a nonprescription  
13                  drug under comparable conditions of  
14                  use;

15                  “(II) if the drug has not been  
16                  previously marketed in the United  
17                  States as a nonprescription drug, in-  
18                  formation sufficient for a threshold  
19                  demonstration that the drug was mar-  
20                  keted and safely used in a foreign  
21                  country under conditions of marketing  
22                  and use—

23                          “(aa) for such period of time  
24                          as needed to provide reasonable  
25                          assurances concerning the safe

1 nonprescription use of the drug;  
2 and

3 “(bb) during such period of  
4 time, was subject to sufficient  
5 monitoring by a regulatory body  
6 of any country listed in section  
7 802(b)(1)(A) or any country des-  
8 ignated by the Secretary in ac-  
9 cordance with section  
10 802(b)(1)(B); or

11 “(III) if the Secretary determines  
12 that information described in sub-  
13 clause (I) or (II) is not needed to pro-  
14 vide a threshold demonstration that  
15 the drug can be safely marketed and  
16 used as a nonprescription drug; other  
17 information the Secretary determines  
18 sufficient for such purposes.

19 “(iv) ~~MARKETING PURSUANT TO NEW~~  
20 ~~DRUG APPLICATION.~~—In the case of a re-  
21 quest described in clause (i)(II), the drug  
22 subject to such request may be re-sub-  
23 mitted for filing only if—

24 “(I) the drug is marketed as a  
25 nonprescription drug, under condi-

1 tions of use comparable to the re-  
2 quirements specified in the request,  
3 for such period of the time as the Sec-  
4 retary determines appropriate (not to  
5 exceed 5 consecutive years) pursuant  
6 to an application approved under sec-  
7 tion 505; and

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

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

23 “(7) TREATMENT OF FINAL AND TENTATIVE  
24 FINAL MONOGRAPHS.—A final monograph or ten-  
25 tative final monograph establishing requirements of



1 use for a drug described in subsection (b)(1) shall  
2 be deemed to be a final administrative order under  
3 this subsection and may be amended, revoked, or  
4 otherwise modified in accordance with the proce-  
5 dures of this subsection.

6 ~~“(8) PACKAGING.—~~

7 ~~“(A) IN GENERAL.—An administrative~~  
8 ~~order issued under paragraph (3), (5)(A), or~~  
9 ~~(6) may include requirements for the packaging~~  
10 ~~of a drug, such as to promote use in accordance~~  
11 ~~with labeling, unit dose packaging, or require-~~  
12 ~~ments to prevent accidental overdose or inges-~~  
13 ~~tion, misuse, or abuse, including by pediatric~~  
14 ~~populations. The Secretary shall consider, as~~  
15 ~~appropriate, any such nonprescription drugs~~  
16 ~~currently available, and the impact of the re-~~  
17 ~~moval of such drugs without such packaging~~  
18 ~~and the changing of such packaging on patients~~  
19 ~~and manufacturers when establishing such re-~~  
20 ~~quirements.~~

21 ~~“(B) EFFECTIVE DATE.—Requirements for~~  
22 ~~packaging in an administrative order under~~  
23 ~~paragraph (5)(B) shall not take effect earlier~~  
24 ~~than the day after the date on which the com-~~

1           ment period under paragraph (5)(B)(i)(III)  
2           ends.

3           “(C) CLARIFICATION.—This paragraph  
4           does not authorize the Secretary to require spe-  
5           cial packaging or child-resistant packaging  
6           under the Poison Prevention Packaging Act of  
7           1970.

8           “(d) PROCEDURE FOR MINOR CHANGES.—

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

14               “(A) the requestor maintains information  
15               necessary to demonstrate that the change—

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

18                       “(ii) will not materially affect the ex-  
19                       tent of absorption or other exposure to the  
20                       active ingredient in comparison to a suit-  
21                       able reference product;

22               “(B) the requestor submits updated drug  
23               listing information for the drug in accordance  
24               with the requirements of section 510(j) within  
25               30 calendar days of the date on which the drug

1 is first introduced into interstate commerce  
2 with the change; and

3 “(C) the change is in conformity with the  
4 requirements of an applicable administrative  
5 order issued by the Secretary under paragraph  
6 (3).

7 “(2) ADDITIONAL INFORMATION.—

8 “(A) ACCESS TO RECORDS.—The requestor  
9 shall submit to the Secretary, under section  
10 704(a)(4), records requested by the Secretary  
11 related to a minor change within 15 business  
12 days of receiving such request, or such longer  
13 period as the Secretary may provide. Such re-  
14 quest shall be specific to a company and limited  
15 to the product and the minor change that  
16 prompted such request. Such request shall be  
17 specific to a company and limited to the prod-  
18 uct and the minor change that prompted such  
19 request.

20 “(B) INSUFFICIENT INFORMATION.—If the  
21 Secretary determines that the information con-  
22 tained in such records is not sufficient to dem-  
23 onstrate that the change does not affect the  
24 safety or effectiveness of the drug or materially

1 affect the extent of absorption or other expo-  
2 sure to the active ingredient, the Secretary—

3 “(i) may so inform the requestor of  
4 the drug in writing; and

5 “(ii) provide the requestor of the drug  
6 with a reasonable opportunity to provide  
7 additional information.

8 “(C) FAILURE TO SUBMIT SUFFICIENT IN-  
9 FORMATION.—If the requestor fails to provide  
10 such additional information within the pre-  
11 scribed time, or if the Secretary determines that  
12 such additional information does not dem-  
13 onstrate that the change does not affect the  
14 safety or effectiveness of the drug or materially  
15 affect the extent of absorption or other expo-  
16 sure to the active ingredient, the drug as modi-  
17 fied is a new drug within the meaning of sec-  
18 tion 201(p) and shall be deemed to be mis-  
19 branded under section 502(cc).

20 “(3) DETERMINING WHETHER CHANGE WILL  
21 AFFECT SAFETY OR EFFECTIVENESS.—

22 “(A) IN GENERAL.—The Secretary shall  
23 issue one or more administrative orders under  
24 subsection (c) specifying requirements for deter-  
25 mining whether a minor change made by a re-

1           requestor pursuant to this subsection will affect  
2           the safety or effectiveness of a drug or materi-  
3           ally affect the extent of absorption or other ex-  
4           posure to an active ingredient in the drug in  
5           comparison to a suitable reference product, to-  
6           gether with guidance for applying those orders  
7           to specific dosage forms.

8           “(B) STANDARD PRACTICES AND SPECIAL  
9           NEEDS OF POPULATIONS.—The orders and  
10          guidance issued by the Secretary under sub-  
11          paragraph (A) shall take into account relevant  
12          public standards and standard practices for  
13          evaluating the quality of drug products and  
14          may take into account special needs of popu-  
15          lations, including children.

16          “(e) INFORMATION SUBMITTED BY REQUESTORS.—

17          “(1) CONFIDENTIAL INFORMATION.—Any infor-  
18          mation, including reports of testing conducted on the  
19          drug or drugs involved, that is submitted by a re-  
20          questor in connection with proceedings on an admin-  
21          istrative order under this section (or any minor  
22          change under subsection (d)) and is a trade secret  
23          or confidential information subject to section  
24          552(b)(4) of title 5, United States Code, or section  
25          1905 of title 18, United States Code, shall not be

1 disclosed to the public unless the requestor consents  
2 to that disclosure.

3 ~~“(2) PUBLIC AVAILABILITY LIMITATIONS.—The~~  
4 ~~Secretary shall make available to the public any in-~~  
5 ~~formation (other than information contained in sub-~~  
6 ~~ject-level data sets, such as those derived from indi-~~  
7 ~~vidual case report forms) submitted by a requestor~~  
8 ~~in support of a request under subsection (e)(6)(A)~~  
9 ~~as of the date on which the proposed order is issued~~  
10 ~~unless—~~

11 ~~“(A) the information pertains to pharma-~~  
12 ~~ceutical quality, unless such information is nec-~~  
13 ~~essary to establish standards under which a~~  
14 ~~drug is generally recognized as safe and effec-~~  
15 ~~tive within the meaning of section 201(p)(1);~~

16 ~~“(B) the information is submitted in a re-~~  
17 ~~questor-initiated request, but the requestor~~  
18 ~~withdraws such request before the Secretary~~  
19 ~~issues the proposed order in accordance with~~  
20 ~~withdrawal procedures established by the Sec-~~  
21 ~~retary; or~~

22 ~~“(C) the Secretary otherwise obtains the~~  
23 ~~information under subsection (d).~~

24 ~~“(f) PUBLIC AVAILABILITY OF ADMINISTRATIVE OR-~~  
25 ~~DERS.—The Secretary shall establish, maintain, update~~

1 (as the Secretary determines necessary, but not less fre-  
 2 quently than annually), and make available on the internet  
 3 website of the Food and Drug Administration—

4           “(1) a repository of each final administrative  
 5 order and interim final order issued under sub-  
 6 section (e) that is in effect, including the complete  
 7 text of the administrative order; and

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

11                   “(A) a brief description of the administra-  
 12 tive order; and

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

16           “(g) UPDATES TO DRUG LISTING INFORMATION.—

17 A sponsor who makes a change to a drug other than a  
 18 change in dosage form, which is in conformity with the  
 19 requirements under subparagraph (A) or (B) of subsection  
 20 (b)(1), shall not be subject to the requirements of sub-  
 21 section (e) or (d) with respect to such change, and shall  
 22 submit updated drug listing information for the drug in  
 23 accordance with the requirements of section 510(j) within  
 24 30 calendar days of the date on which the drug, with the

1 change, is first introduced or delivered for introduction  
2 into interstate commerce.

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

16       “(i) DEVELOPMENT ADVICE TO REQUESTORS OR  
17 SPONSORS.—

18               “(1) IN GENERAL.—The Secretary shall estab-  
19 lish procedures under which requestors may meet  
20 with appropriate officials of the Food and Drug Ad-  
21 ministration to obtain advice on the studies and  
22 other information necessary to support requests  
23 under this section and other matters relevant to the  
24 regulation of monograph drugs and the development  
25 of new monograph drugs under this section.



1           “(2) PARTICIPATION OF MULTIPLE SPON-  
2           SORS.—The Secretary shall establish procedures to  
3           facilitate efficient participation by multiple request-  
4           tors in proceedings under this section, including pro-  
5           vision for joint meetings with multiple requestors or  
6           with organizations nominated by requestors to rep-  
7           resent their interests in a proceeding.

8           “(3) PRIVATE MEETINGS WITH REQUESTORS.—  
9           The procedures established under this subsection  
10          shall include appropriate provision for confidential  
11          meetings with requestors with respect to discussion  
12          of matters involving confidential commercial infor-  
13          mation or trade secrets.

14          “(j) EFFECT ON EXISTING REGULATIONS GOV-  
15          ERNING NONPRESCRIPTION DRUGS.—

16          “(1) REGULATIONS OF GENERAL APPLICA-  
17          BILITY TO NONPRESCRIPTION DRUGS.—Except as  
18          provided in this subsection, nothing in this section  
19          supersedes regulations establishing general require-  
20          ments for nonprescription drugs, including regula-  
21          tions of general applicability contained in parts 201,  
22          250, and 330 of title 21, Code of Federal Regula-  
23          tions, or any successor regulations. The Secretary  
24          shall establish or modify such regulations by means

1 of rulemaking in accordance with section ~~553~~ of title  
2 ~~5~~, United States Code.

3 ~~“(2) REGULATIONS ESTABLISHING REQUIRE-~~  
4 ~~MENTS FOR SPECIFIC NONPRESCRIPTION DRUGS.—~~

5 ~~“(A) IN GENERAL.—Section 310.545 of~~  
6 ~~title 21, Code of Federal Regulations, as in ef-~~  
7 ~~fect on the date of enactment of this section,~~  
8 ~~shall be deemed to be final administrative order~~  
9 ~~under subsection (e).~~

10 ~~“(B) OTHER REGULATIONS.—Regulations~~  
11 ~~establishing requirements for specific non-~~  
12 ~~prescription drugs marketed pursuant to this~~  
13 ~~section that are in effect on the day before the~~  
14 ~~date of enactment of this section (including~~  
15 ~~such requirements in parts 201, 250, and 330~~  
16 ~~of title 21, Code of Federal Regulations), shall~~  
17 ~~be deemed to be final administrative orders~~  
18 ~~under subsection (e) only as such requirements~~  
19 ~~apply to monograph drugs.~~

20 ~~“(C) EFFECTIVE DATE PERIOD.—Unless~~  
21 ~~withdrawn or revised by the Secretary, the reg-~~  
22 ~~ulations under title 21 of the Code of Federal~~  
23 ~~Regulations that are described in subparagraph~~  
24 ~~(B) shall remain in effect with respect to drugs~~

1 not subject to subparagraph (A), (B), (C), or  
2 (D) of subsection (b)(1).

3 ~~“(3) WITHDRAWAL OF REGULATIONS.—The~~  
4 Secretary shall withdraw regulations establishing  
5 final monographs and the procedures governing the  
6 ~~over-the-counter drug review under part 330 and~~  
7 ~~other relevant parts of title 21, Code of Federal~~  
8 ~~Regulations (as in effect on the day before the date~~  
9 ~~of enactment of this Act), or make technical changes~~  
10 ~~to such regulations to ensure conformity with appro-~~  
11 ~~priate terminology and cross references, to the ex-~~  
12 ~~tent needed to effectuate or harmonize the provi-~~  
13 ~~sions of this section. Notwithstanding subchapter H~~  
14 ~~of chapter 5 of title 5, United States Code, any such~~  
15 ~~withdrawal or technical amendments shall be made~~  
16 ~~without public notice and comment and be effective~~  
17 ~~upon publication through notice in the Federal Reg-~~  
18 ~~ister (or upon such date as specified in such notice).~~

19 ~~“(k) GUIDANCE.—~~

20 ~~“(1) ISSUANCE.—The Secretary shall issue~~  
21 ~~guidance that provides—~~

22 ~~“(A) the procedures and principles for for-~~  
23 ~~mal meetings between the Secretary and spon-~~  
24 ~~sors or requestors for drugs subject to this sec-~~  
25 ~~tion;~~

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

3           “(C) the format of electronic submissions  
4           to the Secretary under this section;

5           “(D) consolidated proceedings and the pro-  
6           cedures for such proceedings where appropriate;  
7           and

8           “(E) for minor changes in drugs, rec-  
9           ommendations on how to comply with the re-  
10          quirements in administrative orders issued  
11          under subsection (e)(3).

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

15          “(m) INAPPLICABILITY OF PAPERWORK REDUCTION  
16          ACT.—Chapter 35 of title 44, United States Code, shall  
17          not apply to collections of information made under this  
18          section.”.

19          **SEC. 102. MISBRANDING.**

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

23          “(ee) If it is a nonprescription drug that is not the  
24          subject of an application approved under section 505, and

1 does not comply with the requirements under section  
2 505G.

3 “~~(ff)~~ If it is a drug for which fees under section  
4 744L-1 have been assessed but have not been paid.”.

5 **SEC. 103. CONFORMING AMENDMENTS TO THE SUNSCREEN**  
6 **INNOVATION ACT.**

7 (a) REVIEW OF NONPRESCRIPTION INGREDIENTS  
8 SUBJECT TO SUNSCREEN INNOVATION ACT.—

9 (1) PENDING SUNSCREEN INGREDIENTS.—Non-  
10 prescription sunscreen active ingredients or combina-  
11 tions of sunscreen active ingredients subject, on the  
12 date of enactment of this Act, to a proposed sun-  
13 screen order, as defined in section 586(7) of the  
14 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
15 360fff(7)), shall—

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

19 (B) be reviewed under section 505G of  
20 such Act upon notification of the Secretary by  
21 the sponsor that such sponsor elects to have  
22 such ingredient or combination of ingredients  
23 reviewed under such section 505G, and such  
24 proposed sunscreen order under such section  
25 586C shall be considered a proposed adminis-

1           trative order under section 505G(e)(3)(A)(ii) of  
2           such Act.

3           ~~(2) PENDING NONSUNSCREEN INGREDIENTS.—~~

4           The sponsor of any application described in section  
5           586F of the Federal Food, Drug, and Cosmetic Act  
6           (21 U.S.C. 360fff-6) that was submitted to the Sec-  
7           retary of Health and Human Services (referred to in  
8           this section as the “Secretary”) pursuant to section  
9           330.14 of title 21, Code of Federal Regulations (as  
10          in effect on the day before the date of enactment of  
11          this Act), shall—

12                   (A) notify the Secretary that the sponsor  
13                   elects to withdraw such application; or

14                   (B) notify the Secretary that the sponsor  
15                   elects for such ingredient to be considered  
16                   under section 505G of the Federal Food, Drug,  
17                   and Cosmetic Act, and any proposed order  
18                   under such section 586F shall be considered a  
19                   proposed administrative order under section  
20                   505G(e)(3)(A)(ii) of that Act.

21           ~~(3) INGREDIENTS SUBMITTED AFTER THE~~  
22           ~~DATE OF ENACTMENT OF SECTION 506G.—Any in-~~  
23           ~~redient that is eligible for review under section~~  
24           ~~506G of the Federal Food, Drug, and Cosmetic Act~~

1 and is submitted after the date of enactment of this  
2 Act shall be considered under that section.

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

7 “(11) MEETINGS WITH SPONSORS.—A sponsor  
8 may request an individual, confidential meeting to  
9 discuss the data requirements to support a general  
10 recognition of safety and effectiveness with respect  
11 to the subject of a pending sunscreen ingredient.  
12 The Secretary shall respond within 14 calendar days  
13 of the request and schedule such meeting within 45  
14 calendar days, or within such timeline as specified in  
15 the letters described in section 201 of the Over-the-  
16 Counter Drug Safety, Innovation, and Reform Act.  
17 If a sponsor requests more than one confidential  
18 meeting for the same request, the Secretary may  
19 refuse to grant an additional confidential meeting  
20 request if the Secretary determines such additional  
21 confidential meeting is not reasonably necessary for  
22 the sponsor to advance its request. The Secretary  
23 shall publish a post-meeting summary on the inter-  
24 net website of the Food and Drug Administration of  
25 any confidential meeting that does not disclose con-

1       fidential business information. Such meetings shall  
2       not be required to comply with guidance issued by  
3       the Secretary addressing formal meetings for spon-  
4       sors of human drug applications, as defined in sec-  
5       tion 735.”.

6       (c) PRODUCT DIFFERENTIATION.—Section 586C of  
7       the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
8       360fff-3) is amended by adding at the end the following:

9       “(f) PRODUCT DIFFERENTIATION.—

10           “(1) IN GENERAL.—A final sunscreen order  
11       shall have the effect of providing the order requestor  
12       (or the licensee, assignee, or successors in interest  
13       of such requestor with respect to the subject of such  
14       request and listed under paragraph (5)) the exclu-  
15       sive right, for a period of 2 years, to market a sun-  
16       screen ingredient under this section incorporating  
17       changes described in paragraph (2) subject to the  
18       limitations under paragraph (4), beginning on the  
19       date the requestor (or any licensee, assignee, or  
20       successors in interest of such requestor with respect  
21       to the subject of such request and listed under para-  
22       graph (5)) may lawfully market such sunscreen in-  
23       gredient pursuant to the order.



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

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

7                   “(B) permits a change in the conditions of  
8                   use of a sunscreen ingredient, for which human  
9                   data studies conducted or sponsored by the re-  
10                  questor (or for which the requestor has an ex-  
11                  clusive right of reference) were essential to the  
12                  issuance of such order.

13           “(3) MARKETED SUNSCREEN.—The marketed  
14           sunscreen ingredients described this paragraph are  
15           sunscreen ingredients—

16                   “(A) marketed in accordance with a final  
17                   monograph issued under part 330 of title 21,  
18                   Code of Federal Regulations (including condi-  
19                   tions of use thereunder), as in effect on the day  
20                   before the date of enactment of this section;

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

1           “(C) marketed as category I in accordance  
2 with an advance notice of proposed rulemaking  
3 issued under such part 330 (including condi-  
4 tions of use and any applicable subsequent de-  
5 terminations thereunder), as so in effect; or

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

8           “(4) LIMITATIONS ON PRODUCT DIFFERENTIA-  
9 TION.—

10           “(A) ONLY ONE PERIOD.—Only one 2-year  
11 period may be granted per ingredient under  
12 paragraph (1).

13           “(B) EXCLUSIONS.—No period of product  
14 differentiation under this subparagraph shall  
15 apply to changes to a sunscreen that are—

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

18           “(ii) safety-related changes described  
19 in section 744L-1(a)(2)(C), required under  
20 section 505G(e)(5), or any other change  
21 the Secretary determines necessary to en-  
22 sure safe use; or

23           “(iii) changes related to methods of  
24 testing safety or efficacy.

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

8           “(6) HUMAN DATA DEFINED.—For purposes of  
 9           this subsection, the term ‘human data’ means data  
 10          from clinical trials of safety or effectiveness (includ-  
 11          ing actual use studies), pharmacokinetics, or bio-  
 12          availability.”.

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

17                 “(3) RELATIONSHIP TO ORDERS UNDER SEC-  
 18                 TION 505G.—A final sunscreen order shall be deemed  
 19                 to be a final administrative order under section  
 20                 505G and subject to the applicable provisions under  
 21                 such section 505G, including with respect to amend-  
 22                 ment of such order.”.

23          (e) PRECLUSION OF NEW SUNSCREEN SUBMISSIONS;  
 24          OPTION TO TRANSFER SUBMISSIONS TO OTC MONO-  
 25          GRAPH ORDER PROCESS.—

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

5           (2) ~~OPTION TO TRANSFER SUBMISSIONS TO OTC~~  
 6           ~~MONOGRAPH ORDER PROCESS.~~—

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

16          (B) ~~REQUESTS.~~—A request described in  
 17          this subparagraph is—

18               (i) a request under section 586A of  
 19               the Federal Food, Drug, and Cosmetic Act  
 20               submitted before the date of enactment of  
 21               this Act; or

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

24          (f) ~~TREATMENT OF AUTHORITY REGARDING FINAL-~~  
 25          ~~IZATION OF SUNSCREEN MONOGRAPH.~~—Section 586E of

1 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
2 360fff-5) is amended to read as follows:

3 **“SEC. 586E. SUNSCREEN ORDER.**

4 “(a) IN GENERAL.—

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

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

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

18 “(A) effective not later than November 26,  
19 2019; and

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

22 “(b) REPORTS.—If a revised sunscreen order issued  
23 under subsection (a) does not include provisions related  
24 to the effectiveness of various sun protection factor levels,  
25 and does not address all dosage forms known to the Sec-

1 retary to be used in sunscreens marketed in the United  
 2 States without a new drug application approved under sec-  
 3 tion 505, the Secretary shall submit a report to the Com-  
 4 mittee on Health, Education, Labor, and Pensions of the  
 5 Senate and the Committee on Energy and Commerce of  
 6 the House of Representatives on the rationale for omission  
 7 of such provisions from such order, and a plan and  
 8 timeline to compile any information necessary to address  
 9 such provisions through such order.”.

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

15 **“SEC. 586H. SUNSET.**

16 “This subchapter shall no longer be effective upon  
 17 the later of—

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

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

1 **SEC. 104. DRUGS EXCLUDED FROM OVER-THE-COUNTER**  
2 **REVIEW.**

3 (a) **IN GENERAL.**—Nothing in this Act (or the  
4 amendments made by this Act) shall apply to any non-  
5 prescription drug which was excluded by the Food and  
6 Drug Administration from the Over-the-Counter Drug Re-  
7 view in accordance with the statement set out at page  
8 9466 of volume 37 of the Federal Register, published on  
9 May 11, 1972.

10 (b) **RULE OF CONSTRUCTION.**—Nothing in this sec-  
11 tion shall be construed to preclude or limit the applica-  
12 bility of any provision of the Federal Food, Drug, and  
13 Cosmetic Act.

14 **SEC. 105. CONFORMING AMENDMENT.**

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

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

18 (A) by striking “final regulation” and in-  
19 serting “final order”; and

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

21 (2) in subparagraph (A), by striking “regula-  
22 tion in effect” and inserting “regulation or order in  
23 effect”.

1 **SEC. 106. ANNUAL UPDATE TO CONGRESS ON APPRO-**  
2 **PRIATE PEDIATRIC INDICATION FOR CER-**  
3 **TAIN COUGH AND COLD MONOGRAPH DRUGS.**

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

12 (1) in evaluating the cough and cold monograph  
13 described in subsection (b) with respect to children  
14 under age 6; and

15 (2) as appropriate, revising such cough and cold  
16 monograph to address such children, through the ad-  
17 ministrative order process under section 505G(b) of  
18 the Federal Food, Drug, and Cosmetic Act, as  
19 added by section 101.

20 (b) **COUGH AND COLD MONOGRAPH DESCRIBED.**—

21 The cough and cold monograph described in this sub-  
22 section consists of the conditions under which nonprescrip-  
23 tion drug products containing antitussive, expectorant,  
24 nasal decongestant, or antihistamine active ingredients (or  
25 combinations thereof) are generally recognized as safe and  
26 effective, as specified in part 341 of title 21, Code of Fed-



1 eral Regulations (as in effect on the day before the date  
 2 of enactment of this Act), and included in an administra-  
 3 tive order deemed established under such section 505G(b)  
 4 of the Federal Food, Drug, and Cosmetic Act.

5 (e) DURATION OF AUTHORITY.—Subsection (a) shall  
 6 have no force or effect beginning on the date on which  
 7 the Secretary submits a letter under subsection (a) in  
 8 which the Secretary indicates that the Food and Drug Ad-  
 9 ministration has completed its evaluation and revised, in  
 10 a final administrative order, as applicable, the cough and  
 11 cold monograph in accordance with this section.

## 12 **TITLE II—FEES RELATING TO** 13 **MONOGRAPH DRUGS**

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

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

17 (b) FINDINGS.—The Congress finds that the fees au-  
 18 thorized by the amendments made in this title will be dedi-  
 19 cated toward the regulation of monograph drugs under  
 20 section 505G of the Federal, Food, Drug, and Cosmetic  
 21 Act, as set forth in the goals identified for purposes of  
 22 such section, in the letters from the Secretary of Health  
 23 and Human Services to the Chairman of the Committee  
 24 on Health, Education, Labor, and Pensions of the Senate  
 25 and the Chairman of the Committee on Energy and Com-

1 merce of the House of Representatives, as set forth in the  
2 Congressional Record.

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

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

7 **“PART 10—FEES RELATING TO MONOGRAPH**  
8 **DRUGS**

9 **“SEC. 744L. DEFINITIONS.**

10 “For purposes of this part:

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

14 “(A) one business entity controls, or has  
15 the power to control, the other business entity;  
16 or

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

19 “(2) the term ‘contract manufacturing organi-  
20 zation facility’ means a monograph drug facility  
21 where neither the owner of such manufacturing fa-  
22 cility nor any affiliate of such owner or facility sells  
23 such monograph drug produced at such facility di-  
24 rectly to wholesalers, retailers, or consumers in the  
25 United States.

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

4           “(A) officers and employees of the Food  
5 and Drug Administration, contractors of the  
6 Food and Drug Administration, advisory com-  
7 mittees, and costs related to such officers, em-  
8 ployees, and committees and to contracts with  
9 such contractors;

10           “(B) management of information, and the  
11 acquisition, maintenance, and repair of com-  
12 puter resources;

13           “(C) leasing, maintenance, renovation, and  
14 repair of facilities and acquisition, maintenance,  
15 and repair of fixtures, furniture, scientific  
16 equipment, and other necessary materials and  
17 supplies; and

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

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

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

3           ~~“(6) The term ‘monograph drug activities’~~  
4           ~~means activities of the Secretary associated with~~  
5           ~~monograph drug products and inspection of facilities~~  
6           ~~associated with such products, including—~~

7                   ~~“(A) the activities necessary for review and~~  
8                   ~~evaluation of monograph drugs and monograph~~  
9                   ~~drug order requests, including—~~

10                           ~~“(i) orders proposing or finalizing ap-~~  
11                           ~~plicable requirements of use for monograph~~  
12                           ~~drugs products;~~

13                           ~~“(ii) orders affecting status regarding~~  
14                           ~~general recognition of safety and effective-~~  
15                           ~~ness of a monograph drug ingredient or~~  
16                           ~~combination of ingredients under specified~~  
17                           ~~requirements of use;~~

18                           ~~“(iii) all monograph drug development~~  
19                           ~~and review activities, including intra-agen-~~  
20                           ~~cy collaboration;~~

21                           ~~“(iv) regulation and policy develop-~~  
22                           ~~ment activities related to monograph~~  
23                           ~~drugs;~~

- 1                   “(v) development of product standards  
2                   for products subject to review and evalua-  
3                   tion;
- 4                   “(vi) meetings regarding monograph  
5                   drug activities;
- 6                   “(vii) review of labeling prior to  
7                   issuance of orders related to monograph  
8                   drugs or conditions of use; and
- 9                   “(viii) regulatory science activities re-  
10                  lated to monograph drugs;
- 11                  “(B) inspections related to monograph  
12                  drugs;
- 13                  “(C) monitoring of clinical and other re-  
14                  search conducted in connection with monograph  
15                  drugs;
- 16                  “(D) safety activities with respect to mono-  
17                  graph drugs, including—
- 18                       “(i) collecting, developing, and review-  
19                       ing safety information on monograph  
20                       drugs, including adverse event reports;
- 21                       “(ii) developing and using improved  
22                       adverse event data-collection systems, in-  
23                       cluding information technology systems;  
24                       and

1           “(iii) developing and using improved  
2           analytical tools to assess potential safety  
3           risks, including access to external data-  
4           bases; and

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

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

10           “(i) that is under one management, either  
11           direct or indirect;

12           “(ii) at one geographic location or address  
13           engaged in manufacturing or processing a  
14           monograph drug in finished dosage form;

15           “(iii) includes a finished dosage form man-  
16           ufacturer facility or an affiliate thereof in a  
17           contractual relationship with a monograph drug  
18           requestor or requestors to manufacture or proc-  
19           ess monograph drugs; and

20           “(iv) does not include a business or other  
21           entity whose only manufacturing or processing  
22           activities relate to—

23           “(I) production of clinical research  
24           supplies;

25           “(II) testing; or

1           ~~“(III) packaging of packaged final~~  
2           ~~dosages in a manner that does not affect~~  
3           ~~the drug.~~

4           ~~“(B) For purposes of subparagraph (A), separ-~~  
5           ~~ate buildings or locations within close proximity are~~  
6           ~~considered to be at 1 geographic location or address~~  
7           ~~if the activities conducted in them are—~~

8           ~~“(i) closely related to the same business~~  
9           ~~enterprise;~~

10          ~~“(ii) under the supervision of the same~~  
11          ~~local management; and~~

12          ~~“(iii) under a single firm establishment~~  
13          ~~identifier and capable of being inspected by the~~  
14          ~~Food and Drug Administration during a single~~  
15          ~~inspection.~~

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

22          ~~“(8) The term ‘monograph drug meeting’~~  
23          ~~means any meeting regarding the content of a pro-~~  
24          ~~posed monograph drug order request.~~

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

5           “(10) The term ‘monograph drug order request’  
6 means a request for an order under section 505G for  
7 the issuance of an administrative order for a change  
8 to the monograph drug product.

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

14           “(12) The term ‘person’ includes an affiliate  
15 thereof.

16           “(13) The term ‘Tier 1 monograph drug order  
17 request’ means any monograph drug order request  
18 not determined to be a Tier 2 monograph drug order  
19 request.

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

23                   “(i) the reordering of existing information  
24 in the drug facts label of a monograph drug  
25 product;



1           “(ii) the addition of information to the  
2 other information section of the drug facts label  
3 of a nonprescription drug product, as limited by  
4 part 201.66(c)(7) of title 21, Code of Federal  
5 Regulations;

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

10           “(iv) the standardization of the concentra-  
11 tion or dose of a specific finalized ingredient  
12 within a particular finalized monograph;

13           “(v) a change to ingredient nomenclature  
14 to align with nomenclature of a standards-set-  
15 ting organization; or

16           “(vi) addition of an interchangeable term  
17 in accordance with part 330.1 of title 21, Code  
18 of Federal Regulations.

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

1       mination in a proposed order issued pursuant to sec-  
2       tion 505G(e).

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

5       “(a) TYPES OF FEES.—Beginning with fiscal year  
6       2018, the Secretary shall assess and collect fees in accord-  
7       ance with this section as follows:

8               “(1) FACILITY FEE.—

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

16                     “(B) EXCEPTION.—

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

1 establishment registration set forth in sec-  
2 tion 510.

3 “(ii) FEE AMOUNT.—The amount of  
4 the fee for a contract manufacturing orga-  
5 nization facility shall be equal to two-thirds  
6 the amount of the fee for a monograph  
7 drug facility that is not a contract manu-  
8 facturing organization facility.

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

12 “(i) the first business day of April of  
13 such year; and

14 “(ii) the first business day after the  
15 date of enactment of an appropriations Act  
16 providing for the collection and obligation  
17 of fees under this section for such year.

18 “(2) MONOGRAPH DRUG ORDER REQUEST  
19 FEE.—

20 “(A) IN GENERAL.—Each person that sub-  
21 mits a monograph drug order request shall be  
22 subject to a fee for a monograph drug order re-  
23 quest. The monograph drug order request fee  
24 under paragraph (2) shall be—

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

5           “(ii) for a Tier 2 monograph drug  
6           order request other than a Tier 1 request,  
7           \$100,000 adjusted for inflation for the fis-  
8           cal year (as determined under subsection  
9           (e)(1)).

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

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

22                 “(i) a contraindication, warning, or  
23                 precaution;

24                 “(ii) a statement about risk associated  
25                 with misuse or abuse; or

1           “(iii) an instruction about dosage and  
2           administration that is intended to increase  
3           the safe use of the monograph drug prod-  
4           uct.

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

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

22          “(F) FEES FOR ORDER REQUESTS PRE-  
23          VIOUSLY REFUSED FOR FILING OR WITHDRAWN  
24          BEFORE FILING.—A monograph drug order re-  
25          quest that was submitted but was refused for

1 filing, or was withdrawn before being accepted  
2 or refused for filing, shall be subject to the full  
3 fee under subparagraph (A) upon being resub-  
4 mitted or filed over protest.

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

16 “(3) REFUNDS.—

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

22 “(B) DISPUTES CONCERNING FEES.—To  
23 qualify for the return of a fee claimed to have  
24 been paid in error under this paragraph, a per-  
25 son shall submit to the Secretary a written re-

1           quest justifying such return within 180 cal-  
2           endar days after such fee was paid.

3           “(b) FEE REVENUE AMOUNTS.—

4           “(1) FISCAL YEAR 2018.—For fiscal year 2018,  
5           fees under subsection (a)(1) shall be established to  
6           generate a total facility fee revenue amount equal to  
7           the sum of—

8                   “(A) the annual base revenue for fiscal  
9                   year 2018 (as determined under paragraph  
10                  (3));

11                  “(B) the dollar amount equal to the oper-  
12                  ating reserve adjustment for the fiscal year, if  
13                  applicable (as determined under subsection  
14                  (e)(2)); and

15                  “(C) additional direct cost adjustments (as  
16                  determined under subsection (e)(3)).

17           “(2) SUBSEQUENT FISCAL YEARS.—For each of  
18           the fiscal years 2019 through 2022, fees under sub-  
19           section (a)(1) shall be established to generate a total  
20           facility fee revenue amount equal to the sum of—

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

23                   “(B) the dollar amount equal to the infla-  
24                   tion adjustment for the fiscal year (as deter-  
25                   mined under subsection (e)(1));

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

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

7           “(E) additional dollar amounts for each  
 8           fiscal year as follows:

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

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

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

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

13           “(3) ANNUAL BASE REVENUE.—For purposes  
 14           of paragraphs (1)(A) and (2)(A), the dollar amount  
 15           of the annual base revenue for a fiscal year shall  
 16           be—

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

18                   “(B) for fiscal years 2019 through 2022,

19           the dollar amount of the total revenue amount

20           established under this subsection for the pre-

21           vious fiscal year, not including any adjustments

22           made under subsection (c)(2) or (c)(3).

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

24           “(1) INFLATION ADJUSTMENT.—



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

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

8           “(ii) the inflation adjustment percent-  
9 age under subparagraph (B).

10          “(B) INFLATION ADJUSTMENT PERCENT-  
11 AGE.—The inflation adjustment percentage  
12 under this subparagraph for a fiscal year is  
13 equal to—

14          “(i) for each of fiscal years 2019  
15 through 2020, the average annual percent  
16 change that occurred in the Consumer  
17 Price Index for urban consumers (Wash-  
18 ington-Baltimore, ~~DC MD VA WV~~; Not  
19 Seasonally Adjusted; All items; Annual  
20 Index) for the first 3 years of the pre-  
21 ceeding 4 years of available data; and

22          “(ii) for each of fiscal years 2021 and  
23 2022, the sum of—

24                  “(I) the average annual percent  
25 change in the cost, per full-time equiv-

1           alent position of the Food and Drug  
2           Administration, of all personnel com-  
3           pensation and benefits paid with re-  
4           spect to such positions for the first 3  
5           years of the preceding 4 fiscal years,  
6           multiplied by the proportion of per-  
7           sonnel compensation and benefits  
8           costs to total costs of monograph drug  
9           activities (as defined in subsection  
10          (a)) for the first 3 years of the pre-  
11         ceding 4 fiscal years; and

12                 “(H) the average annual percent  
13           change that occurred in the Consumer  
14           Price Index for urban consumers  
15           (~~Washington-Baltimore, DC-MD-VA-~~  
16           ~~WV; Not Seasonally Adjusted; All~~  
17           ~~items; Annual Index)~~ for the first 3  
18           years of the preceding 4 years of  
19           available data multiplied by the pro-  
20           portion of all costs other than per-  
21           sonnel compensation and benefits  
22           costs to total costs of monograph drug  
23           activities for the first 3 years of the  
24           preceding 4 fiscal years.

25                 “(2) OPERATING RESERVE ADJUSTMENT.—

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

9           “(B) For each fiscal year the number of  
10 weeks of operating reserves shall be no more  
11 than—

12                   “(i) 3 weeks for fiscal year 2018;

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

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

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

16           and

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

18           “(C) If, for fiscal years 2019 through  
19 2022, the Secretary has carryover balances for  
20 monograph drug activities in excess of the num-  
21 ber of weeks of such operating reserves speci-  
22 fied in subparagraph B, the Secretary shall re-  
23 duce such fee revenue and fees to provide for  
24 not more than the number of weeks of such op-

1 erating reserves specified in subparagraph  
2 (B)(v).

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

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

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

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

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

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

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

19 “(4) ANNUAL FEE SETTING.—

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

22 “(i) establish monograph drug facility  
23 fees for fiscal year 2018 under subsection  
24 (a)(1), based on the revenue amount for  
25 such year under subsection (b) and the ad-

1           justments provided under this subsection;  
2           and

3           “~~(ii)~~ publish such fee revenue and fa-  
4           cility fees in the Federal Register.

5           “~~(B)~~ SUBSEQUENT FISCAL YEARS.—The  
6           Secretary shall, not later than January 31 of  
7           each fiscal year that begins after September 30,  
8           2018, establish for each such fiscal year, based  
9           on the revenue amounts under subsection (b)  
10          and the adjustments provided under this sub-  
11          section—

12           “~~(i)~~ monograph drug facility fees  
13           under subsection (a)(1);

14           “~~(ii)~~ monograph drug order request  
15           fees under subsection (a)(2); and

16           “~~(iii)~~ publish such fee revenue, facility  
17           fees, and monograph drug order request  
18           fees in the Federal Register.

19          “~~(d)~~ IDENTIFICATION OF FACILITIES.—Each person  
20          that owns a monograph drug facility shall submit to the  
21          Secretary the information required under this subsection  
22          each year. Such information shall, for each fiscal year—

23           “~~(1)~~ be submitted as part of the requirements  
24           for drug establishment registration set forth in sec-  
25           tion 510; and

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

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

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

10           “(2) EFFECT ON ELIGIBILITY FOR MEET-  
11           INGS.—If a monograph drug requestor fails to pay  
12           a fee assessed under subsection (a), the requestor  
13           shall be considered ineligible for monograph drug  
14           meetings.

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

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

22           “(1) IN GENERAL.—Subject to paragraph  
23           (2)(D), fees authorized under subsection (a) shall be  
24           collected and available for obligation only to the ex-  
25           tent and in the amount provided in advance in ap-

1       appropriations Acts. Such fees are authorized to re-  
 2       main available until expended. Such sums as may be  
 3       necessary may be transferred from the Food and  
 4       Drug Administration salaries and expenses appro-  
 5       priation account without fiscal year limitation to  
 6       such appropriation account for salaries and expenses  
 7       with such fiscal year limitation. The sums trans-  
 8       ferred shall be available solely for monograph drug  
 9       activities.

10           “(2)   COLLECTIONS   AND   APPROPRIATION  
 11       ACTS.—

12           “(A)   IN GENERAL.—Subject to subpara-  
 13       graphs (C) and (D), the fees authorized by this  
 14       section shall be collected and available in each  
 15       fiscal year in an amount not to exceed the  
 16       amount specified in appropriation Acts, or oth-  
 17       erwise made available for obligation, for such  
 18       fiscal year.

19           “(B)   USE OF FEES AND LIMITATION.—  
 20       The fees authorized by this section shall be  
 21       available to defray increases in the costs of the  
 22       resources allocated for monograph drug activi-  
 23       ties (including increases in such costs for an ad-  
 24       ditional number of full-time equivalent positions  
 25       in the Department of Health and Human Serv-

1           ices to be engaged in such activities), only if the  
2           Secretary allocates for such purpose an amount  
3           for such fiscal year (excluding amounts from  
4           fees collecting under this section) no less than  
5           \$12,000,000, multiplied by the adjustment fac-  
6           tor applicable to the fiscal year involved.

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

14          “(D) FEE COLLECTION DURING FIRST  
15          PROGRAM YEAR.—Until the date of enactment  
16          of an Act making appropriations and providing  
17          for the collection and obligation of fees under  
18          this section through September 30, 2018, for  
19          the salaries and expenses account of the Food  
20          and Drug Administration, fees authorized by  
21          this section for fiscal year 2018 may be col-  
22          lected and shall be credited to such account and  
23          remain available until expended.

24          “(E) PROVISION FOR EARLY PAYMENTS IN  
25          SUBSEQUENT YEARS.—Payment of fees author-



1           ized under this section for a fiscal year (after  
2           fiscal year 2018), prior to the due date for such  
3           fees, may be accepted by the Secretary in ac-  
4           cordance with authority provided in advance in  
5           a prior year appropriations Act.

6           “(3) AUTHORIZATION OF APPROPRIATIONS.—

7           For each of the fiscal years 2018 through 2022,  
8           there is authorized to be appropriated for fees under  
9           this section an amount equal to the total amount of  
10          fees assessed for such fiscal year under this section.

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

17          “(i) CONSTRUCTION.—This section may not be con-  
18         strued to require that the number of full-time equivalent  
19         positions in the Department of Health and Human Serv-  
20         ices, for officers, employers, and advisory committees not  
21         engaged in monograph drug activities, be reduced to offset  
22         the number of officers, employees, and advisory commit-  
23         tees so engaged.

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

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

15 “(b) **FISCAL REPORT.**—Not later than 120 calendar  
16 days after the end of fiscal year 2018 and each subsequent  
17 fiscal year for which fees are collected under this part,  
18 the Secretary shall prepare and submit to the Committee  
19 on Health, Education, Labor, and Pensions of the Senate  
20 and the Committee on Energy and Commerce of the  
21 House of Representatives a report on the implementation  
22 of the authority for such fees during such fiscal year and  
23 the use, by the Food and Drug Administration, of the fees  
24 collected for such fiscal year.

25 “(c) **PUBLIC AVAILABILITY.**—The Secretary shall  
26 make the reports required under subsections (a) and (b)

1 available to the public on the internet website of the Food  
2 and Drug Administration.

3 “(d) REAUTHORIZATION.—

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

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

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

15 “(C) scientific and academic experts;

16 “(D) health care professionals;

17 “(E) representatives of patient and con-  
18 sumer advocacy groups; and

19 “(F) the regulated industry.

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

23 “(A) present the recommendations devel-  
24 oped under paragraph (1) to the congressional  
25 committees specified in such paragraph;

1           “(B) publish such recommendations in the  
2           Federal Register;

3           “(C) provide for a period of 30 calendar  
4           days for the public to provide written comments  
5           on such recommendations;

6           “(D) hold a meeting at which the public  
7           may present its views on such recommenda-  
8           tions; and

9           “(E) after consideration of such public  
10          views and comments, revise such recommenda-  
11          tions as necessary.

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

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

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

23          (b) *TABLE OF CONTENTS.*—*The table of contents for*  
24          *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 assess 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 ‘non-***  
 14                   ***prescription drug’ means a drug that is not subject***  
 15                   ***to section 503(b)(1).***

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

1           “(3) *SPONSOR*.—*The term ‘sponsor’ means a*  
2           *person or group of persons marketing, manufacturing,*  
3           *or processing a drug and who has a listing in effect*  
4           *under section 510(j) for such drug.*

5           “(b) *TREATMENT OF MONOGRAPH DRUGS MARKETED*  
6           *WITHOUT AN APPROVED APPLICATION*.—

7           “(1) *IN GENERAL*.—*A nonprescription drug that*  
8           *is marketed without an approved application under*  
9           *section 505 shall be treated in accordance with this*  
10           *subsection beginning on the date of enactment of the*  
11           *Over-the-Counter Drug Safety, Innovation, and Re-*  
12           *form Act:*

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

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

22           “(bb) *in conformity with the require-*  
23           *ments for nonprescription use of such mono-*  
24           *graph, the general requirements specified for*

1           *nonprescription drugs, and the requirements*  
2           *under subsections (c), (d), and (j); and*

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

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

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

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

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

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

12           *“(III) in conformity with—*

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

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

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



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

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

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

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

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

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

3           *“(bb) classified in category III for safe-*  
4           *ty or effectiveness in the preamble of a pro-*  
5           *posed rule establishing such tentative final*  
6           *monograph;*

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

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

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

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

3           *“(bb) classified in category I for safety*  
4           *and effectiveness under such proposed mono-*  
5           *graph or advance notice of proposed rule-*  
6           *making;*

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

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

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

1            *tion drug is deemed to be not generally recog-*  
2            *nized as safe and effective within the meaning of*  
3            *section 201(p)(1), a new drug under section*  
4            *201(p), and misbranded under section 502(ee), if*  
5            *such drug—*

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

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

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

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

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

3            *“(D) A drug that is subject to the final*  
4            *monograph for sunscreen drug products set forth*  
5            *at part 352 of title 21, Code of Federal Regula-*  
6            *tions (as published at volume 64 page 27687 of*  
7            *the Federal Register), shall comply with the re-*  
8            *quirements of that monograph, except that the*  
9            *testing requirements for effectiveness and the pro-*  
10           *visions governing labeling shall be in accordance*  
11           *with section 201.327 of title 21, Code of Federal*  
12           *Regulations (as in effect on the date of enact-*  
13           *ment of the Over-the-Counter Drug Safety, Inno-*  
14           *vation, and Reform Act), or such changes to*  
15           *those requirements as may be made under sub-*  
16           *sections (c), (d), and (j).*

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

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

24           *“(B) not a nonprescription sunscreen active*  
25           *ingredient or combination of ingredients subject*

1           to a final sunscreen order, as defined in section  
2           586(2).

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

6           “(4) *RULES OF CONSTRUCTION.*—

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

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

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

17                 “(B) *APPLICABILITY OF OTHER PROVI-*  
18                 *SIONS.*—Nothing in this paragraph shall be con-  
19                 strued to preclude or limit the applicability of  
20                 any other provision of this Act.

21                 “(C) *NO EFFECT ON OTHER AUTHORI-*  
22                 *TIES.*—Nothing in this subsection shall be con-  
23                 strued to prohibit the Secretary from issuing an  
24                 order under this section finding a drug to be not  
25                 generally recognized as safe and effective.

1       “(c) *ADMINISTRATIVE ORDERS.*—

2               “(1) *IN GENERAL.*—

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

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

12                      “(ii) *generally recognized as safe and*  
13                      *effective within the meaning of section*  
14                      *201(p)(1); and*

15                      “(iii) *not required to be approved*  
16                      *under section 505.*

17                      “(B) *NOT GENERALLY RECOGNIZED AS SAFE*  
18                      *AND EFFECTIVE.*—*The Secretary shall issue an*  
19                      *order determining that a drug is not generally*  
20                      *recognized as safe and effective within the mean-*  
21                      *ing of section 201(p)(1) for the specified require-*  
22                      *ments if the Secretary determines that—*

23                      “(i) *the evidence shows that the drug is*  
24                      *not generally recognized as safe and effective*  
25                      *within the meaning of section 201(p)(1); or*

1           “(ii) *the evidence is inadequate to show*  
2           *that the drug is generally recognized as safe*  
3           *and effective within the meaning of section*  
4           *201(p)(1).*

5           “(2) *ADMINISTRATIVE ORDERS INITIATED BY*  
6           *THE SECRETARY; CITIZEN PETITIONS.—*

7           “(A) *IN GENERAL.—Except as provided in*  
8           *paragraph (5), in issuing an administrative*  
9           *order under paragraph (1) on the initiative of*  
10          *the Secretary, the Secretary shall—*

11           “(i) *not later than 2 business days be-*  
12           *fore issuance of the proposed order, infor-*  
13           *mally communicate the pending issuance of*  
14           *the order to sponsors of drugs that have a*  
15           *listing in effect under section 510(j) for*  
16           *drugs will be subject to such order;*

17           “(ii) *after making any such informal*  
18           *communication—*

19           “(I) *issue such a proposed admin-*  
20           *istrative order by publishing it on the*  
21           *internet website of the Food and Drug*  
22           *Administration and include in such*  
23           *order the reasons for the issuance of*  
24           *such order; and*



1           “(II) publish notice of availability  
2           of such proposed order in the *Federal*  
3           *Register*;

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

8           “(iv) if, after satisfying the require-  
9           ments of clauses (i) through (iii), the *Sec-*  
10          *retary* determines that it is appropriate to  
11          issue a final administrative order—

12           “(I) issue the final administrative  
13          order, together with a detailed state-  
14          ment of reasons, but such order shall  
15          not take effect until the time for re-  
16          questing judicial review under para-  
17          graph (4)(D)(ii) has expired;

18           “(II) publish a notice of avail-  
19          ability of such final administrative  
20          order in the *Federal Register*;

21           “(III) afford requestors of prod-  
22          ucts that will be subject to such order  
23          the opportunity for formal dispute res-  
24          olution up to the level of the *Director*  
25          of the *Center for Drug Evaluation and*

1           *Research, which initially shall be re-*  
2           *quested within 45 calendar days of the*  
3           *issuance of the order, and, for subse-*  
4           *quent levels of appeal, within 30 cal-*  
5           *endar days of the prior decision; and*

6                     *“(IV) except with respect to drugs*  
7           *described in paragraph (3)(B), upon*  
8           *completion of the formal dispute reso-*  
9           *lution procedure, inform the person or*  
10          *persons which sought such dispute reso-*  
11          *lution of their right to request a hear-*  
12          *ing.*

13                     *“(B) SPECIAL REQUIREMENTS WITH RE-*  
14          *SPECT TO CERTAIN MONOGRAPH DRUGS.—When*  
15          *issuing an administrative order under para-*  
16          *graph (1) on the initiative of the Secretary (ex-*  
17          *cept as provided under paragraph (4)) proposing*  
18          *to determine that a monograph drug described in*  
19          *subsection (b)(1)(B) is not generally recognized*  
20          *as safe and effective within the meaning of sec-*  
21          *tion 201(p)(1), the Secretary shall follow the pro-*  
22          *cedures in subparagraph (A) except that—*

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

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

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

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

14          “(iii) any person who submits data in  
15          such comment period shall include a certifi-  
16          cation that the person has submitted all evi-  
17          dence created, obtained, or received by that  
18          person that is both within the categories of  
19          data identified in the proposed order and  
20          relevant to a determination as to whether  
21          the drug is generally recognized as safe and  
22          effective within the meaning of section  
23          201(p)(1).

24          “(C) CITIZEN PETITIONS.—

1           “(i) *IN GENERAL.*—*The Secretary may*  
2           *issue an administrative order under para-*  
3           *graph (1) in response to a citizen petition*  
4           *submitted under section 10.30 of title 21,*  
5           *Code of Federal Regulations (or any suc-*  
6           *cessor regulation), subject to clause (ii).*

7           “(ii) *EFFECT OF PETITION.*—*Nothing*  
8           *in clause (i) shall be construed to provide*  
9           *an alternative to, or otherwise supplant or*  
10           *supersede—*

11                   “(I) *the processes through which a*  
12                   *requestor may seek an administrative*  
13                   *order pursuant to paragraph (5); or*

14                   “(II) *the fee structure under sec-*  
15                   *tion 744L-1(a)(2).*

16           “(3) *HEARINGS; JUDICIAL REVIEW.*—

17                   “(A) *IN GENERAL.*—*A person who partici-*  
18                   *ipated in each level of formal dispute resolution*  
19                   *under paragraph (2)(A)(iv)(III) of an adminis-*  
20                   *trative order with respect to a drug may request*  
21                   *a hearing concerning a final administrative*  
22                   *order issued under paragraph (2)(A)(iv) with re-*  
23                   *spect to such drug. Such person may submit a*  
24                   *request for a hearing, which shall be based solely*  
25                   *on the information in the administrative record,*

1           to the Secretary not later than 30 calendar days  
2           after receiving notice of the final decision of the  
3           formal dispute resolution procedure.

4           “(B) NO HEARING REQUIRED WITH RE-  
5           SPECT TO ORDERS RELATING TO CERTAIN  
6           DRUGS.—The Secretary is not required to pro-  
7           vide notice and an opportunity for a hearing  
8           pursuant to paragraph (2)(A)(iv) if the final ad-  
9           ministrative order involved relates to a drug—

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

12           “(ii) with respect to which no data rel-  
13           evant to the safety or effectiveness of such  
14           drug have been submitted to the administra-  
15           tive record since the issuance of the most re-  
16           cent tentative final monograph relating to  
17           such drug (or, as applicable, since the deem-  
18           ing of such tentative final monograph as a  
19           final administrative order under paragraph  
20           (6)).

21           “(C) HEARING PROCEDURES.—

22           “(i) DENIAL OF REQUEST FOR HEAR-  
23           ING.—If the Secretary determines that a re-  
24           quest for a hearing under subparagraph (A)  
25           with respect to a final administrative order

1            *issued under paragraph (2)(A)(iv), does not*  
2            *establish the existence of a genuine and sub-*  
3            *stantial question of material fact, the Sec-*  
4            *retary may deny such request. In making*  
5            *such a determination, the Secretary may*  
6            *consider only information and data that*  
7            *are based on relevant and reliable scientific*  
8            *principles and methodologies.*

9            *“(ii) SINGLE HEARING FOR MULTIPLE*  
10           *RELATED REQUESTS.—If more than one re-*  
11           *quest for a hearing is submitted with re-*  
12           *spect to the same administrative order*  
13           *under subparagraph (A), the Secretary may*  
14           *direct that a single hearing be conducted in*  
15           *which all persons whose hearing requests*  
16           *were granted may participate.*

17           *“(iii) PRESIDING OFFICER.—The Sec-*  
18           *retary shall designate a presiding officer of*  
19           *a hearing requested under subparagraph*  
20           *(A) who—*

21                    *“(I) is not an employee of the*  
22                    *Center for Drug Evaluation and Re-*  
23                    *search; and*

24                    *“(II) has not previously been in-*  
25                    *volved in the development of the appli-*

1            *cable administrative order or in the*  
2            *proceedings relating to that adminis-*  
3            *trative order.*

4            “(iv) *RIGHTS OF PARTIES TO HEAR-*  
5            *ING.—The parties to a hearing requested*  
6            *under subparagraph (A) shall have the right*  
7            *to present testimony, including testimony of*  
8            *expert witnesses, and to cross-examine wit-*  
9            *nesses presented by other parties. Where ap-*  
10           *propriate, the presiding officer may require*  
11           *that cross-examination by parties rep-*  
12           *resenting substantially the same interests be*  
13           *consolidated to promote efficiency and avoid*  
14           *duplication.*

15           “(v) *FINAL DECISION.—At the conclu-*  
16           *sion of a hearing requested under subpara-*  
17           *graph (A), the presiding officer of the hear-*  
18           *ing shall issue a decision containing find-*  
19           *ings of fact and conclusions of law. The de-*  
20           *cision of the presiding officer shall be final.*  
21           *The final decision may not take effect until*  
22           *the period under subparagraph (D)(ii) for*  
23           *submitting a request for judicial review of*  
24           *such decision expires.*

1                   “(D) *JUDICIAL REVIEW OF FINAL ADMINIS-*  
2                   *TRATIVE ORDER.*—

3                   “(i) *IN GENERAL.*—*The procedures de-*  
4                   *scribed in section 505(h) shall apply with*  
5                   *respect to judicial review of final adminis-*  
6                   *trative orders issued under this subsection*  
7                   *in the same manner and to the same extent*  
8                   *as such section applies to an order described*  
9                   *in such section except that the judicial re-*  
10                   *view shall be taken by filing in an appro-*  
11                   *priate district court of the United States in*  
12                   *lieu of the appellate courts specified in such*  
13                   *section.*

14                   “(ii) *TIME TO SUBMIT A REQUEST FOR*  
15                   *JUDICIAL REVIEW.*—*A person eligible to re-*  
16                   *quest a hearing under this paragraph and*  
17                   *seeking judicial review of a final adminis-*  
18                   *trative order issued under this subsection*  
19                   *shall file a request for such review not later*  
20                   *than 60 calendar days after the latest of—*

21                   “(I) *the date on which notice of*  
22                   *such order is published;*

23                   “(II) *the date on which any hear-*  
24                   *ing with respect to such order is denied*  
25                   *under subparagraph (C)(i);*



1                   “(III) the date on which a final  
2                   decision is made following any hearing  
3                   with respect to such order under sub-  
4                   paragraph (C)(v); or

5                   “(IV) if no hearing is requested,  
6                   the date on which the time for request-  
7                   ing a hearing expires.

8                   “(4) *EXPEDITED PROCEDURE WITH RESPECT TO*  
9                   *ADMINISTRATIVE ORDERS INITIATED BY THE SEC-*  
10                  *RETARY.—*

11                  “(A) *IMMINENT HAZARD TO THE PUBLIC*  
12                  *HEALTH.—*

13                  “(i) *IN GENERAL.—In the case of a de-*  
14                  *termination by the Secretary that a mono-*  
15                  *graph drug poses an imminent hazard to*  
16                  *the public health, the Secretary, after infor-*  
17                  *mally communicating with any sponsor*  
18                  *that has a listing in effect under section*  
19                  *510(j) for such drug not later than 48 hours*  
20                  *before issuance of an order under this sub-*  
21                  *paragraph, may—*

22                  “(I) *issue an interim final ad-*  
23                  *ministrative order for such drug or*  
24                  *combination of drugs under paragraph*

1                   (1), together with a detailed statement  
2                   of the reasons for such order;

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

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

10                  “(i) NONDELEGATION.—The Secretary  
11                  may not delegate the authority to issue an  
12                  interim final administrative order under  
13                  this subparagraph.

14                  “(B) SAFETY LABELING CHANGES.—

15                  “(i) IN GENERAL.—In the case of a de-  
16                  termination by the Secretary that a change  
17                  in the labeling of a drug, class of drugs, or  
18                  combination of drugs subject to this section  
19                  is reasonably expected to mitigate a signifi-  
20                  cant or unreasonable risk of a serious ad-  
21                  verse event associated with use of the drug,  
22                  the Secretary may—

23                  “(I) informally communicate, not  
24                  later than 48 hours before issuance of  
25                  an interim final order under this sub-

1           *paragraph any sponsors of a drug who*  
2           *has a listing in effect under section*  
3           *510(j) for such drug or combination of*  
4           *drugs;*

5           “(II) *after informally commu-*  
6           *nicating with the sponsors under sub-*  
7           *clause (I), issue an interim final ad-*  
8           *ministrative order under paragraph*  
9           *(1) to require such change, together*  
10          *with a detailed statement of the rea-*  
11          *sons for such order and, in the case of*  
12          *a required change to the packaging, a*  
13          *brief description of the factors consid-*  
14          *ered in accordance with paragraph*  
15          *(7)(B)(i);*

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

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

23          “(ii) *CONTENT OF ORDER.—An in-*  
24          *terim final order issued under this subpara-*  
25          *graph with respect to the labeling of a drug*

1           *may provide for new warnings and other*  
2           *information required for safe use of the*  
3           *drug.*

4           “(C) *EFFECTIVE DATE.*—*An order under*  
5           *subparagraph (A) or (B) shall take effect on a*  
6           *date specified by the Secretary.*

7           “(D) *FINAL ORDER.*—*After the completion*  
8           *of the proceedings in subparagraph (A) or (B),*  
9           *the Secretary shall—*

10            “(i) *issue a final order in accordance*  
11            *with paragraph (1);*

12            “(ii) *publish a notice of availability of*  
13            *such final administrative order in the Fed-*  
14            *eral Register; and*

15            “(iii) *afford sponsors of drugs that will*  
16            *be subject to such an order the opportunity*  
17            *for formal dispute resolution up to the level*  
18            *of the Director of the Center for Drug Eval-*  
19            *uation and Research, which initially shall*  
20            *be within 45 calendar days of the issuance*  
21            *of the order; and, for subsequent levels of*  
22            *appeal, within 30 calendar days of the*  
23            *prior decision.*

24           “(E) *HEARINGS.*—

1           “(i) *IN GENERAL.*—A sponsor of a  
2           drug subject to a final order issued under  
3           subparagraph (D) who participated in each  
4           level of formal dispute resolution under sub-  
5           paragraph (D)(iii) may request a hearing  
6           on such order. The provisions of subpara-  
7           graphs (A), (B), and (C) of paragraph (3)  
8           shall apply with respect to a hearing on  
9           such order in the same manner and to the  
10          same extent as such provisions apply with  
11          respect to a hearing on an administrative  
12          order issued under paragraph (2)(A)(iv),  
13          except that, with respect to a final order  
14          issued under subparagraph (D), the final  
15          decision under paragraph (3)(C)(v) may  
16          take effect prior to the expiration of the pe-  
17          riod under paragraph (3)(D)(ii) for submit-  
18          ting a request for judicial review.

19           “(ii) *REFERENCES.*—For purposes of a  
20          hearing under this subparagraph, the ref-  
21          erences in subparagraphs (A), (B), and (C)  
22          of paragraph (3)—

23                   “(I) to ‘each level of dispute reso-  
24                   lution                   under                   paragraph  
25                   (2)(A)(iv)(III)’ shall be deemed to

1           mean ‘each level of formal dispute reso-  
2           lution under subparagraph (D)(iii);  
3           and

4                   “(II) to ‘final administrative  
5           order issued under paragraph  
6           (2)(A)(iv)’ shall be deemed to mean  
7           ‘final order under subparagraph  
8           (D)(i)’.

9                   “(F) FINAL ORDER.—Not later than 1 year  
10           after the date on which an interim final order is  
11           issued under subparagraph (A) or (B), the Sec-  
12           retary shall issue a final order in accordance  
13           with paragraph (1) and complete any required  
14           hearing.

15                   “(G) JUDICIAL REVIEW.—A final order  
16           issued pursuant to subparagraph (F) shall be  
17           subject to judicial review in accordance with  
18           paragraph (3)(D).

19                   “(H) CLARIFICATION.—Paragraph (2) shall  
20           not apply to the orders issued under this para-  
21           graph.

22                   “(5) ADMINISTRATIVE ORDER INITIATED BY RE-  
23           QUEST.—

24                   “(A) IN GENERAL.—In issuing an adminis-  
25           trative order under paragraph (1) at the request

1           *of a requestor or a group of requestors with re-*  
2           *spect to certain drugs, classes of drugs, or com-*  
3           *binations of drugs—*

4                   “(i) *the Secretary shall, after receiving*  
5                   *a request under this subparagraph, deter-*  
6                   *mine whether the request is sufficiently*  
7                   *complete and formatted to permit a sub-*  
8                   *stantive review;*

9                   “(ii) *subject to subparagraph (D), if*  
10                   *the Secretary determines that the request is*  
11                   *sufficiently complete and formatted to per-*  
12                   *mit a substantive review, the Secretary*  
13                   *shall—*

14                           “(I) *file the request; and*

15                           “(II) *initiate proceedings with re-*  
16                           *spect to issuing an administrative*  
17                           *order in accordance with paragraphs*  
18                           *(2) and (3); and*

19                   “(iii) *except as provided in subpara-*  
20                   *graph (D)(v), if the Secretary determines*  
21                   *that a request does not meet the require-*  
22                   *ments for filing or is not sufficiently com-*  
23                   *plete or formatted to permit a substantive*  
24                   *review, the requestor may elect that the Sec-*  
25                   *retary file the request over protest, and the*

1            *Secretary shall initiate proceedings to re-*  
2            *view the request in accordance with para-*  
3            *graph (2)(A).*

4            “(B)    *REQUEST TO INITIATE PRO-*  
5            *CEEDINGS.—*

6            “(i) *IN GENERAL.—A requestor seeking*  
7            *an administrative order with respect to cer-*  
8            *tain drugs, classes of drugs, or combinations*  
9            *of drugs, shall submit to the Secretary a re-*  
10           *quest to initiate proceedings for such order*  
11           *in the form and manner as specified by the*  
12           *Secretary. Such requestor may submit a re-*  
13           *quest under this subparagraph for the*  
14           *issuance of an administrative order—*

15           “(I) *determining whether a drug*  
16           *is generally recognized as safe and ef-*  
17           *fective within the meaning of section*  
18           *201(p)(1), exempt from section*  
19           *503(b)(1), and not required to be the*  
20           *subject of an approved application*  
21           *under section 505; or*

22           “(II) *determining whether a*  
23           *change to a condition of use or a new*  
24           *condition of use of a drug is generally*  
25           *recognized as safe and effective within*



1           *the meaning of section 201(p)(1), ex-*  
2           *empt from section 503(b)(1), and not*  
3           *required to be the subject of an ap-*  
4           *proved application under section 505,*  
5           *if such drug is—*

6                     *“(aa) described in subsection*  
7                     *(b)(1)(A); or*

8                     *“(bb) described in subsection*  
9                     *(b)(1)(B), but only if such re-*  
10                    *questor initiates such request in*  
11                    *conjunction with a request for the*  
12                    *Secretary to determine whether*  
13                    *such drug is generally recognized*  
14                    *as safe and effective within the*  
15                    *meaning of section 201(p)(1),*  
16                    *which is filed by the Secretary*  
17                    *under subparagraph (A)(ii)(I).*

18           *The Secretary is not required to complete*  
19           *review of the request for a change described*  
20           *in subclause (II) if the Secretary deter-*  
21           *mines, in accordance with paragraph*  
22           *(1)(B), that there is an inadequate basis to*  
23           *find the drug is generally recognized as safe*  
24           *and effective under paragraph (1) and*

1            *issues a final order announcing that deter-*  
2            *mination.*

3            *“(ii) WITHDRAWAL OF REQUEST.—The*  
4            *requestor may withdraw a request under*  
5            *this paragraph, according to the procedures*  
6            *established by the Secretary. Notwith-*  
7            *standing any other provision of this section,*  
8            *if such request is withdrawn, the Secretary*  
9            *may cease proceedings under this subpara-*  
10           *graph.*

11           *“(C) PRODUCT DIFFERENTIATION.—*

12           *“(i) IN GENERAL.—A final adminis-*  
13           *trative order issued in response to a request*  
14           *under this paragraph shall have the effect of*  
15           *authorizing solely the order requestor (or the*  
16           *licensees, assignees, or successors in interest*  
17           *of such requestor with respect to the subject*  
18           *of such order and listed under clause (v)),*  
19           *for a 2-year period beginning on the effec-*  
20           *tive date of such order, to market drugs*  
21           *under this section—*

22           *“(I) incorporating changes de-*  
23           *scribed in clause (ii); and*

24           *“(II) subject to the limitations*  
25           *under clause (iv).*

1           “(ii) *CHANGES DESCRIBED.*—A change  
2           described in this clause is a change subject  
3           to an order specified in clause (i), which—

4                   “(I) provides for a drug to con-  
5                   tain an active ingredient (including  
6                   any ester or salt of the active ingre-  
7                   dient) not previously incorporated in a  
8                   drug described in clause (iii); or

9                   “(II) provides for a change in the  
10                  conditions of use of a drug, for which  
11                  new human data studies conducted or  
12                  sponsored by the requestor (or for  
13                  which the requestor has an exclusive  
14                  right of reference) were essential to the  
15                  issuance of such order.

16           “(iii) *DRUGS DESCRIBED.*—The drugs  
17           described in this clause are drugs—

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

20                   “(II) subject to a final order  
21                   issued under this section;

22                   “(III) subject to a final sunscreen  
23                   order (as defined in section 586(2)(A));

24                   or

1           “(IV) described in subsection  
2           (b)(4)(A), other than drugs subject to  
3           an active enforcement action under  
4           chapter III.

5           “(iv) *LIMITATIONS ON PRODUCT DIF-*  
6           *FERENTIATION.—*

7           “(I) *ONLY ONE PERIOD.—Only*  
8           *one 2-year period under this subpara-*  
9           *graph shall be granted for each order*  
10           *described in clause (i) with respect to*  
11           *changes (to the drug subject to such*  
12           *order) that are—*

13           “(aa) changes described in  
14           clause (ii)(I), relating to active  
15           ingredients; or

16           “(bb) changes described in  
17           clause (ii)(II), relating to condi-  
18           tions of use.

19           “(II) *EXCLUSIONS.—No 2-year*  
20           *period under this subparagraph shall*  
21           *apply to changes to a drug that are—*

22           “(aa) the subject of a ‘Tier 2’  
23           monograph drug order requested  
24           as described in section  
25           744L(14)(A);

1           “(bb) *safety-related changes*  
2           *described in section 744L-*  
3           *1(a)(2)(C), required under this*  
4           *paragraph, or any other change*  
5           *the Secretary determines nec-*  
6           *essary to ensure safe use; or*

7           “(cc) *changes related to*  
8           *methods of testing safety or effi-*  
9           *cacy.*

10           “(v) *LISTING OF LICENSEES, ASSIGN-*  
11           *EES, OR SUCCESSORS IN INTEREST.—The*  
12           *requestors of an order described in clause (i)*  
13           *shall, as applicable, submit to the Secretary,*  
14           *at a time when a drug subject to such order*  
15           *is introduced or delivered for introduction*  
16           *into interstate commerce, a list of licensees,*  
17           *assignees, or successors in interest under*  
18           *such clause.*

19           “(vi) *NEW HUMAN DATA STUDIES DE-*  
20           *FINED.—For purposes of this subparagraph,*  
21           *the term ‘new human data studies’ means*  
22           *studies from clinical trials of safety or effec-*  
23           *tiveness, pharmacokinetics studies, or bio-*  
24           *availability studies, the results of which—*

1           “(I) the Secretary has not relied  
2           on to support—

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

9                   “(bb) approval of a drug  
10                  under section 505; and

11           “(II) do not duplicate the results  
12           of another study that the Secretary re-  
13           lied on to support—

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

20                   “(bb) approval of a drug that  
21                  was approved under section 505.

22                   “(D) INFORMATION REGARDING SAFE NON-  
23                   PRESCRIPTION MARKETING AND USE AS A CONDI-  
24                   TION FOR FILING A GRASE REQUEST.—

1           “(i) *IN GENERAL.*—*In response to a re-*  
2           *quest under this paragraph that a drug de-*  
3           *scribed in clause (ii) be generally recognized*  
4           *as safe and effective, the Secretary—*

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

10                   “(II) *if the request fails to include*  
11                   *information specified under clause*  
12                   *(iii), shall refuse to file such request*  
13                   *and may require that nonprescription*  
14                   *marketing of the drug be pursuant to*  
15                   *a new drug application as described in*  
16                   *clause (iv).*

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

21                   “(I) *described in subparagraph*  
22                   *(A), (B), or (D) of subsection (b)(1);*

23                   “(II) *subject to a final order*  
24                   *under this section; or*

1                   “(III) subject to a final sunscreen  
2                   order (as defined in section 586(2)(A)).

3                   “(iii) SUFFICIENT INFORMATION FOR A  
4                   THRESHOLD DEMONSTRATION OF NON-  
5                   PRESCRIPTION MARKETING AND USE.—In-  
6                   formation specified in this subparagraph,  
7                   with respect to a request described in clause  
8                   (i)(I), is—

9                   “(I) information sufficient for a  
10                  threshold demonstration that the drug  
11                  subject to such request has a verifiable  
12                  history of being marketed and safely  
13                  used by consumers in the United States  
14                  as a nonprescription drug under com-  
15                  parable conditions of use;

16                  “(II) if the drug has not been pre-  
17                  viously marketed in the United States  
18                  as a nonprescription drug, information  
19                  sufficient for a threshold demonstration  
20                  that the drug was marketed and safely  
21                  used in a foreign country under condi-  
22                  tions of marketing and use—

23                  “(aa) for such period of time  
24                  as needed to provide reasonable  
25                  assurances concerning the safe



1           *nonprescription use of the drug;*  
2           *and*

3           “(bb) *during such period of*  
4           *time, was subject to sufficient*  
5           *monitoring by a regulatory body*  
6           *of any country listed in section*  
7           *802(b)(1)(A) or any country des-*  
8           *ignated by the Secretary in ac-*  
9           *cordance with section*  
10           *802(b)(1)(B); or*

11           “(III) *if the Secretary determines*  
12           *that information described in subclause*  
13           *(I) or (II) is not needed to provide a*  
14           *threshold demonstration that the drug*  
15           *can be safely marketed and used as a*  
16           *nonprescription drug, other informa-*  
17           *tion the Secretary determines sufficient*  
18           *for such purposes.*

19           “(iv) *MARKETING PURSUANT TO NEW*  
20           *DRUG APPLICATION.—In the case of a re-*  
21           *quest described in clause (i)(II), the drug*  
22           *subject to such request may be re-submitted*  
23           *for filing only if—*

24           “(I) *the drug is marketed as a*  
25           *nonprescription drug, under conditions*

1           *of use comparable to the requirements*  
2           *specified in the request, for such period*  
3           *of time as the Secretary determines ap-*  
4           *propriate (not to exceed 5 consecutive*  
5           *years) pursuant to an application ap-*  
6           *proved under section 505; and*

7                   “(II) *during such period of time,*  
8                   *1,000,000 retail packages of the drug,*  
9                   *or an equivalent quantity of the active*  
10                  *ingredient or ingredients of such drug*  
11                  *as determined by the Secretary, were*  
12                  *distributed for retail sale, as deter-*  
13                  *mined in such manner as the Secretary*  
14                  *may require.*

15                  “(v) *RULE OF APPLICATION.—If the*  
16                  *Secretary refuses to file a request under this*  
17                  *subparagraph, the requestor may not file*  
18                  *over protest under subparagraph (A)(iii)*  
19                  *unless the request involves a drug described*  
20                  *in section 586(9) as in effect on January 1,*  
21                  *2017.*

22                  “(6) *TREATMENT OF FINAL AND TENTATIVE*  
23                  *FINAL MONOGRAPHS.—*

24                   “(A) *IN GENERAL.—A final monograph or*  
25                   *tentative final monograph described in subpara-*

1           *graph (B) shall be deemed to be a final adminis-*  
2           *trative order under this subsection and may be*  
3           *amended, revoked, or otherwise modified in ac-*  
4           *cordance with the procedures of this subsection.*

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

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

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

17           “(7) *PACKAGING.*—

18           “(A) *IN GENERAL.*—*An administrative*  
19           *order issued under paragraph (2), (4), or (5)*  
20           *may include requirements for the packaging of a*  
21           *drug, such as to promote use in accordance with*  
22           *labeling, unit dose packaging, or requirements to*  
23           *prevent overdose or accidental ingestion, includ-*  
24           *ing by pediatric populations.*

1           “(B) *SAFETY LABELING CHANGES.*—An ad-  
2           ministrative order issued under paragraph  
3           (4)(B) that includes requirements for the pack-  
4           aging of a drug may be issued only after—

5                   “(i) consideration of—

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

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

13                           “(ii) consultation with sponsors on the  
14                           impact of the removal of such drugs without  
15                           such packaging and the change of such  
16                           packaging on patients and manufacturers  
17                           when establishing such requirements.

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

22           “(d) *PROCEDURE FOR MINOR CHANGES.*—

23                   “(1) *IN GENERAL.*—Minor changes in the dosage  
24                   form of a drug that is described in subparagraph (A)  
25                   or (B) of subsection (b)(1) may be made by a re-

1        *requestor without the issuance of an administrative*  
2        *order under subsection (c) if—*

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

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

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

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

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

21        *“(2) ADDITIONAL INFORMATION.—*

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

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

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

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

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

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

1           *active ingredient, the drug as modified is a new*  
2           *drug within the meaning of section 201(p) and*  
3           *shall be deemed to be misbranded under section*  
4           *502(ee).*

5           “(3) *DETERMINING WHETHER CHANGE WILL AF-*  
6           *FFECT SAFETY OR EFFECTIVENESS.—*

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

18                   “(B) *STANDARD PRACTICES AND SPECIAL*  
19                   *NEEDS OF POPULATIONS.—The orders and guid-*  
20                   *ance issued by the Secretary under subparagraph*  
21                   *(A) shall take into account relevant public stand-*  
22                   *ards and standard practices for evaluating the*  
23                   *quality of drug products and may take into ac-*  
24                   *count special needs of populations, including*  
25                   *children.*

1       “(e) *INFORMATION SUBMITTED BY REQUESTORS.*—

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

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

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



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

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

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

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

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

22           “(A) a brief description of the administra-  
23           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.—A*  
5                   *sponsor who makes a change to a drug subject to this section*  
6                   *shall submit updated drug listing information for the drug*  
7                   *in accordance with the requirements of section 510(j) not*  
8                   *later than the date on which the drug is first introduced*  
9                   *or delivered for introduction into interstate commerce with*  
10                   *the change.*

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

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

1           “(1) *IN GENERAL.*—*The Secretary shall establish*  
2           *procedures under which requestors may meet with ap-*  
3           *propriate officials of the Food and Drug Administra-*  
4           *tion to obtain advice on the studies and other infor-*  
5           *mation necessary to support requests under this sec-*  
6           *tion and other matters relevant to the regulation and*  
7           *development of monograph drugs under this section.*

8           “(2) *PARTICIPATION OF MULTIPLE SPONSORS.*—  
9           *The Secretary shall establish procedures to facilitate*  
10          *efficient participation by multiple requestors in pro-*  
11          *ceedings under this section, including provision for*  
12          *joint meetings with multiple requestors or with orga-*  
13          *nizations nominated by requestors to represent their*  
14          *interests in a proceeding.*

15          “(3) *PRIVATE MEETINGS WITH REQUESTORS.*—  
16          *The procedures established under this subsection shall*  
17          *include appropriate provision for confidential meet-*  
18          *ings with requestors with respect to discussion of mat-*  
19          *ters involving confidential commercial information or*  
20          *trade secrets.*

21          “(j) *EFFECT ON EXISTING REGULATIONS GOVERNING*  
22          *NONPRESCRIPTION DRUGS.*—

23                 “(1) *REGULATIONS OF GENERAL APPLICABILITY*  
24                 *TO NONPRESCRIPTION DRUGS.*—*Except as provided in*  
25                 *this subsection, nothing in this section supersedes reg-*

1 *ulations establishing general requirements for non-*  
2 *prescription drugs, including regulations of general*  
3 *applicability contained in parts 201, 250, and 330 of*  
4 *title 21, Code of Federal Regulations, or any successor*  
5 *regulations. The Secretary shall establish or modify*  
6 *such regulations by means of rulemaking in accord-*  
7 *ance with section 553 of title 5, United States Code.*

8 “(2) *REGULATIONS ESTABLISHING REQUIRE-*  
9 *MENTS FOR SPECIFIC NONPRESCRIPTION DRUGS.—*

10 “(A) *IN GENERAL.—*Section 310.545 of title  
11 *21, Code of Federal Regulations, as in effect on*  
12 *the day before the date of enactment of this sec-*  
13 *tion, shall be deemed to be final administrative*  
14 *order under subsection (c).*

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

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

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

25          “(k) *GUIDANCE.*—

1           “(1) *ISSUANCE.*—*The Secretary shall issue guid-*  
2           *ance that provides—*

3                   “(A) *the procedures and principles for for-*  
4                   *mal meetings between the Secretary and sponsors*  
5                   *or requestors for drugs subject to this section;*

6                   “(B) *the format and content of data submis-*  
7                   *sions to the Secretary under this section;*

8                   “(C) *the format of electronic submissions to*  
9                   *the Secretary under this section;*

10                   “(D) *consolidated proceedings and the pro-*  
11                   *cedures for such proceedings where appropriate;*  
12                   *and*

13                   “(E) *for minor changes in drugs, rec-*  
14                   *ommendations on how to comply with the re-*  
15                   *quirements in administrative orders issued*  
16                   *under subsection (d)(3)(A).*

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

20           “(m) *INAPPLICABILITY OF PAPERWORK REDUCTION*  
21           *ACT.*—*Chapter 35 of title 44, United States Code, shall not*  
22           *apply to collections of information made under this section.*

23           “(n) *NONAPPLICATION OF CERTAIN REQUIREMENTS.*—  
24           *The requirements of subchapter II of chapter 5 of title 5,*

1 *United States Code, shall not apply with respect to admin-*  
 2 *istrative orders issued under this section.*

3 “(o) *INVESTIGATIONAL NEW DRUGS.*—A drug for  
 4 *which an exemption under section 505(i) is in effect is not*  
 5 *subject to this section.*”.

6 **SEC. 102. MISBRANDING.**

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

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

13 “(ff) *If it is a drug for which fees under section 744L-*  
 14 *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 SUB-*  
 18 *JECT TO SUNSCREEN INNOVATION ACT.*—

19 (1) *PENDING SUNSCREEN INGREDIENTS.*—Non-  
 20 *prescription sunscreen active ingredients or combina-*  
 21 *tions of sunscreen active ingredients for use under*  
 22 *specified conditions subject, on the date of enactment*  
 23 *of this Act, to a proposed sunscreen order, as defined*  
 24 *in section 586(7) of the Federal Food, Drug, and Cos-*  
 25 *metic Act (21 U.S.C. 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 such  
5 Act upon written notification of the Secretary by  
6 the sponsor within 180 calendar days after the  
7 date of enactment of the Over-the-Counter Drug  
8 Safety, Innovation, and Reform Act that such  
9 sponsor elects to have such ingredient or com-  
10 bination of ingredients reviewed under such sec-  
11 tion 505G, and, upon notification, such proposed  
12 sunscreen order under such section 586C shall be  
13 considered to be a request for an administrative  
14 order that has been accepted for filing under sec-  
15 tion 505G(c)(6)(A)(ii) of such Act.

16       (2) *PENDING NONSUNSCREEN INGREDIENTS.*—

17           (A) *IN GENERAL.*—Any application de-  
18 scribed in section 586F of the Federal Food,  
19 Drug, and Cosmetic Act (21 U.S.C. 360fff-6)  
20 that was submitted to the Secretary of Health  
21 and Human Services pursuant to section 330.14  
22 of title 21, Code of Federal Regulations (as such  
23 provisions were in effect on the day before the  
24 date of enactment of this Act), shall be voided as



1           *of such date of enactment, subject to subpara-*  
2           *graph (B).*

3           *(B) ORDER REQUEST.—Nothing in sub-*  
4           *paragraph (A) precludes the submission of an*  
5           *order request under section 505G(b) of the Fed-*  
6           *eral Food, Drug, and Cosmetic Act, as added by*  
7           *section 101 of this Act, with respect to a drug*  
8           *that was the subject of an application voided*  
9           *under subparagraph (A).*

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

17           *(b) MEETINGS REGARDING SUNSCREEN INGREDI-*  
18           *ENTS.—Section 586C(b) of the Federal Food, Drug, and*  
19           *Cosmetic Act (21 U.S.C. 360fff–3(b)) is amended by adding*  
20           *at the end the following:*

21           *“(11) MEETINGS WITH SPONSORS.—A sponsor*  
22           *may request an individual, confidential meeting to*  
23           *discuss the data requirements to support a general*  
24           *recognition of safety and effectiveness with respect to*  
25           *the subject of a pending sunscreen ingredient. The*

1     *Secretary shall respond within 14 calendar days of*  
2     *the request and schedule such meeting within 45 cal-*  
3     *endar days, or within such timeline as specified in*  
4     *the letters described in section 201 of the Over-the-*  
5     *Counter Drug Safety, Innovation, and Reform Act. If*  
6     *a sponsor requests more than one confidential meeting*  
7     *for the same proposed sunscreen order, the Secretary*  
8     *may refuse to grant an additional confidential meet-*  
9     *ing request if the Secretary determines such addi-*  
10    *tional confidential meeting is not reasonably nec-*  
11    *essary for the sponsor to advance the proposed sun-*  
12    *screen order, or if the sponsor does not provide suffi-*  
13    *cient information upon which to base a substantive*  
14    *discussion. The Secretary shall publish a post-meeting*  
15    *summary on the internet website of the Food and*  
16    *Drug Administration of any confidential meeting*  
17    *that does not disclose confidential business informa-*  
18    *tion.”.*

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

22     *“(f) PRODUCT DIFFERENTIATION.—*

23         *“(1) IN GENERAL.—A final sunscreen order shall*  
24     *have the effect of authorizing solely the order requestor*  
25     *(or the licensees, assignees, or successors in interest of*

1        *such requestor with respect to the subject of such re-*  
2        *quest and listed under paragraph (5)) for a period of*  
3        *2 years, to market a sunscreen ingredient under this*  
4        *section incorporating changes described in paragraph*  
5        *(2) subject to the limitations under paragraph (4), be-*  
6        *ginning on the date the requestor (or any licensees,*  
7        *assignees, or successors in interest of such requestor*  
8        *with respect to the subject of such request and listed*  
9        *under paragraph (5)) may lawfully market such sun-*  
10       *screen ingredient pursuant to the order.*

11            *“(2) CHANGES DESCRIBED.—A change described*  
12        *in this paragraph is a change subject to an order*  
13        *specified in paragraph (1) that permits a sunscreen*  
14        *to contain an active sunscreen ingredient not pre-*  
15        *viously incorporated in a marketed sunscreen listed*  
16        *in paragraph (3).*

17            *“(3) MARKETED SUNSCREEN.—The marketed*  
18        *sunscreen ingredients described this paragraph are*  
19        *sunscreen ingredients—*

20            *“(A) marketed in accordance with a final*  
21        *monograph for sunscreen drug products set forth*  
22        *at part 352 of title 21, Code of Federal Regula-*  
23        *tions (as published at 64 Fed. Reg. 27687); or*

24            *“(B) marketed in accordance with a final*  
25        *order issued under this section.*

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

4           “(5) *LISTING OF LICENSEES, ASSIGNEES, OR*  
5           *SUCCESSORS IN INTEREST.—Requestors shall submit*  
6           *to the Secretary at the time when a drug subject to*  
7           *such request is introduced or delivered for introduc-*  
8           *tion into interstate commerce, a list of licensees, as-*  
9           *signees, or successors in interest under paragraph*  
10          *(1).”.*

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

15                 “(3) *RELATIONSHIP TO ORDERS UNDER SECTION*  
16                 *505G.—A final sunscreen order shall be deemed to be*  
17                 *a final administrative order under section 505G and*  
18                 *subject to the applicable provisions under such section*  
19                 *505G, including with respect to amendment of such*  
20                 *order.”.*

21          *(e) PRECLUSION OF NEW SUNSCREEN SUBMISSIONS;*  
22          *OPTION TO TRANSFER SUBMISSIONS TO OTC MONOGRAPH*  
23          *ORDER PROCESS.—*

24                 “(1) *SUNSET.—Beginning on the date of enact-*  
25                 *ment of this Act, section 586A of the Federal Food,*

1       *Drug, and Cosmetic Act (21 U.S.C. 360fff-1) shall*  
2       *have no force or effect.*

3               (2) *OPTION TO TRANSFER SUBMISSIONS TO OTC*  
4       *MONOGRAPH ORDER PROCESS.—*

5               (A) *IN GENERAL.—Any person who sub-*  
6       *mitted a request described in subparagraph (B)*  
7       *may, at any time prior to the sunset of sub-*  
8       *chapter I of chapter V of the Federal Food, Drug,*  
9       *and Cosmetic Act (21 U.S.C. 360fff et seq.)*  
10       *under section 586H of such Act, withdraw such*  
11       *request from the process under such subchapter*  
12       *and resubmit such request as an order request*  
13       *under section 505G of such Act.*

14              (B) *REQUESTS.—A request described in this*  
15       *subparagraph is—*

16                   (i) *a request under section 586A of the*  
17                   *Federal Food, Drug, and Cosmetic Act sub-*  
18                   *mitted before the date of enactment of this*  
19                   *Act; or*

20                   (ii) *a pending request described in sec-*  
21                   *tion 586(6).*

22              (f) *TREATMENT OF AUTHORITY REGARDING FINALIZA-*  
23       *TION OF SUNSCREEN MONOGRAPH.—Section 586E of the*  
24       *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff-*  
25       *5) is amended to read as follows:*

1 **“SEC. 586E. SUNSCREEN ORDER.**

2 “(a) *IN GENERAL.*—

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

4 *Not later than November 26, 2019, the Secretary shall*  
5 *amend and revise the final administrative order con-*  
6 *cerning nonprescription sunscreen (referred to in this*  
7 *section as the ‘sunscreen order’) for which the sub-*  
8 *stance, prior to the date of enactment of the Over-the-*  
9 *Counter Drug Safety, Innovation, and Reform Act,*  
10 *was marketed in accordance with a final monograph*  
11 *for sunscreen drug products set forth in part 352 of*  
12 *title 21, Code of Federal Regulations (as published at*  
13 *64 Fed. Reg. 27687)*

14 “(2) *ISSUANCE OF REVISED SUNSCREEN ORDER;*  
15 *EFFECTIVE DATE.*—*A revised sunscreen order de-*  
16 *scribed in paragraph (1) shall be—*

17 “(A) *issued in accordance with the proce-*  
18 *dures described in section 505G(c)(2);*

19 “(B) *issued in proposed form not later than*  
20 *May 28, 2019;*

21 “(C) *effective not later than November 26,*  
22 *2020; and*

23 “(D) *issued by the Secretary at least 1 year*  
24 *prior to such effective date.*

25 “(b) *REPORTS.*—*If a revised sunscreen order issued*  
26 *under subsection (a) does not include provisions related to*

1 *the effectiveness of various sun protection factor levels, and*  
 2 *does not address all dosage forms known to the Secretary*  
 3 *to be used in sunscreens marketed in the United States*  
 4 *without a new drug application approved under section*  
 5 *505, the Secretary shall submit a report to the Committee*  
 6 *on Health, Education, Labor, and Pensions of the Senate*  
 7 *and the Committee on Energy and Commerce of the House*  
 8 *of Representatives on the rationale for omission of such pro-*  
 9 *visions from such order, and a plan and timeline to compile*  
 10 *any information necessary to address such provisions*  
 11 *through such order.”.*

12 *(g) SUNSET OF PROCESS UNDER SUNSCREEN INNOVA-*  
 13 *TION ACT.—Subchapter I of chapter V of the Federal Food,*  
 14 *Drug, and Cosmetic Act (21 U.S.C. 360fff et seq.), as*  
 15 *amended by subsection (f), is further amended by inserting*  
 16 *at the end the following new section:*

17 **“SEC. 586H. SUNSET.**

18 *“This subchapter shall no longer be effective upon the*  
 19 *later of—*

20 *“(1) a final determination by the Secretary*  
 21 *under this subchapter with respect to every request de-*  
 22 *scribed in section 586A(b)(2) (other than any with-*  
 23 *drawn requests and requests resubmitted as order re-*  
 24 *quests under section 505G); or*

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

3   **SEC. 104. DRUGS EXCLUDED FROM OVER-THE-COUNTER RE-**  
4                                   **VIEW.**

5           (a) *IN GENERAL.*—Nothing in this Act (or the amend-  
6           ments made by this Act) shall apply to any nonprescription  
7           drug which was excluded by the Food and Drug Adminis-  
8           tration from the Over-the-Counter Drug Review in accord-  
9           ance with the statement set out at page 9466 of volume 37  
10          of the Federal Register, published on May 11, 1972.

11          (b) *RULE OF CONSTRUCTION.*—Nothing in this section  
12          shall be construed to preclude or limit the applicability of  
13          any provision of the Federal Food, Drug, and Cosmetic Act.

14   **SEC. 105. CONFORMING AMENDMENT.**

15          Section 751(d)(1) of the Federal Food, Drug, and Cos-  
16          metic Act (21 U.S.C. 379r(d)(1)) is amended—

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

18                         (A) by striking “final regulation promul-  
19                         gated” and inserting “final order issued under  
20                         section 505G”; and

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

22                 (2) in subparagraph (A), by striking “regulation  
23                         in effect” and inserting “regulation or order in ef-  
24                         fect”.



1 **SEC. 106. ANNUAL UPDATE TO CONGRESS ON APPROPRIATE**  
2 **PEDIATRIC INDICATION FOR CERTAIN COUGH**  
3 **AND COLD MONOGRAPH DRUGS.**

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

12 (1) *in evaluating the cough and cold monograph*  
13 *described in subsection (b) with respect to children*  
14 *under age 6; and*

15 (2) *as appropriate, revising such cough and cold*  
16 *monograph to address such children, through the ad-*  
17 *ministrative order process under section 505G(c) of*  
18 *the Federal Food, Drug, and Cosmetic Act, as added*  
19 *by section 101.*

20 (b) *COUGH AND COLD MONOGRAPH DESCRIBED.*—The  
21 cough and cold monograph described in this subsection con-  
22 sists of the conditions under which nonprescription drug  
23 products containing antitussive, expectorant, nasal decon-  
24 gestant, or antihistamine active ingredients (or combina-  
25 tions thereof) are generally recognized as safe and effective,  
26 as specified in part 341 of title 21, Code of Federal Regula-

1 tions (as in effect on the day before the date of enactment  
 2 of this Act), and included in an administrative order  
 3 deemed established under such section 505G(c) of the Fed-  
 4 eral Food, Drug, and Cosmetic Act.

5 (c) *DURATION OF AUTHORITY.*—Subsection (a) shall  
 6 have no force or effect beginning on the date on which the  
 7 Secretary submits a letter under subsection (a) in which  
 8 the Secretary indicates that the Food and Drug Adminis-  
 9 tration has completed its evaluation and revised, in a final  
 10 administrative order, as applicable, the cough and cold  
 11 monograph in accordance with this section.

## 12 **TITLE II—FEES RELATING TO** 13 **MONOGRAPH DRUGS**

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

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

17 (b) *FINDINGS.*—The Congress finds that the fees au-  
 18 thorized by the amendments made in this title will be dedi-  
 19 cated toward the regulation of monograph drugs under sec-  
 20 tion 505G of the Federal, Food, Drug, and Cosmetic Act,  
 21 as set forth in the goals identified for purposes of such sec-  
 22 tion, in the letters from the Secretary of Health and Human  
 23 Services to the Chairman of the Committee on Health, Edu-  
 24 cation, Labor, and Pensions of the Senate and the Chair-  
 25 man of the Committee on Energy and Commerce of the

1 *House of Representatives, as set forth in the Congressional*  
2 *Record.*

3 **SEC. 202. AUTHORITY TO ASSESS AND USE FEES.**

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

7 **“PART 10—FEES RELATING TO MONOGRAPH**

8 **DRUGS**

9 **“SEC. 744L. DEFINITIONS.**

10 *“For purposes of this part:*

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

14 *“(A) one business entity controls, or has the*  
15 *power to control, the other business entity; or*

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

18 *“(2) the term ‘contract manufacturing organiza-*  
19 *tion facility’ means a monograph drug facility where*  
20 *neither the owner of such manufacturing facility nor*  
21 *any affiliate of such owner or facility sells such mono-*  
22 *graph drug produced at such facility directly to*  
23 *wholesalers, retailers, or consumers in the United*  
24 *States.*

1           “(3) *The term ‘costs of resources allocated for*  
2 *monograph drug activities’ means the expenses in*  
3 *connection with monograph drug activities for—*

4                   “(A) *officers and employees of the Food and*  
5 *Drug Administration, contractors of the Food*  
6 *and Drug Administration, advisory committees,*  
7 *and costs related to such officers, employees, and*  
8 *committees and to contracts with such contrac-*  
9 *tors;*

10                   “(B) *management of information, and the*  
11 *acquisition, maintenance, and repair of com-*  
12 *puter resources;*

13                   “(C) *leasing, maintenance, renovation, and*  
14 *repair of facilities and acquisition, maintenance,*  
15 *and repair of fixtures, furniture, scientific equip-*  
16 *ment, and other necessary materials and sup-*  
17 *plies; and*

18                   “(D) *collecting fees under section 744L-1*  
19 *and accounting for resources allocated for mono-*  
20 *graph drug activities.*

21           “(4) *The term ‘firm establishment identifier’ is*  
22 *the unique number automatically generated by the*  
23 *Field Accomplishments and Compliance Tracking*  
24 *System of the Food and Drug Administration.*

1           “(5) *The term ‘monograph drug’ means a drug*  
2           *subject to section 505G.*

3           “(6) *The term ‘monograph drug activities’ means*  
4           *activities of the Secretary associated with monograph*  
5           *drugs and inspection of facilities associated with such*  
6           *drugs, including—*

7                   “(A) *the activities necessary for review and*  
8                   *evaluation of monograph drugs and monograph*  
9                   *drug order requests, including—*

10                           “(i) *orders proposing or finalizing ap-*  
11                           *plicable requirements for monograph drugs;*

12                           “(ii) *orders affecting status regarding*  
13                           *general recognition of safety and effective-*  
14                           *ness of a monograph drug ingredient or*  
15                           *combination of ingredients under specified*  
16                           *requirements;*

17                           “(iii) *all monograph drug development*  
18                           *and review activities, including intra-agen-*  
19                           *cy collaboration;*

20                           “(iv) *regulation and policy develop-*  
21                           *ment activities related to monograph drugs;*

22                           “(v) *development of product standards*  
23                           *for drugs subject to review and evaluation;*

24                           “(vi) *meetings regarding monograph*  
25                           *drug activities;*

1           “(vii) review of labeling prior to  
2           issuance of orders related to monograph  
3           drugs or conditions of use; and

4           “(viii) regulatory science activities re-  
5           lated to monograph drugs;

6           “(B) inspections related to monograph  
7           drugs;

8           “(C) monitoring of clinical and other re-  
9           search conducted in connection with monograph  
10          drugs;

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

13               “(i) collecting, developing, and review-  
14               ing safety information on monograph drugs,  
15               including adverse event reports;

16               “(ii) developing and using improved  
17               adverse event data-collection systems, in-  
18               cluding information technology systems;  
19               and

20               “(iii) developing and using improved  
21               analytical tools to assess potential safety  
22               risks, including access to external databases;  
23               and

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

1           “(7)(A) *The term ‘monograph drug facility’*  
2           *means a foreign or domestic business or other enti-*  
3           *ty—*

4                   “(i) *that is under one management, either*  
5                   *direct or indirect;*

6                   “(ii) *at one geographic location or address*  
7                   *engaged in manufacturing or processing a mono-*  
8                   *graph drug in finished dosage form;*

9                   “(iii) *includes a finished dosage form man-*  
10                   *ufacturer facility or an affiliate thereof in a con-*  
11                   *tractual relationship with a monograph drug re-*  
12                   *questor or requestors to manufacture or process*  
13                   *monograph drugs; and*

14                   “(iv) *does not include a business or other*  
15                   *entity whose only manufacturing or processing*  
16                   *activities relate to—*

17                           “(I) *production of clinical research*  
18                           *supplies;*

19                           “(II) *testing; or*

20                           “(III) *placement of outer overpack-*  
21                           *aging on packages containing multiple*  
22                           *products, for such purposes as creating*  
23                           *multipacks, when each monograph drug*  
24                           *product contained within the overpackaging*

1            *is already in a final packaged form prior to*  
2            *placement in the outer overpackaging.*

3            *“(B) For purposes of subparagraph (A), separate*  
4            *buildings or locations within close proximity are con-*  
5            *sidered to be at 1 geographic location or address if the*  
6            *activities conducted in them are—*

7            *“(i) closely related to the same business en-*  
8            *terprise;*

9            *“(ii) under the supervision of the same local*  
10           *management; and*

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

15           *“(C) If a business or other entity would meet the*  
16           *definition of a facility under this paragraph but for*  
17           *being under multiple management, the business or*  
18           *other entity is deemed to constitute multiple facilities,*  
19           *one per management entity, for purposes of this para-*  
20           *graph.*

21           *“(8) The term ‘monograph drug meeting’ means*  
22           *any meeting regarding the content of a proposed*  
23           *monograph drug order request.*

24           *“(9) The term ‘monograph drug product’ means*  
25           *a monograph drug product that is marketed without*



1        *an approved new drug application in accordance*  
2        *with section 505G.*

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

7            *“(11) The term ‘monograph drug requestor’*  
8        *means an entity submitting a monograph drug order*  
9        *request or a monograph drug meeting request or any*  
10       *other inquiry relating to a request for an order or de-*  
11       *velopment of a monograph drug order request.*

12           *“(12) The term ‘person’ includes an affiliate*  
13        *thereof.*

14           *“(13) The term ‘Tier 1 monograph drug order*  
15        *request’ means any monograph drug order request not*  
16        *determined to be a Tier 2 monograph drug order re-*  
17        *quest.*

18           *“(14)(A) The term ‘Tier 2 monograph drug order*  
19        *request’ means, subject to subparagraph (B), a mono-*  
20        *graph drug order request for—*

21                *“(i) the reordering of existing information*  
22                *in the drug facts label of a monograph drug*  
23                *product;*

24                *“(ii) the addition of information to the*  
25                *other information section of the drug facts label*

1           *of a nonprescription drug product, as limited by*  
2           *part 201.66(c)(7) of title 21, Code of Federal*  
3           *Regulations;*

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

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

11          *“(v) a change to ingredient nomenclature to*  
12          *align with nomenclature of a standards-setting*  
13          *organization; or*

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

18          *“(B) The Secretary may, based on program im-*  
19          *plementation experience or other factors found appro-*  
20          *priate by the Secretary, characterize any monograph*  
21          *drug order request as a Tier 2 monograph drug order*  
22          *request (including recategorizing a request from Tier*  
23          *1 to Tier 2) and publish such determination in a pro-*  
24          *posed order issued pursuant to section 505G(c).*

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

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

6 *“(1) FACILITY FEE.—*

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

14 *“(B) EXCEPTION.—*

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

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

1           *the amount of the fee for a monograph drug*  
2           *facility that is not a contract manufac-*  
3           *turing organization facility.*

4           “(C) *DUE DATE.*—

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

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

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

17                     “(II) *the first business day after*  
18                     *the date of enactment of an appropri-*  
19                     *ations Act providing for the collection*  
20                     *and obligation of fees under this sec-*  
21                     *tion for such year.*

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

23                 “(A) *IN GENERAL.*—*Each person that sub-*  
24                 *mits a monograph drug order request shall be*  
25                 *subject to a fee for a monograph drug order re-*

1           *quest. The monograph drug order request fee*  
2           *under paragraph (2) shall be—*

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

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

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

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

24                   “(i) a contraindication, warning, or  
25                   precaution;

1           “(ii) a statement about risk associated  
2           with misuse or abuse; or

3           “(iii) an instruction about dosage and  
4           administration that is intended to increase  
5           the safe use of the monograph drug product.

6           “(D) REFUND OF FEE IF ORDER REQUEST  
7           IS RECATEGORIZED AS A TIER 2 MONOGRAPH  
8           DRUG ORDER REQUEST.—If the Secretary deter-  
9           mines that a monograph drug request initially  
10          characterized as Tier 1 should be re-characterized  
11          as a Tier 2 monograph drug order request, and  
12          the requestor has paid a Tier 1 fee in accordance  
13          with subparagraph (A)(i), the Secretary shall re-  
14          fund the requestor the difference between the Tier  
15          1 and Tier 2 fees determined under subpara-  
16          graphs (A)(i) and (A)(ii), respectively.

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

22          “(F) FEES FOR ORDER REQUESTS PRE-  
23          VIOUSLY REFUSED FOR FILING OR WITHDRAWN  
24          BEFORE FILING.—A monograph drug order re-  
25          quest that was submitted but was refused for fil-

1            *ing, or was withdrawn before being accepted or*  
2            *refused for filing, shall be subject to the full fee*  
3            *under subparagraph (A) upon being resubmitted*  
4            *or filed over protest.*

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

16           *“(3) REFUNDS.—*

17           *“(A) IN GENERAL.—Other than refunds*  
18           *under subparagraphs (D) through (G) of para-*  
19           *graph (2), the Secretary shall not refund any fee*  
20           *paid under this subsection, except as provided in*  
21           *subparagraph (B).*

22           *“(B) DISPUTES CONCERNING FEES.—To*  
23           *qualify for the return of a fee claimed to have*  
24           *been paid in error under this paragraph, a per-*  
25           *son shall submit to the Secretary a written re-*

1           *quest justifying such return within 180 calendar*  
2           *days after such fee was paid.*

3           “(b) *FEE REVENUE AMOUNTS.*—

4           “(1) *FISCAL YEAR 2019.*—*For fiscal year 2019,*  
5           *fees under subsection (a)(1) shall be established to*  
6           *generate a total facility fee revenue amount equal to*  
7           *the sum of—*

8                   “(A) *the annual base revenue for fiscal year*  
9                   *2019 (as determined under paragraph (3));*

10                   “(B) *the dollar amount equal to the oper-*  
11                   *ating reserve adjustment for the fiscal year, if*  
12                   *applicable (as determined under subsection*  
13                   *(c)(2)); and*

14                   “(C) *additional direct cost adjustments (as*  
15                   *determined under subsection (c)(3)).*

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

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

22                   “(B) *the dollar amount equal to the infla-*  
23                   *tion adjustment for the fiscal year (as deter-*  
24                   *mined under subsection (c)(1));*



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

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

7           “(E) additional dollar amounts for each fis-  
 8           cal year as follows:

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

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

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

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

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

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

17                   “(B) for fiscal years 2020 through 2023, the  
 18           dollar amount of the total revenue amount estab-  
 19           lished under this subsection for the previous fis-  
 20           cal year, not including any adjustments made  
 21           under subsection (c)(2) or (c)(3).

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

23                   “(1) INFLATION ADJUSTMENT.—

24                   “(A) IN GENERAL.—For purposes of sub-  
 25           section (b)(2)(B), the dollar amount of the infla-

1            *tion adjustment to the annual base revenue for*  
2            *fiscal year 2020 and each subsequent fiscal year*  
3            *shall be equal to the product of—*

4                    *“(i) such annual base revenue for the*  
5                    *fiscal year under subsection (b)(2); and*

6                    *“(ii) the inflation adjustment percent-*  
7                    *age under subparagraph (B).*

8                    *“(B) INFLATION ADJUSTMENT PERCENT-*  
9                    *AGE.—The inflation adjustment percentage*  
10                   *under this subparagraph for a fiscal year is*  
11                   *equal to—*

12                    *“(i) for each of fiscal years 2020*  
13                    *through 2021, the average annual percent*  
14                    *change that occurred in the Consumer Price*  
15                    *Index for urban consumers (Washington-*  
16                    *Baltimore, DC–MD–VA–WV; Not Season-*  
17                    *ally Adjusted; All items; Annual Index) for*  
18                    *the first 3 years of the preceding 4 years of*  
19                    *available data; and*

20                    *“(ii) for each of fiscal years 2022 and*  
21                    *2023, the sum of—*

22                    *“(I) the average annual percent*  
23                    *change in the cost, per full-time equiv-*  
24                    *alent position of the Food and Drug*  
25                    *Administration, of all personnel com-*

1                    *compensation and benefits paid with re-*  
2                    *spect to such positions for the first 3*  
3                    *years of the preceding 4 fiscal years,*  
4                    *multiplied by the proportion of per-*  
5                    *sonnel compensation and benefits costs*  
6                    *to total costs of monograph drug ac-*  
7                    *tivities (as defined in subsection (a))*  
8                    *for the first 3 years of the preceding 4*  
9                    *fiscal years; and*

10                    *“(II) the average annual percent*  
11                    *change that occurred in the Consumer*  
12                    *Price Index for urban consumers*  
13                    *(Washington-Baltimore, DC–MD–VA–*  
14                    *WV; Not Seasonally Adjusted; All*  
15                    *items; Annual Index) for the first 3*  
16                    *years of the preceding 4 years of avail-*  
17                    *able data multiplied by the proportion*  
18                    *of all costs other than personnel com-*  
19                    *penetration and benefits costs to total*  
20                    *costs of monograph drug activities for*  
21                    *the first 3 years of the preceding 4 fis-*  
22                    *cal years.*

23                    *“(2) OPERATING RESERVE ADJUSTMENT.—*

24                    *“(A) For fiscal year 2019 and subsequent*  
25                    *fiscal years, the Secretary may, in addition to*

1           *adjustments under paragraphs (1) and (2), fur-*  
2           *ther increase the fee revenue and fees if such an*  
3           *adjustment is necessary to provide operating re-*  
4           *serves of carryover user fees for monograph drug*  
5           *activities for the number of weeks specified in*  
6           *subparagraph (B).*

7           “(B) *For each fiscal year the number of*  
8           *weeks of operating reserves shall be no more*  
9           *than—*

10                   “(i) *3 weeks for fiscal year 2019;*

11                   “(ii) *7 weeks for fiscal year 2020;*

12                   “(iii) *10 weeks for fiscal year 2021;*

13                   “(iv) *10 weeks for fiscal year 2022;*

14                   *and*

15                   “(v) *10 weeks for fiscal year 2023.*

16           “(C) *If, for fiscal years 2020 through 2023,*  
17           *the Secretary has carryover balances for mono-*  
18           *graph drug activities in excess of the number of*  
19           *weeks of such operating reserves specified in sub-*  
20           *paragraph B, the Secretary shall reduce such fee*  
21           *revenue and fees to provide for not more than the*  
22           *number of weeks of such operating reserves speci-*  
23           *fied in subparagraph (B)(v).*

24           “(D) *If an adjustment under this para-*  
25           *graph is made, the rationale for the amount of*

1           *the increase or decrease (as applicable) in fee*  
2           *revenue and fees shall be contained in the annual*  
3           *Federal Register notice under paragraph (5) es-*  
4           *tablishing fee revenue and fees for the fiscal year*  
5           *involved.*

6           “(3) *ADDITIONAL DIRECT COST ADJUSTMENT.—*

7           *The Secretary shall, in addition to adjustments under*  
8           *paragraphs (1) and (2), further increase the fee rev-*  
9           *enue by an amount equal to—*

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

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

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

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

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

15           “(4) *ANNUAL FEE SETTING.—*

16                   “(A) *FISCAL YEAR 2019.—The Secretary*  
17           *shall, not later than January 31, 2019—*

18                           “(i) *establish monograph drug facility*  
19                           *fees for fiscal year 2019 under subsection*  
20                           *(a)(1), based on the revenue amount for*  
21                           *such year under subsection (b) and the ad-*  
22                           *justments provided under this subsection;*  
23                           *and*

24                           “(ii) *publish such fee revenue and fa-*  
25                           *cility fees in the Federal Register.*

1           “(B) *SUBSEQUENT FISCAL YEARS.*—*The*  
2           *Secretary shall, not later than January 31 of*  
3           *each fiscal year that begins after September 30,*  
4           *2019, establish for each such fiscal year, based on*  
5           *the revenue amounts under subsection (b) and*  
6           *the adjustments provided under this subsection—*

7                   “(i) *monograph drug facility fees*  
8                   *under subsection (a)(1);*

9                   “(ii) *monograph drug order request*  
10                  *fees under subsection (a)(2); and*

11                  “(iii) *publish such fee revenue, facility*  
12                  *fees, and monograph drug order request fees*  
13                  *in the Federal Register.*

14           “(d) *IDENTIFICATION OF FACILITIES.*—*Each person*  
15           *that owns a monograph drug facility shall submit to the*  
16           *Secretary the information required under this subsection*  
17           *each year. Such information shall, for each fiscal year—*

18                   “(1) *be submitted as part of the requirements for*  
19                   *drug establishment registration set forth in section*  
20                   *510; and*

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

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

1           “(1) *IN GENERAL.*—*A monograph drug order re-*  
2           *quest submitted by a person subject to fees under sub-*  
3           *section (a) shall be considered incomplete and shall*  
4           *not be accepted for filing by the Secretary until all*  
5           *fees owed by such person have been paid.*

6           “(2) *EFFECT ON ELIGIBILITY FOR MEETINGS.*—  
7           *If a monograph drug requestor fails to pay a fee as-*  
8           *essed under subsection (a), the requestor shall be con-*  
9           *sidered ineligible for monograph drug meetings.*

10          “(f) *MONOGRAPH DRUG FACILITY FEE.*—*Failure to*  
11          *pay the fee under subsection (a)(1) within 20 calendar days*  
12          *of the due date as specified in subparagraph (D) of such*  
13          *subsection shall result in the Secretary placing the facility*  
14          *on a publicly available arrears list until such fee has been*  
15          *paid.*

16          “(g) *CREDITING AND AVAILABILITY OF FEES.*—

17                 “(1) *IN GENERAL.*—*Fees authorized under sub-*  
18                 *section (a) shall be collected and available for obliga-*  
19                 *tion only to the extent and in the amount provided*  
20                 *in advance in appropriations Acts. Such fees are au-*  
21                 *thorized to remain available until expended. Such*  
22                 *sums as may be necessary may be transferred from*  
23                 *the Food and Drug Administration salaries and ex-*  
24                 *penses appropriation account without fiscal year lim-*  
25                 *itation to such appropriation account for salaries and*

1 *expenses with such fiscal year limitation. The sums*  
2 *transferred shall be available solely for monograph*  
3 *drug activities.*

4 “(2) *COLLECTIONS AND APPROPRIATION ACTS.—*

5 “(A) *IN GENERAL.—Subject to subpara-*  
6 *graph (C), the fees authorized by this section*  
7 *shall be collected and available in each fiscal*  
8 *year in an amount not to exceed the amount*  
9 *specified in appropriation Acts, or otherwise*  
10 *made available for obligation, for such fiscal*  
11 *year.*

12 “(B) *USE OF FEES AND LIMITATION.—The*  
13 *fees authorized by this section shall be available*  
14 *to defray increases in the costs of the resources*  
15 *allocated for monograph drug activities (includ-*  
16 *ing increases in such costs for an additional*  
17 *number of full-time equivalent positions in the*  
18 *Department of Health and Human Services to be*  
19 *engaged in such activities), only if the Secretary*  
20 *allocates for such purpose an amount for such*  
21 *fiscal year (excluding amounts from fees col-*  
22 *lecting under this section) no less than*  
23 *\$12,000,000, multiplied by the adjustment factor*  
24 *applicable to the fiscal year involved.*



1           “(C) *COMPLIANCE.*—*The Secretary shall be*  
2           *considered to have met the requirements of sub-*  
3           *paragraph (B) in any fiscal year if the costs*  
4           *funded by appropriations and allocated for the*  
5           *monograph drug activities are not more than 15*  
6           *percent below the level specified in such subpara-*  
7           *graph.*

8           “(D) *PROVISION FOR EARLY PAYMENTS IN*  
9           *SUBSEQUENT YEARS.*—*Payment of fees author-*  
10           *ized under this section for a fiscal year (after fis-*  
11           *cal year 2019), prior to the due date for such*  
12           *fees, may be accepted by the Secretary in accord-*  
13           *ance with authority provided in advance in a*  
14           *prior year appropriations Act.*

15           “(3) *AUTHORIZATION OF APPROPRIATIONS.*—*For*  
16           *each of the fiscal years 2019 through 2023, there is*  
17           *authorized to be appropriated for fees under this sec-*  
18           *tion an amount equal to the total amount of fees as-*  
19           *essed for such fiscal year under this section.*

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



1 *Secretary shall prepare and submit to the Committee on*  
2 *Health, Education, Labor, and Pensions of the Senate and*  
3 *the Committee on Energy and Commerce of the House of*  
4 *Representatives a report on the implementation of the au-*  
5 *thority for such fees during such fiscal year and the use,*  
6 *by the Food and Drug Administration, of the fees collected*  
7 *for such fiscal year.*

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

12       “(d) *REAUTHORIZATION.*—

13               “(1) *CONSULTATION.*—*In developing rec-*  
14 *ommendations to present to Congress with respect to*  
15 *the goals described in subsection (a), and plans for*  
16 *meeting the goals, for monograph drug activities for*  
17 *the first 5 fiscal years after fiscal year 2023, and for*  
18 *the reauthorization of this part for such fiscal years,*  
19 *the Secretary shall consult with—*

20                       “(A) *the Committee on Health, Education,*  
21 *Labor, and Pensions of the Senate;*

22                       “(B) *the Committee on Energy and Com-*  
23 *merce of the House of Representatives;*

24                       “(C) *scientific and academic experts;*

25                       “(D) *health care professionals;*

1           “(E) representatives of patient and con-  
2           sumer advocacy groups; and

3           “(F) the regulated industry.

4           “(2) PUBLIC REVIEW OF RECOMMENDATIONS.—  
5           After negotiations with the regulated industry, the  
6           Secretary shall—

7           “(A) present the recommendations developed  
8           under paragraph (1) to the congressional com-  
9           mittees specified in such paragraph;

10           “(B) publish such recommendations in the  
11           Federal Register;

12           “(C) provide for a period of 30 calendar  
13           days for the public to provide written comments  
14           on such recommendations;

15           “(D) hold a meeting at which the public  
16           may present its views on such recommendations;  
17           and

18           “(E) after consideration of such public  
19           views and comments, revise such recommenda-  
20           tions as necessary.

21           “(3) TRANSMITTAL OF RECOMMENDATIONS.—Not  
22           later than January 15, 2023, the Secretary shall  
23           transmit to Congress the revised recommendations  
24           under paragraph (2), a summary of the views and  
25           comments received under such paragraph, and any

- 1 *changes made to the recommendations in response to*
- 2 *such views and comments.”.*

**Calendar No. 413**

115<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

**S. 2315**

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**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.

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MAY 14, 2018

Reported with an amendment