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S. 2315

To amend the Federal Food, Drug, and Cosmetic Act to clarify the regulatory framework with respect to certain nonprescription drugs that are marketed without an approved new drug application, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JANUARY 17, 2018

Mr. ISAKSON (for himself, 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*]

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 assess 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 (c) 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 “(II) 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 (c) 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 (c), (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 “(H) 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 (c) 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 “(c) 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-

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

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

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

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

“(4) HEARINGS; JUDICIAL REVIEW.—

“(A) IN GENERAL.—A person who partici-
pated in each level of formal dispute resolution
under paragraph (3)(A)(iv)(III) of an adminis-
trative order with respect to a drug may re-
quest a hearing concerning a final administra-
tive order issued under paragraph (3)(A)(iv)
with respect to such drug. Such person may
submit a request for a hearing, which shall be
based solely on the information in the adminis-
trative record, to the Secretary not later than
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

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

~~“(D) JUDICIAL REVIEW OF FINAL ADMINISTRATIVE ORDER.—~~

~~“(i) IN GENERAL.—The procedures described in section 505(h) shall apply with respect to judicial review of final administrative orders issued under this subsection in the same manner and to the same extent as such section applies to an order described in such section except that the judicial review shall be taken by filing in an appropriate district court of the United States in lieu of the appellate courts specified in such section.~~

~~“(ii) TIME TO SUBMIT A REQUEST FOR JUDICIAL REVIEW.—A person eligible to request a hearing under this paragraph and seeking judicial review of a final administrative order issued under this subsection shall file a request for such review not later than 60 calendar days after the latest of—~~

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

1 “(H) 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.—

“(i) IN GENERAL.—A sponsor of a drug subject to a final order issued under subparagraph (D) who participated in each level of formal dispute resolution under subparagraph (D)(iii) may request a hearing on such order. The provisions of subparagraphs (A), (B), and (C) of paragraph (4) shall apply with respect to a hearing on such order in the same manner and to the same extent as such provisions apply with respect to a hearing on an administrative order issued under paragraph (3)(A)(iv).

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

“(I) to ‘each level of dispute resolution under paragraph (3)(A)(iv)(III)’ shall be deemed to mean ‘each level of formal dispute resolution under subparagraph (D)(iii)’; and

“(II) to ‘final administrative order issued under paragraph (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

complete and formatted to permit a substantive review;

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

“(I) file the request; and

“(II) initiate proceedings with respect to issuing an administrative order in accordance with paragraphs (3) and (4); and

“(iii) except as provided in subparagraph (D)(v), if the Secretary determines that a request does not meet the requirements for filing or is not sufficiently complete or formatted to permit a substantive review, the requestor may elect that the Secretary file the request over protest, and the Secretary shall initiate proceedings to review the request in accordance with paragraph (3)(A).

“(B) REQUEST TO INITIATE PROCEEDINGS.—

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 “(H) 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 cacy.

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

nonprescription use of the drug;
and

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

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

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

“(I) the drug is marketed as a
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-

questor pursuant to this subsection will affect the safety or effectiveness of a drug or materially affect the extent of absorption or other exposure to an active ingredient in the drug in comparison to a suitable reference product, together with guidance for applying those orders to specific dosage forms.

“(B) STANDARD PRACTICES AND SPECIAL NEEDS OF POPULATIONS.—The orders and guidance issued by the Secretary under subparagraph (A) shall take into account relevant public standards and standard practices for evaluating the quality of drug products and may take into account special needs of populations, including children.

“(c) INFORMATION SUBMITTED BY REQUESTORS.—

“(1) CONFIDENTIAL INFORMATION.—Any information, including reports of testing conducted on the drug or drugs involved, that is submitted by a requestor in connection with proceedings on an administrative order under this section (or any minor change under subsection (d)) and is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 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 (c)(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 (c).

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 (c) 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 (c)(3).

12 “(1) 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 licensees, assignees, 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 licensees, assignees, 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 (c) 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), separate buildings or locations within close proximity are
5 considered to be at 1 geographic location or address
6 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 facilities, one per management entity, for purposes of
20 this paragraph.

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

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 (c)(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 (c)(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 ~~(c)(2)); and~~

15 ~~“(C) additional direct cost adjustments (as~~
16 ~~determined under subsection (c)(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 (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
 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 ceding 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-

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

“(D) If an adjustment under this paragraph is made, the rationale for the amount of the increase or decrease (as applicable) in fee revenue and fees shall be contained in the annual Federal Register notice under paragraph (5) establishing fee revenue and fees for the fiscal year involved.

“(3) **ADDITIONAL DIRECT COST ADJUSTMENT.**—The Secretary shall, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenue by an amount equal to—

“(A) 14,000,000 for fiscal year 2018;

“(B) 7,000,000 for fiscal year 2019;

“(C) 4,000,000 for fiscal year 2020;

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

“(E) 3,000,000 for fiscal year 2022.

“(4) **ANNUAL FEE SETTING.**—

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

“(i) establish monograph drug facility fees for fiscal year 2018 under subsection (a)(1), based on the revenue amount for 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 “(c) 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-

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

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

“(D) FEE COLLECTION DURING FIRST PROGRAM YEAR.—Until the date of enactment of an Act making appropriations and providing for the collection and obligation of fees under this section through September 30, 2018, for the salaries and expenses account of the Food and Drug Administration, fees authorized by this section for fiscal year 2018 may be collected and shall be credited to such account and remain available until expended.

“(E) PROVISION FOR EARLY PAYMENTS IN 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 ~~mmerce 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 MARKETING 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 MARKETING 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 MARKETING*
 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-*

tion drug is deemed to be not generally recognized as safe and effective within the meaning of section 201(p)(1), a new drug under section 201(p), and misbranded under section 502(ee), if such drug—

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

“(II) is subject to a determination to be not generally recognized as safe and effective under a proposed rule that is the most recently applicable proposal issued under part 330 of title 21, Code of Federal Regulations.

“(ii) A nonprescription drug that the Secretary has determined to be not generally recognized as safe and effective under a final determination issued under part 330 of title 21, Code of Federal Regulations is deemed to be not generally recognized as safe and effective within the meaning of section 201(p)(1), a new drug under section 201(p), and misbranded under section 502(ee).

“(iii) A 180-day period described in clause (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 “(ii) 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 DIFF-*
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-*

graph (B) shall be deemed to be a final administrative order under this subsection and may be amended, revoked, or otherwise modified in accordance with the procedures of this subsection.

“(B) *MONOGRAPHS DESCRIBED.*—For purposes of subparagraph (A), a final monograph or tentative final monograph, as applicable, is described in this subparagraph if such monograph—

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

“(ii) represents the most recently promulgated version of such requirements, including as modified, in whole or in part, by any proposed or final rule.

“(7) *PACKAGING.*—

“(A) *IN GENERAL.*—An administrative order issued under paragraph (2), (4), or (5) may include requirements for the packaging of a drug, such as to promote use in accordance with labeling, unit dose packaging, or requirements to prevent overdose or accidental ingestion, including 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 *questor 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 *FECT 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-

tion adjustment to the annual base revenue for
fiscal year 2020 and each subsequent fiscal year
shall be equal to the product of—

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

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

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

“(i) for each of fiscal years 2020
through 2021, the average annual percent
change that occurred in the Consumer Price
Index for urban consumers (Washington-
Baltimore, DC–MD–VA–WV; Not Season-
ally Adjusted; All items; Annual Index) for
the first 3 years of the preceding 4 years of
available data; and

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

“(I) the average annual percent
change in the cost, per full-time equiv-
alent position of the Food and Drug
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*

adjustments under paragraphs (1) and (2), further increase the fee revenue and fees if such an adjustment is necessary to provide operating reserves of carryover user fees for monograph drug activities for the number of weeks specified in subparagraph (B).

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

“(i) 3 weeks for fiscal year 2019;

“(ii) 7 weeks for fiscal year 2020;

“(iii) 10 weeks for fiscal year 2021;

“(iv) 10 weeks for fiscal year 2022;

and

“(v) 10 weeks for fiscal year 2023.

“(C) If, for fiscal years 2020 through 2023, the Secretary has carryover balances for monograph drug activities in excess of the number of weeks of such operating reserves specified in subparagraph B, the Secretary shall reduce such fee revenue and fees to provide for not more than the number of weeks of such operating reserves specified in subparagraph (B)(v).

“(D) If an adjustment under this paragraph 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 “(i) *CONSTRUCTION.*—*This section may not be con-*
 2 *strued to require that the number of full-time equivalent*
 3 *positions in the Department of Health and Human Serv-*
 4 *ices, for officers, employers, and advisory committees not*
 5 *engaged in monograph drug activities, be reduced to offset*
 6 *the number of officers, employees, and advisory committees*
 7 *so engaged.*

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

10 “(a) *PERFORMANCE REPORT.*—*Beginning with fiscal*
 11 *year 2019, and not later than 120 calendar days after the*
 12 *end of each fiscal year thereafter for which fees are collected*
 13 *under this part, the Secretary shall prepare and submit to*
 14 *the Committee on the Health, Education, Labor, and Pen-*
 15 *sions of the Senate and the Committee on Energy and Com-*
 16 *merce of the House of Representatives a report concerning*
 17 *the progress of the Food and Drug Administration in*
 18 *achieving the goals identified in the letters described in sec-*
 19 *tion 201 of the Over-the-Counter Drug Safety, Innovation,*
 20 *and Reform Act during such fiscal year and the future*
 21 *plans of the Food and Drug Administration for meeting*
 22 *such goals.*

23 “(b) *FISCAL REPORT.*—*Not later than 120 calendar*
 24 *days after the end of fiscal year 2019 and each subsequent*
 25 *fiscal year for which fees are collected under this part, the*

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.”.*

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2^D Session

S. 2315

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.

May 14, 2018

Reported with an amendment