

Calendar No. 290

116TH CONGRESS
1ST SESSION

S. 2740

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

OCTOBER 30, 2019

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

NOVEMBER 5, 2019

Reported by Mr. ALEXANDER, without amendment

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 Monograph Safety, Innovation, and
4 Reform Act of 2019”.

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—OTC DRUG REVIEW

Sec. 101. Regulation of certain nonprescription drugs that are marketed with-
out an approved drug application.

Sec. 102. Misbranding.

Sec. 103. Drugs excluded from the over-the-counter drug review.

Sec. 104. Treatment of Sunscreen Innovation Act.

Sec. 105. Annual update to Congress on appropriate pediatric indication for
certain OTC cough and cold drugs.

Sec. 106. Technical corrections.

TITLE II—USER FEES

Sec. 201. Short title; finding.

Sec. 202. Fees relating to over-the-counter drugs.

7 **TITLE I—OTC DRUG REVIEW**

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

11 (a) IN GENERAL.—Chapter V of the Federal Food,
12 Drug, and Cosmetic Act is amended by inserting after sec-
13 tion 505F of such Act (21 U.S.C. 355g) the following:

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

17 “(a) NONPRESCRIPTION DRUGS MARKETED WITH-
18 OUT AN APPROVED APPLICATION.—Nonprescription

1 drugs marketed without an approved drug application
2 under section 505, as of the date of the enactment of this
3 section, shall be treated in accordance with this sub-
4 section.

5 “(1) DRUGS SUBJECT TO A FINAL MONOGRAPH;
6 CATEGORY I DRUGS SUBJECT TO A TENTATIVE
7 FINAL MONOGRAPH.—A drug is deemed to be gen-
8 erally recognized as safe and effective under section
9 201(p)(1), not a new drug under section 201(p), and
10 not subject to section 503(b)(1), if—

11 “(A) the drug is—

12 “(i) in conformity with the require-
13 ments for nonprescription use of a final
14 monograph issued under part 330 of title
15 21, Code of Federal Regulations (except as
16 provided in paragraph (2)), the general re-
17 quirements for nonprescription drugs, and
18 conditions or requirements under sub-
19 sections (b), (c), and (k); and

20 “(ii) except as permitted by an order
21 issued under subsection (b) or, in the case
22 of a minor change in the drug, in con-
23 formity with an order issued under sub-
24 section (c), in a dosage form that, imme-
25 diately prior to the date of the enactment

1 of this section, has been used to a material
2 extent and for a material time under sec-
3 tion 201(p)(2); or

4 “(B) the drug is—

5 “(i) classified in category I for safety
6 and effectiveness under a tentative final
7 monograph that is the most recently appli-
8 cable proposal or determination issued
9 under part 330 of title 21, Code of Federal
10 Regulations;

11 “(ii) in conformity with the proposed
12 requirements for nonprescription use of
13 such tentative final monograph, any appli-
14 cable subsequent determination by the Sec-
15 retary, the general requirements for non-
16 prescription drugs, and conditions or re-
17 quirements under subsections (b), (c), and
18 (k); and

19 “(iii) except as permitted by an order
20 issued under subsection (b) or, in the case
21 of a minor change in the drug, in con-
22 formity with an order issued under sub-
23 section (c), in a dosage form that, imme-
24 diately prior to the date of the enactment
25 of this section, has been used to a material

1 extent and for a material time under sec-
2 tion 201(p)(2).

3 “(2) TREATMENT OF SUNSCREEN DRUGS.—

4 With respect to sunscreen drugs subject to this sec-
5 tion, the applicable requirements in terms of con-
6 formity with a final monograph, for purposes of
7 paragraph (1)(A)(i), shall be the requirements speci-
8 fied in part 352 of title 21, Code of Federal Regula-
9 tions, as published on May 21, 1999, beginning on
10 page 27687 of volume 64 of the Federal Register,
11 except that the applicable requirements governing ef-
12 fectiveness and labeling shall be those specified in
13 section 201.327 of title 21, Code of Federal Regula-
14 tions.

15 “(3) CATEGORY III DRUGS SUBJECT TO A TEN-

16 TATIVE FINAL MONOGRAPH; CATEGORY I DRUGS
17 SUBJECT TO PROPOSED MONOGRAPH OR ADVANCE
18 NOTICE OF PROPOSED RULEMAKING.—A drug that
19 is not described in paragraph (1), (2), or (4) is not
20 required to be the subject of an application approved
21 under section 505, and is not subject to section
22 503(b)(1), if—

23 “(A) the drug is—

24 “(i) classified in category III for safe-
25 ty or effectiveness in the preamble of a

1 proposed rule establishing a tentative final
2 monograph that is the most recently appli-
3 cable proposal or determination for such
4 drug issued under part 330 of title 21,
5 Code of Federal Regulations;

6 “(ii) in conformity with—

7 “(I) the conditions of use, includ-
8 ing indication and dosage strength, if
9 any, described for such category III
10 drug in such preamble or in an appli-
11 cable subsequent proposed rule;

12 “(II) the proposed requirements
13 for drugs classified in such tentative
14 final monograph in category I in the
15 most recently proposed rule estab-
16 lishing requirements related to such
17 tentative final monograph and in any
18 final rule establishing requirements
19 that are applicable to the drug; and

20 “(III) the general requirements
21 for nonprescription drugs and condi-
22 tions or requirements under sub-
23 section (b) or (k); and

24 “(iii) in a dosage form that, imme-
25 diately prior to the date of the enactment

1 of this section, had been used to a material
2 extent and for a material time under sec-
3 tion 201(p)(2); or

4 “(B) the drug is—

5 “(i) classified in category I for safety
6 and effectiveness under a proposed mono-
7 graph or advance notice of proposed rule-
8 making that is the most recently applicable
9 proposal or determination for such drug
10 issued under part 330 of title 21, Code of
11 Federal Regulations;

12 “(ii) in conformity with the require-
13 ments for nonprescription use of such pro-
14 posed monograph or advance notice of pro-
15 posed rulemaking, any applicable subse-
16 quent determination by the Secretary, the
17 general requirements for nonprescription
18 drugs, and conditions or requirements
19 under subsection (b) or (k); and

20 “(iii) in a dosage form that, imme-
21 diately prior to the date of the enactment
22 of this section, has been used to a material
23 extent and for a material time under sec-
24 tion 201(p)(2).

1 “(4) CATEGORY II DRUGS DEEMED NEW
2 DRUGS.—A drug that is classified in category II for
3 safety or effectiveness under a tentative final mono-
4 graph or that is subject to a determination to be not
5 generally recognized as safe and effective in a pro-
6 posed rule that is the most recently applicable pro-
7 posal issued under part 330 of title 21, Code of Fed-
8 eral Regulations, shall be deemed to be a new drug
9 under section 201(p), misbranded under section
10 502(ee), and subject to the requirement for an ap-
11 proved new drug application under section 505 be-
12 ginning on the day that is 180 calendar days after
13 the date of the enactment of this section, unless, be-
14 fore such day, the Secretary determines that it is in
15 the interest of public health to extend the period
16 during which the drug may be marketed without
17 such an approved new drug application.

18 “(5) DRUGS NOT GRASE DEEMED NEW
19 DRUGS.—A drug that the Secretary has determined
20 not to be generally recognized as safe and effective
21 under section 201(p)(1) under a final determination
22 issued under part 330 of title 21, Code of Federal
23 Regulations, shall be deemed to be a new drug under
24 section 201(p), misbranded under section 502(ee),

1 and subject to the requirement for an approved new
2 drug application under section 505.

3 “(6) OTHER DRUGS DEEMED NEW DRUGS.—
4 Except as provided in subsection (m), a drug is
5 deemed to be a new drug under section 201(p) and
6 misbranded under section 502(ee) if the drug—

7 “(A) is not subject to section 503(b)(1);

8 and

9 “(B) is not described in paragraph (1),
10 (2), (3), (4), or (5), or subsection (b)(1)(B).

11 “(b) ADMINISTRATIVE ORDERS.—

12 “(1) IN GENERAL.—

13 “(A) DETERMINATION.—The Secretary
14 may, on the initiative of the Secretary or at the
15 request of one or more requestors, issue an ad-
16 ministrative order determining whether there
17 are conditions under which a specific drug, a
18 class of drugs, or a combination of drugs, is de-
19 termined to be—

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

21 and

22 “(ii) generally recognized as safe and
23 effective under section 201(p)(1).

24 “(B) EFFECT.—A drug or combination of
25 drugs shall be deemed to not require approval

1 under section 505 if such drug or combination
2 of drugs—

3 “(i) is determined by the Secretary to
4 meet the conditions specified in clauses (i)
5 and (ii) of subparagraph (A);

6 “(ii) is marketed in conformity with
7 an administrative order under this sub-
8 section;

9 “(iii) meets the general requirements
10 for nonprescription drugs; and

11 “(iv) meets the requirements under
12 subsections (c) and (k).

13 “(C) STANDARD.—The Secretary shall find
14 that a drug is not generally recognized as safe
15 and effective under section 201(p)(1) if—

16 “(i) the evidence shows that the drug
17 is not generally recognized as safe and ef-
18 fective under section 201(p)(1); or

19 “(ii) the evidence is inadequate to
20 show that the drug is generally recognized
21 as safe and effective under section
22 201(p)(1).

23 “(2) ADMINISTRATIVE ORDERS INITIATED BY
24 THE SECRETARY.—

1 “(A) IN GENERAL.—In issuing an adminis-
2 trative order under paragraph (1) upon the
3 Secretary’s initiative, the Secretary shall—

4 “(i) make reasonable efforts to notify
5 informally, not later than 2 business days
6 before the issuance of the proposed order,
7 the sponsors of drugs who have a listing in
8 effect under section 510(j) for the drugs or
9 combination of drugs that will be subject
10 to the administrative order;

11 “(ii) after any such reasonable efforts
12 of notification—

13 “(I) issue a proposed administra-
14 tive order by publishing it on the
15 website of the Food and Drug Admin-
16 istration and include in such order the
17 reasons for the issuance of such order;
18 and

19 “(II) publish a notice of avail-
20 ability of such proposed order in the
21 Federal Register;

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

1 “(iv) if, after completion of the pro-
2 ceedings specified in clauses (i) through
3 (iii), the Secretary determines that it is ap-
4 propriate to issue a final administrative
5 order—

6 “(I) issue the final administrative
7 order, together with a detailed state-
8 ment of reasons, which order shall not
9 take effect until the time for request-
10 ing judicial review under paragraph
11 (3)(D)(ii) has expired;

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

15 “(III) afford requestors of drugs
16 that will be subject to such order the
17 opportunity for formal dispute resolu-
18 tion up to the level of the Director of
19 the Center for Drug Evaluation and
20 Research, which initially must be re-
21 quested within 45 calendar days of
22 the issuance of the order, and, for
23 subsequent levels of appeal, within 30
24 calendar days of the prior decision;
25 and

1 “(IV) except with respect to
2 drugs described in paragraph (3)(B),
3 upon completion of the formal dispute
4 resolution procedure, inform the per-
5 sons which sought such dispute reso-
6 lution of their right to request a hear-
7 ing.

8 “(B) EXCEPTIONS.—When issuing an ad-
9 ministrative order under paragraph (1) on the
10 Secretary’s initiative proposing to determine
11 that a drug described in subsection (a)(3) is not
12 generally recognized as safe and effective under
13 section 201(p)(1), the Secretary shall follow the
14 procedures in subparagraph (A), except that—

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

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

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

24 “(ii) the Secretary shall provide for a
25 public comment period of no less than 180

1 calendar days with respect to such pro-
2 posed order, except when the Secretary de-
3 termines, for good cause, that a shorter pe-
4 riod is in the interest of public health; and

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

14 “(3) HEARINGS; JUDICIAL REVIEW.—

15 “(A) IN GENERAL.—Only a person who
16 participated in each stage of formal dispute res-
17 olution under subclause (III) of paragraph
18 (2)(A)(iv) of an administrative order with re-
19 spect to a drug may request a hearing con-
20 cerning a final administrative order issued
21 under such paragraph with respect to such
22 drug. If a hearing is sought, such person must
23 submit a request for a hearing, which shall be
24 based solely on information in the administra-
25 tive record, to the Secretary not later than 30

1 calendar days after receiving notice of the final
2 decision of the formal dispute resolution proce-
3 dure.

4 “(B) NO HEARING REQUIRED WITH RE-
5 SPECT TO ORDERS RELATING TO CERTAIN
6 DRUGS.—

7 “(i) IN GENERAL.—The Secretary
8 shall not be required to provide notice and
9 an opportunity for a hearing pursuant to
10 paragraph (2)(A)(iv) if the final adminis-
11 trative order involved relates to a drug—

12 “(I) that is described in sub-
13 section (a)(3)(A); and

14 “(II) with respect to which no
15 human or non-human data studies rel-
16 evant to the safety or effectiveness of
17 such drug have been submitted to the
18 administrative record since the
19 issuance of the most recent tentative
20 final monograph relating to such
21 drug.

22 “(ii) HUMAN DATA STUDIES AND
23 NON-HUMAN DATA DEFINED.—In this sub-
24 paragraph:

1 “(I) The term ‘human data stud-
2 ies’ means clinical trials of safety or
3 effectiveness (including actual use
4 studies), pharmacokinetics studies, or
5 bioavailability studies.

6 “(II) The term ‘non-human data’
7 means data from testing other than
8 with human subjects which provides
9 information concerning safety or ef-
10 fectiveness.

11 “(C) HEARING PROCEDURES.—

12 “(i) DENIAL OF REQUEST FOR HEAR-
13 ING.—If the Secretary determines that in-
14 formation submitted in a request for a
15 hearing under subparagraph (A) with re-
16 spect to a final administrative order issued
17 under paragraph (2)(A)(iv) does not iden-
18 tify the existence of a genuine and sub-
19 stantial question of material fact, the Sec-
20 retary may deny such request. In making
21 such a determination, the Secretary may
22 consider only information and data that
23 are based on relevant and reliable scientific
24 principles and methodologies.

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

9 “(iii) PRESIDING OFFICER.—The pre-
10 siding officer of a hearing requested under
11 subparagraph (A) shall—

12 “(I) be designated by the Sec-
13 retary;

14 “(II) not be an employee of the
15 Center for Drug Evaluation and Re-
16 search; and

17 “(III) not have been previously
18 involved in the development of the ad-
19 ministrative order involved or pro-
20 ceedings relating to that administra-
21 tive order.

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

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

8 “(v) FINAL DECISION.—

9 “(I) At the conclusion of a hear-
10 ing requested under subparagraph
11 (A), the presiding officer of the hear-
12 ing shall issue a decision containing
13 findings of fact and conclusions of
14 law. The decision of the presiding offi-
15 cer shall be final.

16 “(II) The final decision may not
17 take effect until the period under sub-
18 paragraph (D)(ii) for submitting a re-
19 quest for judicial review of such deci-
20 sion expires.

21 “(D) JUDICIAL REVIEW OF FINAL ADMIN-
22 ISTRATIVE ORDER.—

23 “(i) IN GENERAL.—The procedures
24 described in section 505(h) shall apply
25 with respect to judicial review of final ad-

1 ministrative orders issued under this sub-
2 section in the same manner and to the
3 same extent as such section applies to an
4 order described in such section except that
5 the judicial review shall be taken by filing
6 in an appropriate district court of the
7 United States in lieu of the appellate
8 courts specified in such section.

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

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

19 “(II) the date on which a hearing
20 with respect to such order is denied
21 under subparagraph (B) or (C)(i);

22 “(III) the date on which a final
23 decision is made following a hearing
24 under subparagraph (C)(v); or

1 “(IV) if no hearing is requested,
2 the date on which the time for re-
3 questing a hearing expires.

4 “(4) EXPEDITED PROCEDURE WITH RESPECT
5 TO ADMINISTRATIVE ORDERS INITIATED BY THE
6 SECRETARY.—

7 “(A) IMMINENT HAZARD TO THE PUBLIC
8 HEALTH.—

9 “(i) IN GENERAL.—In the case of a
10 determination by the Secretary that a
11 drug, class of drugs, or combination of
12 drugs subject to this section poses an im-
13 minent hazard to the public health, the
14 Secretary, after first making reasonable ef-
15 forts to notify, not later than 48 hours be-
16 fore issuance of such order under this sub-
17 paragraph, sponsors who have a listing in
18 effect under section 510(j) for such drug
19 or combination of drugs—

20 “(I) may issue an interim final
21 administrative order for such drug,
22 class of drugs, or combination of
23 drugs under paragraph (1), together
24 with a detailed statement of the rea-
25 sons for such order;

1 “(II) shall publish in the Federal
2 Register a notice of availability of any
3 such order; and

4 “(III) shall provide for a public
5 comment period of at least 45 cal-
6 endar days with respect to such in-
7 terim final order.

8 “(ii) NONDELEGATION.—The Sec-
9 retary may not delegate the authority to
10 issue an interim final administrative order
11 under this subparagraph.

12 “(B) SAFETY LABELING CHANGES.—

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

21 “(I) make reasonable efforts to
22 notify informally, not later than 48
23 hours before the issuance of the in-
24 terim final order, the sponsors of
25 drugs who have a listing in effect

1 under section 510(j) for such drug or
2 combination of drugs;

3 “(II) after reasonable efforts of
4 notification, issue an interim final ad-
5 ministrative order in accordance with
6 paragraph (1) to require such change,
7 together with a detailed statement of
8 the reasons for such order;

9 “(III) publish in the Federal
10 Register a notice of availability of
11 such order; and

12 “(IV) provide for a public com-
13 ment period of at least 45 calendar
14 days with respect to such interim final
15 order.

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

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

1 “(D) FINAL ORDER.—After the completion
2 of the proceedings in subparagraph (A) or (B),
3 the Secretary shall—

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

6 “(ii) publish a notice of availability of
7 such final administrative order in the Fed-
8 eral Register; and

9 “(iii) afford sponsors of such drugs
10 that will be subject to such an order the
11 opportunity for formal dispute resolution
12 up to the level of the Director of the Cen-
13 ter for Drug Evaluation and Research,
14 which must initially be within 45 calendar
15 days of the issuance of the order, and for
16 subsequent levels of appeal, within 30 cal-
17 endar days of the prior decision.

18 “(E) HEARINGS.—A sponsor of a drug
19 subject to a final order issued under subpara-
20 graph (D) and that participated in each stage
21 of formal dispute resolution under clause (iii) of
22 such subparagraph may request a hearing on
23 such order. The provisions of subparagraphs
24 (A), (B), and (C) of paragraph (3), other than
25 paragraph (3)(C)(v)(II), shall apply with re-

spect 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 (2)(A)(iv).

“(F) TIMING.—

“(i) FINAL ORDER AND HEARING.—

The Secretary shall—

“(I) not later than 6 months after the date on which the comment period closes under subparagraph (A) or (B), issue a final order in accordance with paragraph (1); and

“(II) not later than 12 months after the date on which such final order is issued, complete any hearing under subparagraph (E).

“(ii) DISPUTE RESOLUTION REQUEST.—The Secretary shall specify in an interim final order issued under subparagraph (A) or (B) such shorter periods for requesting dispute resolution under subparagraph (D)(iii) as are necessary to meet the requirements of this subparagraph.

1 “(G) JUDICIAL REVIEW.—A final order
2 issued pursuant to subparagraph (F) shall be
3 subject to judicial review in accordance with
4 paragraph (3)(D).

5 “(5) ADMINISTRATIVE ORDER INITIATED AT
6 THE REQUEST OF A REQUESTOR.—

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

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

17 “(ii) if the Secretary determines that
18 the request is sufficiently complete and for-
19 matted to permit a substantive review, the
20 Secretary shall—

21 “(I) file the request; and

22 “(II) initiate proceedings with re-
23 spect to issuing an administrative
24 order in accordance with paragraphs
25 (2) and (3); and

1 “(iii) except as provided in paragraph
2 (6), if the Secretary determines that a re-
3 quest does not meet the requirements for
4 filing or is not sufficiently complete and
5 formatted to permit a substantive review,
6 the requestor may demand that the request
7 be filed over protest, and the Secretary
8 shall initiate proceedings to review the re-
9 quest in accordance with paragraph (2)(A).

10 “(B) REQUEST TO INITIATE PRO-
11 CEEDINGS.—

12 “(i) IN GENERAL.—A requestor seek-
13 ing an administrative order under para-
14 graph (1) with respect to certain drugs,
15 classes of drugs, or combinations of drugs,
16 shall submit to the Secretary a request to
17 initiate proceedings for such order in the
18 form and manner as specified by the Sec-
19 retary. Such requestor may submit a re-
20 quest under this subparagraph for the
21 issuance of an administrative order—

22 “(I) determining whether a drug
23 is generally recognized as safe and ef-
24 fective under section 201(p)(1), ex-
25 empt from section 503(b)(1), and not

1 required to be the subject of an ap-
2 proved application under section 505;
3 or

4 “(II) determining whether a
5 change to a condition of use of a drug
6 is generally recognized as safe and ef-
7 fective under section 201(p)(1), ex-
8 empt from section 503(b)(1), and not
9 required to be the subject of an ap-
10 proved application under section 505,
11 if, absent such a changed condition of
12 use, such drug is—

13 “(aa) generally recognized
14 as safe and effective under sec-
15 tion 201(p)(1) in accordance with
16 subsection (a)(1), (a)(2), or an
17 order under this subsection; or

18 “(bb) subject to subsection
19 (a)(3), but only if such requestor
20 initiates such request in conjunc-
21 tion with a request for the Sec-
22 retary to determine whether such
23 drug is generally recognized as
24 safe and effective under section
25 201(p)(1), which is filed by the

1 Secretary under subparagraph
2 (A)(ii).

3 “(ii) EXCEPTION.—The Secretary is
4 not required to complete review of a re-
5 quest for a change described in clause
6 (i)(II) if the Secretary determines that
7 there is an inadequate basis to find the
8 drug is generally recognized as safe and ef-
9 fective under section 201(p)(1) under para-
10 graph (1) and issues a final order an-
11 nouncing that determination.

12 “(iii) WITHDRAWAL.—The requestor
13 may withdraw a request under this para-
14 graph, according to the procedures set
15 forth pursuant to subsection (d)(2)(B).
16 Notwithstanding any other provision of
17 this section, if such request is withdrawn,
18 the Secretary may cease proceedings under
19 this subparagraph.

20 “(C) EXCLUSIVITY.—

21 “(i) IN GENERAL.—A final adminis-
22 trative order issued in response to a re-
23 quest under this section shall have the ef-
24 fect of authorizing solely the order re-
25 questor (or the licensees, assignees, or suc-

cessors in interest of such requestor with respect to the subject of such order), for a period of 18 months following the effective date of such final order and beginning on the date the requestor may lawfully market such drugs pursuant to the order, to market drugs—

“(I) incorporating changes described in clause (ii); and

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

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

“(I) provides for a drug to contain an active ingredient (including any ester or salt of the active ingredient) not previously incorporated in a drug described in clause (iii); or

“(II) provides for a change in the conditions of use of a drug, for which new human data studies conducted or sponsored by the requestor (or for which the requestor has an exclusive

1 right of reference) were essential to
 2 the issuance of such order.

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

5 “(I) specified in subsection
 6 (a)(1), (a)(2), or (a)(3);

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

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

12 “(IV) described in subsection
 13 (m)(1), other than drugs subject to an
 14 active enforcement action under chap-
 15 ter III of this Act.

16 “(iv) LIMITATIONS ON EXCLU-
 17 SIVITY.—

18 “(I) IN GENERAL.—Only one 18-
 19 month period under this subpara-
 20 graph shall be granted, under each
 21 order described in clause (i), with re-
 22 spect to changes (to the drug subject
 23 to such order) which are either—

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

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

7 “(II) NO EXCLUSIVITY AL-
8 LOWED.—No exclusivity shall apply to
9 changes to a drug which are—

10 “(aa) the subject of a Tier 2
11 OTC monograph order request
12 (as defined in section 744L);

13 “(bb) safety-related changes,
14 as defined by the Secretary, or
15 any other changes the Secretary
16 considers necessary to assure
17 safe use; or

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

21 “(v) NEW HUMAN DATA STUDIES DE-
22 FINED.—In this subparagraph, the term
23 ‘new human data studies’ means clinical
24 trials of safety or effectiveness (including
25 actual use studies), pharmacokinetics stud-

1 ies, or bioavailability studies, the results of
2 which—

3 “(I) have not been relied on by
4 the Secretary to support—

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

11 “(bb) approval of a drug
12 that was approved under section
13 505; and

14 “(II) do not duplicate the results
15 of another study that was relied on by
16 the Secretary to support—

17 “(aa) a proposed or final de-
18 termination that a drug described
19 in subclause (I), (II), or (III) of
20 clause (iii) is generally recognized
21 as safe and effective under sec-
22 tion 201(p)(1); or

23 “(bb) approval of a drug
24 that was approved under section
25 505.

1 “(vi) NOTIFICATION OF DRUG NOT
2 AVAILABLE FOR SALE.—A requestor that
3 is granted exclusivity with respect to a
4 drug under this subparagraph shall notify
5 the Secretary in writing within 1 year of
6 the issuance of the final administrative
7 order if the drug that is the subject of
8 such order will not be available for sale
9 within 1 year of the date of issuance of
10 such order. The requestor shall include
11 with such notice the—

12 “(I) identity of the drug by es-
13 tablished name and by proprietary
14 name, if any;

15 “(II) strength of the drug;

16 “(III) date on which the drug
17 will be available for sale, if known;
18 and

19 “(IV) reason for not marketing
20 the drug after issuance of the order.

21 “(6) INFORMATION REGARDING SAFE NON-
22 PRESCRIPTION MARKETING AND USE AS CONDITION
23 FOR FILING A GENERALLY RECOGNIZED AS SAFE
24 AND EFFECTIVE REQUEST.—

1 “(A) IN GENERAL.—In response to a re-
2 quest under this section that a drug described
3 in subparagraph (B) be generally recognized as
4 safe and effective, the Secretary—

5 “(i) may file such request, if the re-
6 quest includes information specified under
7 subparagraph (C) with respect to safe non-
8 prescription marketing and use of such
9 drug; or

10 “(ii) if the request fails to include in-
11 formation specified under subparagraph
12 (C), shall refuse to file such request and
13 require that nonprescription marketing of
14 the drug be pursuant to a new drug appli-
15 cation as described in subparagraph (D).

16 “(B) DRUG DESCRIBED.—A drug de-
17 scribed in this subparagraph is a nonprescrip-
18 tion drug which contains an active ingredient
19 not previously incorporated in a drug—

20 “(i) specified in subsection (a)(1),
21 (a)(2), or (a)(3);

22 “(ii) subject to a final order under
23 this section; or

24 “(iii) subject to a final sunscreen
25 order (as defined in section 586(2)(A)).

1 “(C) INFORMATION DEMONSTRATING
2 PRIMA FACIE SAFE NONPRESCRIPTION MAR-
3 KETING AND USE.—Information specified in
4 this subparagraph, with respect to a request de-
5 scribed in subparagraph (A)(i), is—

6 “(i) information sufficient for a prima
7 facie demonstration that the drug subject
8 to such request has a verifiable history of
9 being marketed and safely used by con-
10 sumers in the United States as a non-
11 prescription drug under comparable condi-
12 tions of use;

13 “(ii) if the drug has not been pre-
14 viously marketed in the United States as a
15 nonprescription drug, information suffi-
16 cient for a prima facie demonstration that
17 the drug was marketed and safely used
18 under comparable conditions of marketing
19 and use in a country listed in section
20 802(b)(1)(A) or designated by the Sec-
21 retary in accordance with section
22 802(b)(1)(B)—

23 “(I) for such period as needed to
24 provide reasonable assurances con-

cerning the safe nonprescription use
of the drug; and

“(II) during such time was sub-
ject to sufficient monitoring by a reg-
ulatory body considered acceptable by
the Secretary for such monitoring
purposes, including for adverse events
associated with nonprescription use of
the drug; or

“(iii) if the Secretary determines that
information described in clause (i) or (ii) is
not needed to provide a prima facie dem-
onstration that the drug can be safely mar-
keted and used as a nonprescription drug,
such other information the Secretary deter-
mines is sufficient for such purposes.

“(D) MARKETING PURSUANT TO NEW
DRUG APPLICATION.—In the case of a request
described in subparagraph (A)(ii), the drug
subject to such request may be resubmitted for
filing only if—

“(i) the drug is marketed as a non-
prescription drug, under conditions of use
comparable to the conditions specified in
the request, for such period as the Sec-

1 retary determines appropriate (not to ex-
2 ceed 5 consecutive years) pursuant to an
3 application approved under section 505;
4 and

5 “(ii) during such period, 1,000,000
6 retail packages of the drug, or an equiva-
7 lent quantity as determined by the Sec-
8 retary, were distributed for retail sale, as
9 determined in such manner as the Sec-
10 retary finds appropriate.

11 “(E) RULE OF APPLICATION.—Except in
12 the case of a request involving a drug described
13 in section 586(9), as in effect on January 1,
14 2017, if the Secretary refuses to file a request
15 under this paragraph, the requestor may not
16 file such request over protest under paragraph
17 (5)(A)(iii).

18 “(7) PACKAGING.—An administrative order
19 issued under paragraph (2), (4)(A), or (5) may in-
20 clude requirements for the packaging of a drug to
21 encourage use in accordance with labeling. Such re-
22 quirements may include unit dose packaging, re-
23 quirements for products intended for use by pedi-
24 atric populations, requirements to reduce risk of
25 harm from unsupervised ingestion, and other appro-

1 appropriate requirements. This paragraph does not au-
 2 thorize the Food and Drug Administration to re-
 3 quire standards or testing procedures as described in
 4 part 1700 of title 16, Code of Federal Regulations.

5 “(8) FINAL AND TENTATIVE FINAL MONO-
 6 GRAPHS FOR CATEGORY I DRUGS DEEMED FINAL
 7 ADMINISTRATIVE ORDERS.—

8 “(A) IN GENERAL.—A final monograph or
 9 tentative final monograph described in subpara-
 10 graph (B) shall be deemed to be a final admin-
 11 istrative order under this subsection and may
 12 be amended, revoked, or otherwise modified in
 13 accordance with the procedures of this sub-
 14 section.

15 “(B) MONOGRAPHS DESCRIBED.—For pur-
 16 poses of subparagraph (A), a final monograph
 17 or tentative final monograph is described in this
 18 subparagraph if it—

19 “(i) establishes conditions of use for a
 20 drug described in paragraph (1) or (2) of
 21 subsection (a); and

22 “(ii) represents the most recently pro-
 23 mulgated version of such conditions, in-
 24 cluding as modified, in whole or in part, by
 25 any proposed or final rule.

1 “(C) DEEMED ORDERS INCLUDE HARMO-
2 NIZING TECHNICAL AMENDMENTS.—The
3 deemed establishment of a final administrative
4 order under subparagraph (A) shall be con-
5 strued to include any technical amendments to
6 such order as the Secretary determines nec-
7 essary to ensure that such order is appro-
8 priately harmonized, in terms of terminology or
9 cross-references, with the applicable provisions
10 of this Act (and regulations thereunder) and
11 any other orders issued under this section.

12 “(c) PROCEDURE FOR MINOR CHANGES.—

13 “(1) IN GENERAL.—Minor changes in the dos-
14 age form of a drug that is described in paragraph
15 (1) or (2) of subsection (a) or the subject of an
16 order issued under subsection (b) may be made by
17 a requestor without the issuance of an order under
18 subsection (b) if—

19 “(A) the requestor maintains such infor-
20 mation as is necessary to demonstrate that the
21 change—

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

24 “(ii) will not materially affect the ex-
25 tent of absorption or other exposure to the

1 active ingredient in comparison to a suit-
2 able reference product; and

3 “(B) 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.—A sponsor
9 shall submit records requested by the Secretary
10 relating to such a minor change under section
11 704(a)(4), within 15 business days of receiving
12 such a request, or such longer period as the
13 Secretary may provide.

14 “(B) INSUFFICIENT INFORMATION.—If the
15 Secretary determines that the information con-
16 tained in such records is not sufficient to dem-
17 onstrate that the change does not affect the
18 safety or effectiveness of the drug or materially
19 affect the extent of absorption or other expo-
20 sure to the active ingredient, the Secretary—

21 “(i) may so inform the sponsor of the
22 drug in writing; and

23 “(ii) if the Secretary so informs the
24 sponsor, shall provide the sponsor of the

1 drug with a reasonable opportunity to pro-
2 vide additional information.

3 “(C) FAILURE TO SUBMIT SUFFICIENT IN-
4 FORMATION.—If the sponsor fails to provide
5 such additional information within a time pre-
6 scribed by the Secretary, or if the Secretary de-
7 termines that such additional information does
8 not demonstrate that the change does not—

9 “(i) affect the safety or effectiveness
10 of the drug; or

11 “(ii) materially affect the extent of
12 absorption or other exposure to the active
13 ingredient in comparison to a suitable ref-
14 erence product,

15 the drug as modified is a new drug under sec-
16 tion 201(p) and shall be deemed to be mis-
17 branded under section 502(ee).

18 “(3) DETERMINING WHETHER A CHANGE WILL
19 AFFECT SAFETY OR EFFECTIVENESS.—

20 “(A) IN GENERAL.—The Secretary shall
21 issue one or more administrative orders speci-
22 fying requirements for determining whether a
23 minor change made by a sponsor pursuant to
24 this subsection will affect the safety or effective-
25 ness of a drug or materially affect the extent of

1 absorption or other exposure to an active ingre-
2 dient in the drug in comparison to a suitable
3 reference product, together with guidance for
4 applying those orders to specific dosage forms.

5 “(B) STANDARD PRACTICES.—The orders
6 and guidance issued by the Secretary under
7 subparagraph (A) shall take into account rel-
8 evant public standards and standard practices
9 for evaluating the quality of drugs, and may
10 take into account the special needs of popu-
11 lations, including children.

12 “(d) CONFIDENTIALITY OF INFORMATION SUB-
13 MITTED TO THE SECRETARY.—

14 “(1) IN GENERAL.—Subject to paragraph (2),
15 any information, including reports of testing con-
16 ducted on the drug or drugs involved, that is sub-
17 mitted by a requestor in connection with proceedings
18 on an order under this section (including any minor
19 change under subsection (c)) and is a trade secret
20 or confidential information subject to section
21 552(b)(4) of title 5, United States Code, or section
22 1905 of title 18, United States Code, shall not be
23 disclosed to the public unless the requestor consents
24 to that disclosure.

25 “(2) PUBLIC AVAILABILITY.—

1 “(A) IN GENERAL.—Except as provided in
2 subparagraph (B), the Secretary shall—

3 “(i) make any information submitted
4 by a requestor in support of a request
5 under subsection (b)(5)(A) available to the
6 public not later than the date on which the
7 proposed order is issued; and

8 “(ii) make any information submitted
9 by any other person with respect to an
10 order requested (or initiated by the Sec-
11 retary) under subsection (b), available to
12 the public upon such submission.

13 “(B) LIMITATIONS ON PUBLIC AVAIL-
14 ABILITY.—Information described in subpara-
15 graph (A) shall not be made public if—

16 “(i) the information pertains to phar-
17 maceutical quality information, unless such
18 information is necessary to establish stand-
19 ards under which a drug is generally rec-
20 ognized as safe and effective under section
21 201(p)(1);

22 “(ii) the information is submitted in a
23 requestor-initiated request, but the re-
24 questor withdraws such request, in accord-
25 ance with withdrawal procedures estab-

1 lished by the Secretary, before the Sec-
2 retary issues the proposed order;

3 “(iii) the Secretary requests and ob-
4 tains the information under subsection (c)
5 and such information is not submitted in
6 relation to an order under subsection (b);
7 or

8 “(iv) the information is of the type
9 contained in raw datasets.

10 “(e) UPDATES TO DRUG LISTING INFORMATION.—

11 A sponsor who makes a change to a drug subject to this
12 section shall submit updated drug listing information for
13 the drug in accordance with section 510(j) within 30 cal-
14 endar days of the date when the drug is first commercially
15 marketed, except that a sponsor who was the order re-
16 questor with respect to an order subject to subsection
17 (b)(5)(C) (or a licensee, assignee, or successor in interest
18 of such requestor) shall submit updated drug listing infor-
19 mation on or before the date when the drug is first com-
20 mercially marketed.

21 “(f) APPROVALS UNDER SECTION 505.—The provi-
22 sions of this section shall not be construed to preclude a
23 person from seeking or maintaining the approval of an ap-
24 plication for a drug under sections 505(b)(1), 505(b)(2),
25 and 505(j). A determination under this section that a drug

1 is not subject to section 503(b)(1), is generally recognized
2 as safe and effective under section 201(p)(1), and is not
3 a new drug under section 201(p) shall constitute a finding
4 that the drug is safe and effective that may be relied upon
5 for purposes of an application under section 505(b)(2), so
6 that the applicant shall be required to submit for purposes
7 of such application only information needed to support any
8 modification of the drug that is not covered by such deter-
9 mination under this section.

10 “(g) PUBLIC AVAILABILITY OF ADMINISTRATIVE OR-
11 DERS.—The Secretary shall establish, maintain, update
12 (as determined necessary by the Secretary but no less fre-
13 quently than annually), and make publicly available, with
14 respect to orders issued under this section—

15 “(1) a repository of each final order and in-
16 terim final order in effect, including the complete
17 text of the order; and

18 “(2) a listing of all orders proposed and under
19 development under subsection (b)(2), including—

20 “(A) a brief description of each such order;
21 and

22 “(B) the Secretary’s expectations, if re-
23 sources permit, for issuance of proposed orders
24 over a 3-year period.

1 “(h) DEVELOPMENT ADVICE TO SPONSORS OR RE-
 2 QUESTORS.—The Secretary shall establish procedures
 3 under which sponsors or requestors may meet with appro-
 4 priate officials of the Food and Drug Administration to
 5 obtain advice on the studies and other information nec-
 6 essary to support submissions under this section and other
 7 matters relevant to the regulation of nonprescription
 8 drugs and the development of new nonprescription drugs
 9 under this section.

10 “(i) PARTICIPATION OF MULTIPLE SPONSORS OR RE-
 11 QUESTORS.—The Secretary shall establish procedures to
 12 facilitate efficient participation by multiple sponsors or re-
 13 questors in proceedings under this section, including provi-
 14 sion for joint meetings with multiple sponsors or reques-
 15 tors or with organizations nominated by sponsors or re-
 16 questors to represent their interests in a proceeding.

17 “(j) ELECTRONIC FORMAT.—All submissions under
 18 this section shall be in electronic format.

19 “(k) EFFECT ON EXISTING REGULATIONS GOV-
 20 ERNING NONPRESCRIPTION DRUGS.—

21 “(1) REGULATIONS OF GENERAL APPLICA-
 22 BILITY TO NONPRESCRIPTION DRUGS.—Except as
 23 provided in this subsection, nothing in this section
 24 supersedes regulations establishing general require-
 25 ments for nonprescription drugs, including regula-

tions of general applicability contained in parts 201, 250, and 330 of title 21, Code of Federal Regulations, or any successor regulations. The Secretary shall establish or modify such regulations by means of rulemaking in accordance with section 553 of title 5, United States Code.

“(2) REGULATIONS ESTABLISHING REQUIREMENTS FOR SPECIFIC NONPRESCRIPTION DRUGS.—

“(A) The provisions of section 310.545 of title 21, Code of Federal Regulations, as in effect on the day before the date of the enactment of this section, shall be deemed to be a final order under subsection (b).

“(B) Regulations in effect on the day before the date of the enactment of this section, establishing requirements for specific nonprescription drugs marketed pursuant to this section (including such requirements in parts 201 and 250 of title 21, Code of Federal Regulations), shall be deemed to be final orders under subsection (b), only as they apply to drugs—

“(i) subject to paragraph (1), (2), (3), or (4) of subsection (a); or

1 “(ii) otherwise subject to an order
2 under this section.

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 the enactment of this section), or make technical
10 changes to such regulations to ensure conformity
11 with appropriate terminology and cross references.
12 Notwithstanding subchapter II of chapter 5 of title
13 5, United States Code, any such withdrawal or tech-
14 nical changes shall be made without public notice
15 and comment and shall be effective upon publication
16 through notice in the Federal Register (or upon such
17 date as specified in such notice).

18 “(1) GUIDANCE.—The Secretary shall issue guidance
19 that specifies—

20 “(1) the procedures and principles for formal
21 meetings between the Secretary and sponsors or re-
22 questors for drugs subject to this section;

23 “(2) the format and content of data submis-
24 sions to the Secretary under this section;

1 “(3) the format of electronic submissions to the
2 Secretary under this section;

3 “(4) consolidated proceedings for appeal and
4 the procedures for such proceedings where appropriate; and
5 appropriate; and

6 “(5) for minor changes in drugs, recommendations on how to comply with the requirements in orders issued under subsection (c)(3).

9 “(m) RULE OF CONSTRUCTION.—

10 “(1) IN GENERAL.—This section shall not affect the treatment or status of a nonprescription
11 drug—
12 drug—

13 “(A) that is marketed without an application approved under section 505 as of the date
14 of the enactment of this section;
15 of the enactment of this section;

16 “(B) that is not subject to an order issued
17 under this section; and

18 “(C) to which paragraph (1), (2), (3), (4),
19 or (5) of subsection (a) do not apply.

20 “(2) TREATMENT OF PRODUCTS PREVIOUSLY
21 FOUND TO BE SUBJECT TO TIME AND EXTENT REQUIREMENTS.—
22 REQUIREMENTS.—

23 “(A) Notwithstanding subsection (a), a
24 drug described in subparagraph (B) may only
25 be lawfully marketed, without an application

1 approved under section 505, pursuant to an
2 order issued under this section.

3 “(B) A drug described in this subpara-
4 graph is a drug which, prior to the date of the
5 enactment of this section, the Secretary deter-
6 mined in a proposed or final rule to be ineligible
7 for review under the OTC drug review (as such
8 phrase ‘OTC drug review’ was used in section
9 330.14 of title 21, Code of Federal Regulations,
10 as in effect on the day before the date of the
11 enactment of this section).

12 “(3) PRESERVATION OF AUTHORITY.—

13 “(A) Nothing in paragraph (1) shall be
14 construed to preclude or limit the applicability
15 of any provision of this Act other than this sec-
16 tion.

17 “(B) Nothing in subsection (a) shall be
18 construed to prohibit the Secretary from issuing
19 an order under this section finding a drug to be
20 not generally recognized as safe and effective
21 under section 201(p)(1), as the Secretary deter-
22 mines appropriate.

23 “(n) INVESTIGATIONAL NEW DRUGS.—A drug is not
24 subject to this section if an exemption for investigational
25 use under section 505(i) is in effect for such drug.

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

5 “(p) INAPPLICABILITY OF NOTICE AND COMMENT
6 RULEMAKING AND OTHER REQUIREMENTS.—The re-
7 quirements of subsection (b) shall apply with respect to
8 orders issued under this section instead of the require-
9 ments of subchapter II of chapter 5 of title 5, United
10 States Code.

11 “(q) DEFINITIONS.—In this section:

12 “(1) The term ‘nonprescription drug’ refers to
13 a drug not subject to the requirements of section
14 503(b)(1).

15 “(2) The term ‘sponsor’ refers to any person
16 marketing, manufacturing, or processing a drug
17 that—

18 “(A) is listed pursuant to section 510(j);

19 and

20 “(B) is or will be subject to an administra-
21 tive order under this section of the Food and
22 Drug Administration.

23 “(3) The term ‘requestor’ refers to any person
24 or group of persons marketing, manufacturing, proc-
25 essing, or developing a drug.”.

1 (b) GAO STUDY.—Not later than 4 years after the
2 date of enactment of this Act, the Comptroller General
3 of the United States shall submit a study to the Com-
4 mittee on Energy and Commerce of the House of Rep-
5 resentatives and the Committee on Health, Education,
6 Labor, and Pensions of the Senate addressing the effec-
7 tiveness and overall impact of exclusivity under section
8 505G of the Federal Food, Drug, and Cosmetic Act, as
9 added by subsection (a), and section 586C of such Act
10 (21 U.S.C. 360fff–3), including the impact of such exclu-
11 sivity on consumer access. Such study shall include—

12 (1) an analysis of the impact of exclusivity
13 under such section 505G for nonprescription drug
14 products, including—

15 (A) the number of nonprescription drug
16 products that were granted exclusivity and the
17 indication for which the nonprescription drug
18 products were determined to be generally recog-
19 nized as safe and effective;

20 (B) whether the exclusivity for such drug
21 products was granted for—

22 (i) a new active ingredient (including
23 any ester or salt of the active ingredient);
24 or

1 (ii) changes in the conditions of use of
2 a drug, for which new human data studies
3 conducted or sponsored by the requestor
4 were essential;

5 (C) whether, and to what extent, the exclu-
6 sivity impacted the requestor's or sponsor's de-
7 cision to develop the drug product;

8 (D) an analysis of the implementation of
9 the exclusivity provision in such section 505G,
10 including—

11 (i) the resources used by the Food
12 and Drug Administration;

13 (ii) the impact of such provision on
14 innovation, as well as research and devel-
15 opment in the nonprescription drug mar-
16 ket;

17 (iii) the impact of such provision on
18 competition in the nonprescription drug
19 market;

20 (iv) the impact of such provision on
21 consumer access to nonprescription drug
22 products;

23 (v) the impact of such provision on
24 the prices of nonprescription drug prod-
25 ucts; and

1 (vi) whether the administrative orders
2 initiated by requestors under such section
3 505G have been sufficient to encourage the
4 development of nonprescription drug prod-
5 ucts that would likely not be otherwise de-
6 veloped, or developed in as timely a man-
7 ner; and

8 (E) whether the administrative orders ini-
9 tiated by requestors under such section 505G
10 have been sufficient incentive to encourage in-
11 novation in the nonprescription drug market;
12 and

13 (2) an analysis of the impact of exclusivity
14 under such section 586C for sunscreen ingredients,
15 including—

16 (A) the number of sunscreen ingredients
17 that were granted exclusivity and the specific
18 ingredient that was determined to be generally
19 recognized as safe and effective;

20 (B) whether, and to what extent, the exclu-
21 sivity impacted the requestor's or sponsor's de-
22 cision to develop the sunscreen ingredient;

23 (C) whether, and to what extent, the sun-
24 screen ingredient granted exclusivity had pre-

1 viously been available outside of the United
2 States;

3 (D) an analysis of the implementation of
4 the exclusivity provision in such section 586C,
5 including—

6 (i) the resources used by the Food
7 and Drug Administration;

8 (ii) the impact of such provision on
9 innovation, as well as research and devel-
10 opment in the sunscreen market;

11 (iii) the impact of such provision on
12 competition in the sunscreen market;

13 (iv) the impact of such provision on
14 consumer access to sunscreen products;

15 (v) the impact of such provision on
16 the prices of sunscreen products; and

17 (vi) whether the administrative orders
18 initiated by requestors under such section
19 505G have been utilized by sunscreen in-
20 gredient sponsors and whether such proc-
21 ess has been sufficient to encourage the
22 development of sunscreen ingredients that
23 would likely not be otherwise developed, or
24 developed in as timely a manner; and

1 (E) whether the administrative orders ini-
 2 tiated by requestors under such section 586C
 3 have been sufficient incentive to encourage in-
 4 novation in the sunscreen market.

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

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

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

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

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

16 **SEC. 102. MISBRANDING.**

17 Section 502 of the Federal Food, Drug, and Cosmetic
 18 Act (21 U.S.C. 352) is amended by adding at the end the
 19 following:

20 “(ee) If it is a nonprescription drug that is subject
 21 to section 505G, is not the subject of an application ap-
 22 proved under section 505, and does not comply with the
 23 requirements under section 505G.

24 “(ff) If it is a drug and it was manufactured, pre-
 25 pared, propagated, compounded, or processed in a facility

1 for which fees have not been paid as required by section
2 744M.”.

3 **SEC. 103. DRUGS EXCLUDED FROM THE OVER-THE-**
4 **COUNTER DRUG REVIEW.**

5 (a) IN GENERAL.—Nothing in this Act (or the
6 amendments made by this Act) shall apply to any non-
7 prescription drug (as defined in section 505G(q) of the
8 Federal Food, Drug, and Cosmetic Act, as added by sec-
9 tion 101 of this Act) which was excluded by the Food and
10 Drug Administration from the Over-the-Counter Drug Re-
11 view in accordance with the paragraph numbered 25 on
12 page 9466 of volume 37 of the Federal Register, published
13 on May 11, 1972.

14 (b) RULE OF CONSTRUCTION.—Nothing in this sec-
15 tion shall be construed to preclude or limit the applica-
16 bility of any other provision of the Federal Food, Drug,
17 and Cosmetic Act (21 U.S.C. 301 et seq.).

18 **SEC. 104. TREATMENT OF SUNSCREEN INNOVATION ACT.**

19 (a) REVIEW OF NONPRESCRIPTION SUNSCREEN AC-
20 TIVE INGREDIENTS.—

21 (1) APPLICABILITY OF SECTION 505G FOR
22 PENDING SUBMISSIONS.—

23 (A) IN GENERAL.—A sponsor of a non-
24 prescription sunscreen active ingredient or com-
25 bination of nonprescription sunscreen active in-

1 gredients that, as of the date of enactment of
2 this Act, is subject to a proposed sunscreen
3 order under section 586C of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 360fff–3)
5 may elect, by means of giving written notifica-
6 tion to the Secretary of Health and Human
7 Services within 180 calendar days of the enact-
8 ment of this Act, to transition into the review
9 of such ingredient or combination of ingredients
10 pursuant to the process set out in section 505G
11 of the Federal Food, Drug, and Cosmetic Act,
12 as added by section 101 of this Act.

13 (B) ELECTION EXERCISED.—Upon receipt
14 by the Secretary of Health and Human Services
15 of a timely notification under subparagraph
16 (A)—

17 (i) the proposed sunscreen order in-
18 volved is deemed to be a request for an
19 order under subsection (b) of section 505G
20 of the Federal Food, Drug, and Cosmetic
21 Act, as added by section 101 of this Act;
22 and

23 (ii) such order is deemed to have been
24 accepted for filing under subsection
25 (b)(6)(A)(i) of such section 505G.

(C) ELECTION NOT EXERCISED.—If a notification under subparagraph (A) is not received by the Secretary of Health and Human Services within 180 calendar days of the date of enactment of this Act, the review of the proposed sunscreen order described in subparagraph (A)—

(i) shall continue under section 586C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3); and

(ii) shall not be eligible for review under section 505G, added by section 101 of this Act.

(2) DEFINITIONS.—In this subsection, the terms “sponsor”, “nonprescription”, “sunscreen active ingredient”, and “proposed sunscreen order” have the meanings given to those terms in section 586 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff).

(b) AMENDMENTS TO SUNSCREEN PROVISIONS.—

(1) FINAL SUNSCREEN ORDERS.—Paragraph (3) of section 586C(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3(e)) is amended to read as follows:

1 “(3) RELATIONSHIP TO ORDERS UNDER SEC-
2 TION 505G.—A final sunscreen order shall be deemed
3 to be a final order under section 505G.”.

4 (2) MEETINGS.—Paragraph (7) of section
5 586C(b) of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 360fff–3(b)) is amended—

7 (A) by striking “A sponsor may request”
8 and inserting the following:

9 “(A) IN GENERAL.—A sponsor may re-
10 quest”; and

11 (B) by adding at the end the following:

12 “(B) CONFIDENTIAL MEETINGS.—A spon-
13 sor may request one or more confidential meet-
14 ings with respect to a proposed sunscreen order,
15 including a letter deemed to be a proposed sun-
16 screen order under paragraph (3), to discuss
17 matters relating to data requirements to sup-
18 port a general recognition of safety and effec-
19 tiveness involving confidential information and
20 public information related to such proposed
21 sunscreen order, as appropriate. The Secretary
22 shall convene a confidential meeting with such
23 sponsor in a reasonable time period. If a spon-
24 sor requests more than one confidential meeting
25 for the same proposed sunscreen order, the Sec-

1 retary may refuse to grant an additional con-
 2 fidential meeting request if the Secretary deter-
 3 mines that such additional confidential meeting
 4 is not reasonably necessary for the sponsor to
 5 advance its proposed sunscreen order, or if the
 6 request for a confidential meeting fails to in-
 7 clude sufficient information upon which to base
 8 a substantive discussion. The Secretary shall
 9 publish a post-meeting summary of each con-
 10 fidential meeting under this subparagraph that
 11 does not disclose confidential commercial infor-
 12 mation or trade secrets. This subparagraph
 13 does not authorize the disclosure of confidential
 14 commercial information or trade secrets subject
 15 to 552(b)(4) of title 5, United States Code, or
 16 section 1905 of title 18, United States Code.”.

17 (3) EXCLUSIVITY.—Section 586C of the Fed-
 18 eral Food, Drug, and Cosmetic Act (21 U.S.C.
 19 360fff–3) is amended by adding at the end the fol-
 20 lowing:

21 “(f) EXCLUSIVITY.—

22 “(1) IN GENERAL.—A final sunscreen order
 23 shall have the effect of authorizing solely the order
 24 requestor (or the licensees, assignees, or successors
 25 in interest of such requestor with respect to the sub-

1 ject of such request and listed under paragraph (5))
2 for a period of 18 months, to market a sunscreen in-
3 gredient under this section incorporating changes
4 described in paragraph (2) subject to the limitations
5 under paragraph (4), beginning on the date the re-
6 questor (or any licensees, assignees, or successors in
7 interest of such requestor with respect to the subject
8 of such request and listed under paragraph (5)) may
9 lawfully market such sunscreen ingredient pursuant
10 to the order.

11 “(2) CHANGES DESCRIBED.—A change de-
12 scribed in this paragraph is a change subject to an
13 order specified in paragraph (1) that permits a sun-
14 screen to contain an active sunscreen ingredient not
15 previously incorporated in a marketed sunscreen list-
16 ed in paragraph (3).

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

20 “(A) marketed in accordance with a final
21 monograph for sunscreen drug products set
22 forth at part 352 of title 21, Code of Federal
23 Regulations (as published at 64 Fed. Reg.
24 27687); or

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

3 “(4) LIMITATIONS ON EXCLUSIVITY.—Only one
4 18-month period may be granted per ingredient
5 under paragraph (1).

6 “(5) LISTING OF LICENSEES, ASSIGNEES, OR
7 SUCCESSORS IN INTEREST.—Requestors shall submit
8 to the Secretary at the time when a drug subject to
9 such request is introduced or delivered for introduc-
10 tion into interstate commerce, a list of licensees, as-
11 signees, or successors in interest under paragraph
12 (1).”.

13 (4) SUNSET PROVISION.—Subchapter I of chap-
14 ter V of the Federal Food, Drug, and Cosmetic Act
15 (21 U.S.C. 360fff et seq.) is amended by adding at
16 the end the following:

17 **“SEC. 586H. SUNSET.**

18 “‘This subchapter shall cease to be effective at the end
19 of fiscal year 2022.’”.

20 (5) TREATMENT OF FINAL SUNSCREEN
21 ORDER.—The Federal Food, Drug, and Cosmetic
22 Act is amended by striking section 586E of such Act
23 (21 U.S.C. 360fff–5).

24 (c) TREATMENT OF AUTHORITY REGARDING FINAL-
25 IZATION OF SUNSCREEN MONOGRAPH.—

1 (1) IN GENERAL.—

2 (A) REVISION OF FINAL SUNSCREEN
3 ORDER.—The Secretary of Health and Human
4 Services (referred to in this subsection as the
5 “Secretary”) shall amend and revise the final
6 administrative order concerning nonprescription
7 sunscreen (referred to in this subsection as the
8 “sunscreen order”) for which the content, prior
9 to the date of enactment of this Act, was rep-
10 resented by the final monograph for sunscreen
11 drug products set forth in part 352 of title 21,
12 Code of Federal Regulations (as in effect on
13 May 21, 1999).

14 (B) ISSUANCE OF REVISED SUNSCREEN
15 ORDER; EFFECTIVE DATE.—A revised sunscreen
16 order described in subparagraph (A) shall be—

17 (i) issued in accordance with the pro-
18 cedures described in section 505G(b)(2) of
19 the Federal Food, Drug, and Cosmetic
20 Act;

21 (ii) issued in proposed form not later
22 than 18 months after the date of enact-
23 ment of this Act; and

1 (iii) issued by the Secretary at least 1
2 year prior to the effective date of the re-
3 vised order.

4 (2) REPORTS.—If a revised sunscreen order
5 issued under paragraph (1) does not include provi-
6 sions related to the effectiveness of various sun pro-
7 tection factor levels, and does not address all dosage
8 forms known to the Secretary to be used in sun-
9 screens marketed in the United States without a
10 new drug application approved under section 505 of
11 the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 355), the Secretary shall submit a report to
13 the Committee on Energy and Commerce of the
14 House of Representatives and the Committee on
15 Health, Education, Labor, and Pensions of the Sen-
16 ate on the rationale for omission of such provisions
17 from such order, and a plan and timeline to compile
18 any information necessary to address such provisions
19 through such order.

20 (d) TREATMENT OF NON-SUNSCREEN TIME AND EX-
21 TENT APPLICATIONS.—

22 (1) IN GENERAL.—Any application described in
23 section 586F of the Federal Food, Drug, and Cos-
24 metic Act (21 U.S.C. 360fff–6) that was submitted
25 to the Secretary pursuant to section 330.14 of title

1 21, Code of Federal Regulations, as such provisions
 2 were in effect immediately prior to the date of enact-
 3 ment date of this Act, shall be extinguished as of
 4 such date of enactment, subject to paragraph (2).

5 (2) ORDER REQUEST.—Nothing in paragraph
 6 (1) precludes the submission of an order request
 7 under section 505G(b) of the Federal Food, Drug,
 8 and Cosmetic Act, as added by section 101 of this
 9 Act, with respect to a drug that was the subject of
 10 an application extinguished under paragraph (1).

11 **SEC. 105. ANNUAL UPDATE TO CONGRESS ON APPRO-**
 12 **PRIATE PEDIATRIC INDICATION FOR CER-**
 13 **TAIN OTC COUGH AND COLD DRUGS.**

14 (a) IN GENERAL.—Subject to subsection (c), the Sec-
 15 retary of Health and Human Services shall, beginning not
 16 later than 1 year after the date of enactment of this Act,
 17 annually submit to the Committee on Energy and Com-
 18 merce of the House of Representatives and the Committee
 19 on Health, Education, Labor, and Pensions of the Senate
 20 a letter describing the progress of the Food and Drug Ad-
 21 ministration—

22 (1) in evaluating the cough and cold monograph
 23 described in subsection (b) with respect to children
 24 under age 6; and

1 (2) as appropriate, revising such cough and cold
2 monograph to address such children through the
3 order process under section 505G(b) of the Federal
4 Food, Drug, and Cosmetic Act, as added by section
5 101 of this Act.

6 (b) COUGH AND COLD MONOGRAPH DESCRIBED.—
7 The cough and cold monograph described in this sub-
8 section consists of the conditions under which nonprescrip-
9 tion drugs containing antitussive, expectorant, nasal de-
10 congestant, or antihistamine active ingredients (or com-
11 binations thereof) are generally recognized as safe and ef-
12 fective, as specified in part 341 of title 21, Code of Federal
13 Regulations (as in effect immediately prior to the date of
14 enactment of this Act), and included in an order deemed
15 to be established under section 505G(b) of the Federal
16 Food, Drug, and Cosmetic Act, as added by section 101
17 of this Act.

18 (c) DURATION OF AUTHORITY.—The requirement
19 under subsection (a) shall terminate as of the date of a
20 letter submitted by the Secretary of Health and Human
21 Services pursuant to such subsection in which the Sec-
22 retary indicates that the Food and Drug Administration
23 has completed its evaluation and revised, in a final order,
24 as applicable, the cough and cold monograph as described
25 in subsection (a)(2).

1 **SEC. 106. TECHNICAL CORRECTIONS.**

2 (a) IMPORTS AND EXPORTS.—Section
3 801(e)(4)(E)(iii) of the Federal Food, Drug, and Cosmetic
4 Act (21 U.S.C. 381(e)(4)(E)(iii)) is amended by striking
5 “subparagraph” each place such term appears and insert-
6 ing “paragraph”.

7 (b) FDA REAUTHORIZATION ACT OF 2017.—

8 (1) IN GENERAL.—Section 905(b)(4) of the
9 FDA Reauthorization Act of 2017 (Public Law 115–
10 52) is amended by striking “Section 744H(e)(2)(B)”
11 and inserting “Section 744H(f)(2)(B)”.

12 (2) EFFECTIVE DATE.—The amendment made
13 by paragraph (1) shall take effect as of the enact-
14 ment of the FDA Reauthorization Act of 2017
15 (Public Law 115–52).

16 **TITLE II—USER FEES**

17 **SEC. 201. SHORT TITLE; FINDING.**

18 (a) SHORT TITLE.—This title may be cited as the
19 “Over-the-Counter Monograph User Fee Act of 2019”.

20 (b) FINDING.—The Congress finds that the fees au-
21 thorized by the amendments made in this title will be dedi-
22 cated to OTC monograph drug activities, as set forth in
23 the goals identified for purposes of part 10 of subchapter
24 C of chapter VII of the Federal Food, Drug, and Cosmetic
25 Act, in the letters from the Secretary of Health and
26 Human Services to the Chairman of the Committee on

1 Health, Education, Labor, and Pensions of the Senate and
 2 the Chairman of the Committee on Energy and Commerce
 3 of the House of Representatives, as set forth in the Con-
 4 gressional Record.

5 **SEC. 202. FEES RELATING TO OVER-THE-COUNTER DRUGS.**

6 Subchapter C of chapter VII of the Federal Food,
 7 Drug, and Cosmetic Act (21 U.S.C. 379f et seq.) is
 8 amended by inserting after part 9 the following:

9 **“PART 10—FEES RELATING TO OVER-THE-**
 10 **COUNTER DRUGS**

11 **“SEC. 744L. DEFINITIONS.**

12 “In this part:

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

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

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

21 “(2) The term ‘contract manufacturing organi-
 22 zation facility’ means an OTC monograph drug facil-
 23 ity where neither the owner of such manufacturing
 24 facility nor any affiliate of such owner or facility
 25 sells the OTC monograph drug produced at such fa-

1 cility directly to wholesalers, retailers, or consumers
2 in the United States.

3 “(3) The term ‘costs of resources allocated for
4 OTC monograph drug activities’ means the expenses
5 in connection with OTC monograph drug activities
6 for—

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

13 “(B) management of information, and the
14 acquisition, maintenance, and repair of com-
15 puter resources;

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

21 “(D) collecting fees under section 744M
22 and accounting for resources allocated for OTC
23 monograph drug activities.

24 “(4) The term ‘FDA establishment identifier’ is
25 the unique number automatically generated by Food

1 and Drug Administration’s Field Accomplishments
2 and Compliance Tracking System (FACTS) (or any
3 successor system).

4 “(5) The term ‘OTC monograph drug’ means a
5 nonprescription drug without an approved new drug
6 application which is governed by the provisions of
7 section 505G.

8 “(6) The term ‘OTC monograph drug activities’
9 means activities of the Secretary associated with
10 OTC monograph drugs and inspection of facilities
11 associated with such products, including the fol-
12 lowing activities:

13 “(A) The activities necessary for review
14 and evaluation of OTC monographs and OTC
15 monograph order requests, including—

16 “(i) orders proposing or finalizing ap-
17 plicable conditions of use for OTC mono-
18 graph drugs;

19 “(ii) orders affecting status regarding
20 general recognition of safety and effective-
21 ness of an OTC monograph ingredient or
22 combination of ingredients under specified
23 conditions of use;

1 “(iii) all OTC monograph drug devel-
2 opment and review activities, including
3 intra-agency collaboration;

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

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

10 “(vi) meetings referred to in section
11 505G(i);

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

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

17 “(B) Inspections related to OTC mono-
18 graph drugs.

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

22 “(D) Safety activities with respect to OTC
23 monograph drugs, including—

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

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

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

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

14 “(7) The term ‘OTC monograph order request’
15 means a request for an order submitted under sec-
16 tion 505G(b)(5).

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

21 “(9)(A) The term ‘Tier 2 OTC monograph
22 order request’ means, subject to subparagraph (B),
23 an OTC monograph order request for—

1 “(i) the reordering of existing information
2 in the drug facts label of an OTC monograph
3 drug;

4 “(ii) the addition of information to the
5 other information section of the drug facts label
6 of an OTC monograph drug, as limited by sec-
7 tion 201.66(c)(7) of title 21, Code of Federal
8 Regulations (or any successor regulations);

9 “(iii) modification to the directions for use
10 section of the drug facts label of an OTC mono-
11 graph drug, if such changes conform to changes
12 made pursuant to section 505G(c)(3)(A);

13 “(iv) the standardization of the concentra-
14 tion or dose of a specific finalized ingredient
15 within a particular finalized monograph;

16 “(v) a change to ingredient nomenclature
17 to align with nomenclature of a standards-set-
18 ting organization; or

19 “(vi) addition of an interchangeable term
20 in accordance with section 330.1 of title 21,
21 Code of Federal Regulations (or any successor
22 regulations).

23 “(B) The Secretary may, based on program im-
24 plementation experience or other factors found ap-
25 propriate by the Secretary, characterize any OTC

1 monograph order request as a Tier 2 OTC mono-
2 graph order request (including recharacterizing a re-
3 quest from Tier 1 to Tier 2) and publish such deter-
4 mination in a proposed order issued pursuant to sec-
5 tion 505G.

6 “(10)(A) The term ‘OTC monograph drug facil-
7 ity’ means a foreign or domestic business or other
8 entity that—

9 “(i) is—

10 “(I) under one management, either di-
11 rect or indirect; and

12 “(II) at one geographic location or ad-
13 dress engaged in manufacturing or proc-
14 essing the finished dosage form of an OTC
15 monograph drug;

16 “(ii) includes a finished dosage form man-
17 ufacturer facility in a contractual relationship
18 with the sponsor of one or more OTC mono-
19 graph drugs to manufacture or process such
20 drugs; and

21 “(iii) does not include a business or other
22 entity whose only manufacturing or processing
23 activities are one or more of the following: pro-
24 duction of clinical research supplies, testing, or
25 placement of outer packaging on packages con-

1 taining multiple products, for such purposes as
2 creating multipacks, when each monograph
3 drug product contained within the overpack-
4 aging is already in a final packaged form prior
5 to placement in the outer overpackaging.

6 “(B) For purposes of subparagraph (A)(i)(II),
7 separate buildings or locations within close proximity
8 are considered to be at one geographic location or
9 address if the activities conducted in such buildings
10 or locations are—

11 “(i) closely related to the same business
12 enterprise;

13 “(ii) under the supervision of the same
14 local management; and

15 “(iii) under a single FDA establishment
16 identifier and capable of being inspected by the
17 Food and Drug Administration during a single
18 inspection.

19 “(C) If a business or other entity would meet
20 criteria specified in subparagraph (A), but for being
21 under multiple management, the business or other
22 entity is deemed to constitute multiple facilities, one
23 per management entity, for purposes of this para-
24 graph.

1 “(11) The term ‘OTC monograph drug meet-
 2 ing’ means any meeting regarding the content of a
 3 proposed OTC monograph order request.

4 “(12) The term ‘person’ includes an affiliate of
 5 a person.

6 “(13) The terms ‘requestor’ and ‘sponsor’ have
 7 the meanings given such terms in section 505G.

8 **“SEC. 744M. AUTHORITY TO ASSESS AND USE OTC MONO-**
 9 **GRAPH FEES.**

10 “(a) TYPES OF FEES.—Beginning with fiscal year
 11 2021, the Secretary shall assess and collect fees in accord-
 12 ance with this section as follows:

13 “(1) FACILITY FEE.—

14 “(A) IN GENERAL.—Each person that
 15 owns a facility identified as an OTC monograph
 16 drug facility on December 31 of the fiscal year
 17 or at any time during the preceding 12-month
 18 period shall be assessed an annual fee for each
 19 such facility as determined under subsection
 20 (c).

21 “(B) EXCEPTIONS.—

22 “(i) FACILITIES THAT CEASE ACTIVI-
 23 TIES.—A fee shall not be assessed under
 24 subparagraph (A) if the identified OTC
 25 monograph drug facility—

1 “(I) has ceased all activities re-
2 lated to OTC monograph drugs prior
3 to December 31 of the year imme-
4 diately preceding the applicable fiscal
5 year; and

6 “(II) has updated its registration
7 to reflect such change under the re-
8 quirements for drug establishment
9 registration set forth in section 510.

10 “(ii) CONTRACT MANUFACTURING OR-
11 GANIZATIONS.—The amount of the fee for
12 a contract manufacturing organization fa-
13 cility shall be equal to two-thirds of the
14 amount of the fee for an OTC monograph
15 drug facility that is not a contract manu-
16 facturing organization facility.

17 “(C) AMOUNT.—The amount of fees estab-
18 lished under subparagraph (A) shall be estab-
19 lished under subsection (c).

20 “(D) DUE DATE.—

21 “(i) FOR FIRST PROGRAM YEAR.—For
22 fiscal year 2021, the facility fees required
23 under subparagraph (A) shall be due on
24 the later of—

1 “(I) the first business day of
2 June of 2020; or

3 “(II) 45 calendar days after pub-
4 lication of the Federal Register notice
5 provided for under subsection
6 (c)(4)(A).

7 “(ii) SUBSEQUENT FISCAL YEARS.—
8 For each fiscal year after fiscal year 2021,
9 the facility fees required under subpara-
10 graph (A) shall be due on the later of—

11 “(I) the first business day of
12 June of such year; or

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

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

20 “(A) IN GENERAL.—Each person that sub-
21 mits an OTC monograph order request shall be
22 subject to a fee for an OTC monograph order
23 request. The amount of such fee shall be—

24 “(i) for a Tier 1 OTC monograph
25 order request, \$500,000, adjusted for in-

1 flation for the fiscal year (as determined
2 under subsection (c)(1)(B)); and

3 “(ii) for a Tier 2 OTC monograph
4 order request, \$100,000, adjusted for in-
5 flation for the fiscal year (as determined
6 under subsection (c)(1)(B)).

7 “(B) DUE DATE.—The OTC monograph
8 order request fees required under subparagraph
9 (A) shall be due on the date of submission of
10 the OTC monograph order request.

11 “(C) EXCEPTION FOR CERTAIN SAFETY
12 CHANGES.—A person who is named as the re-
13 questor in an OTC monograph order shall not
14 be subject to a fee under subparagraph (A) if
15 the Secretary finds that the OTC monograph
16 order request seeks to change the drug facts la-
17 beling of an OTC monograph drug in a way
18 that would add to or strengthen—

19 “(i) a contraindication, warning, or
20 precaution;

21 “(ii) a statement about risk associated
22 with misuse or abuse; or

23 “(iii) an instruction about dosage and
24 administration that is intended to increase
25 the safe use of the OTC monograph drug.

1 “(D) REFUND OF FEE IF ORDER REQUEST
2 IS RECATEGORIZED AS A TIER 2 OTC MONO-
3 GRAPH ORDER REQUEST.—If the Secretary de-
4 termines that an OTC monograph request ini-
5 tially characterized as Tier 1 shall be re-charac-
6 terized as a Tier 2 OTC monograph order re-
7 quest, and the requestor has paid a Tier 1 fee
8 in accordance with subparagraph (A)(i), the
9 Secretary shall refund the requestor the dif-
10 ference between the Tier 1 and Tier 2 fees de-
11 termined under subparagraphs (A)(i) and
12 (A)(ii), respectively.

13 “(E) REFUND OF FEE IF ORDER REQUEST
14 REFUSED FOR FILING OR WITHDRAWN BEFORE
15 FILING.—The Secretary shall refund 75 percent
16 of the fee paid under subparagraph (B) for any
17 order request which is refused for filing or was
18 withdrawn before being accepted or refused for
19 filing.

20 “(F) FEES FOR ORDER REQUESTS PRE-
21 VIOUSLY REFUSED FOR FILING OR WITHDRAWN
22 BEFORE FILING.—An OTC monograph order
23 request that was submitted but was refused for
24 filing, or was withdrawn before being accepted
25 or refused for filing, shall be subject to the full

1 fee under subparagraph (A) upon being resub-
 2 mitted or filed over protest.

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

14 “(3) REFUNDS.—

15 “(A) IN GENERAL.—Other than refunds
 16 provided pursuant to any of subparagraphs (D)
 17 through (G) of paragraph (2), the Secretary
 18 shall not refund any fee paid under paragraph
 19 (1) except as provided in subparagraph (B).

20 “(B) DISPUTES CONCERNING FEES.—To
 21 qualify for the return of a fee claimed to have
 22 been paid in error under paragraph (1) or (2),
 23 a person shall submit to the Secretary a written
 24 request justifying such return within 180 cal-
 25 endar days after such fee was paid.

1 “(4) NOTICE.—Within the timeframe specified
 2 in subsection (c), the Secretary shall publish in the
 3 Federal Register the amount of the fees under para-
 4 graph (1) for such fiscal year.

5 “(b) FEE REVENUE AMOUNTS.—

6 “(1) FISCAL YEAR 2021.—For fiscal year 2021,
 7 fees under subsection (a)(1) shall be established to
 8 generate a total facility fee revenue amount equal to
 9 the sum of—

10 “(A) the annual base revenue for fiscal
 11 year 2021 (as determined under paragraph
 12 (3));

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

17 “(C) additional direct cost adjustments (as
 18 determined under subsection (c)(3)).

19 “(2) SUBSEQUENT FISCAL YEARS.—For each of
 20 the fiscal years 2022 through 2025, fees under sub-
 21 section (a)(1) shall be established to generate a total
 22 facility fee revenue amount equal to the sum of—

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

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

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

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

10 “(E) additional dollar amounts for each
 11 fiscal year as follows:

12 “(i) \$7,000,000 for fiscal year 2022.

13 “(ii) \$6,000,000 for fiscal year 2023.

14 “(iii) \$7,000,000 for fiscal year 2024.

15 “(iv) \$3,000,000 for fiscal year 2025.

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

20 “(A) for fiscal year 2021, \$8,000,000; and

21 “(B) for fiscal years 2022 through 2025,
 22 the dollar amount of the total revenue amount
 23 established under this subsection for the pre-
 24 vious fiscal year, not including any adjustments
 25 made under subsection (c)(2) or (c)(3).

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

2 “(1) INFLATION ADJUSTMENT.—

3 “(A) IN GENERAL.—For purposes of sub-
4 section (b)(2)(B), the dollar amount of the in-
5 flation adjustment to the annual base revenue
6 for fiscal year 2022 and each subsequent fiscal
7 year shall be equal to the product of—

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

10 “(ii) the inflation adjustment percent-
11 age under subparagraph (C).

12 “(B) OTC MONOGRAPH ORDER REQUEST
13 FEES.—For purposes of subsection (a)(2), the
14 dollar amount of the inflation adjustment to the
15 fee for OTC monograph order requests for fis-
16 cal year 2022 and each subsequent fiscal year
17 shall be equal to the product of—

18 “(i) the applicable fee under sub-
19 section (a)(2) for the preceding fiscal year;
20 and

21 “(ii) the inflation adjustment percent-
22 age under subparagraph (C).

23 “(C) INFLATION ADJUSTMENT PERCENT-
24 AGE.—The inflation adjustment percentage

1 under this subparagraph for a fiscal year is
2 equal to—

3 “(i) for each of fiscal years 2022 and
4 2023, the average annual percent change
5 that occurred in the Consumer Price Index
6 for urban consumers (Washington-Balti-
7 more, DC–MD–VA–WV; Not Seasonally
8 Adjusted; All items; Annual Index) for the
9 first 3 years of the preceding 4 years of
10 available data; and

11 “(ii) for each of fiscal years 2024 and
12 2025, the sum of—

13 “(I) the average annual percent
14 change in the cost, per full-time equiv-
15 alent position of the Food and Drug
16 Administration, of all personnel com-
17 pensation and benefits paid with re-
18 spect to such positions for the first 3
19 years of the preceding 4 fiscal years,
20 multiplied by the proportion of per-
21 sonnel compensation and benefits
22 costs to total costs of OTC mono-
23 graph drug activities for the first 3
24 years of the preceding 4 fiscal years;
25 and

1 “(II) the average annual percent
2 change that occurred in the Consumer
3 Price Index for urban consumers
4 (Washington-Baltimore, DC-MD-VA-
5 WV; Not Seasonally Adjusted; All
6 items; Annual Index) for the first 3
7 years of the preceding 4 years of
8 available data multiplied by the pro-
9 portion of all costs other than per-
10 sonnel compensation and benefits
11 costs to total costs of OTC mono-
12 graph drug activities for the first 3
13 years of the preceding 4 fiscal years.

14 “(2) OPERATING RESERVE ADJUSTMENT.—

15 “(A) IN GENERAL.—For fiscal year 2021
16 and subsequent fiscal years, for purposes of
17 subsections (b)(1)(B) and (b)(2)(C), the Sec-
18 retary may, in addition to adjustments under
19 paragraph (1), further increase the fee revenue
20 and fees if such an adjustment is necessary to
21 provide operating reserves of carryover user
22 fees for OTC monograph drug activities for not
23 more than the number of weeks specified in
24 subparagraph (B).

1 “(B) NUMBER OF WEEKS.—The number of
2 weeks specified in this subparagraph is—

3 “(i) 3 weeks for fiscal year 2021;

4 “(ii) 7 weeks for fiscal year 2022;

5 “(iii) 10 weeks for fiscal year 2023;

6 “(iv) 10 weeks for fiscal year 2024;

7 and

8 “(v) 10 weeks for fiscal year 2025.

9 “(C) DECREASE.—If the Secretary has
10 carryover balances for such process in excess of
11 10 weeks of the operating reserves referred to
12 in subparagraph (A), the Secretary shall de-
13 crease the fee revenue and fees referred to in
14 such subparagraph to provide for not more than
15 10 weeks of such operating reserves.

16 “(D) RATIONALE FOR ADJUSTMENT.—If
17 an adjustment under this paragraph is made,
18 the rationale for the amount of the increase or
19 decrease (as applicable) in fee revenue and fees
20 shall be contained in the annual Federal Reg-
21 ister notice under paragraph (4) establishing
22 fee revenue and fees for the fiscal year involved.

23 “(3) ADDITIONAL DIRECT COST ADJUST-
24 MENT.—The Secretary shall, in addition to adjust-
25 ments under paragraphs (1) and (2), further in-

crease the fee revenue and fees for purposes of subsection (b)(2)(D) by an amount equal to—

“(A) \$14,000,000 for fiscal year 2021;

“(B) \$7,000,000 for fiscal year 2022;

“(C) \$4,000,000 for fiscal year 2023;

“(D) \$3,000,000 for fiscal year 2024; and

“(E) \$3,000,000 for fiscal year 2025.

“(4) ANNUAL FEE SETTING.—

“(A) FISCAL YEAR 2021.—The Secretary shall, not later than the second Monday in March of 2020—

“(i) establish OTC monograph drug facility fees for fiscal year 2021 under subsection (a), based on the revenue amount for such year under subsection (b) and the adjustments provided under this subsection; and

“(ii) publish fee revenue, facility fees, and OTC monograph order requests in the Federal Register.

“(B) SUBSEQUENT FISCAL YEARS.—The Secretary shall, for each fiscal year that begins after September 30, 2021, not later than the second Monday in March that precedes such fiscal year—

1 “(i) establish for such fiscal year,
2 based on the revenue amounts under sub-
3 section (b) and the adjustments provided
4 under this subsection—

5 “(I) OTC monograph drug facil-
6 ity fees under subsection (a)(1); and

7 “(II) OTC monograph order re-
8 quest fees under subsection (a)(2);
9 and

10 “(ii) publish such fee revenue
11 amounts, facility fees, and OTC mono-
12 graph order request fees in the Federal
13 Register.

14 “(d) IDENTIFICATION OF FACILITIES.—Each person
15 that owns an OTC monograph drug facility shall submit
16 to the Secretary the information required under this sub-
17 section each year. Such information shall, for each fiscal
18 year—

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

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

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

1 “(1) OTC MONOGRAPH DRUG FACILITY FEE.—

2 “(A) IN GENERAL.—Failure to pay the fee
3 under subsection (a)(1) within 20 calendar days
4 of the due date as specified in subparagraph
5 (D) of such subsection shall result in the fol-
6 lowing:

7 “(i) The Secretary shall place the fa-
8 cility on a publicly available arrears list.

9 “(ii) All OTC monograph drugs man-
10 ufactured in such a facility or containing
11 an ingredient manufactured in such a facil-
12 ity shall be deemed misbranded under sec-
13 tion 502(ff).

14 “(B) APPLICATION OF PENALTIES.—The
15 penalties under this paragraph shall apply until
16 the fee established by subsection (a)(1) is paid.

17 “(2) ORDER REQUESTS.—An OTC monograph
18 order request submitted by a person subject to fees
19 under subsection (a) shall be considered incomplete
20 and shall not be accepted for filing by the Secretary
21 until all fees owed by such person under this section
22 have been paid.

23 “(3) MEETINGS.—A person subject to fees
24 under this section shall be considered ineligible for

1 OTC monograph drug meetings until all such fees
 2 owed by such person have been paid.

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

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

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

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

1 “(B) USE OF FEES AND LIMITATION.—

2 The fees authorized by this section shall be
3 available to defray increases in the costs of the
4 resources allocated for OTC monograph drug
5 activities (including increases in such costs for
6 an additional number of full-time equivalent po-
7 sitions in the Department of Health and
8 Human Services to be engaged in such activi-
9 ties), only if the Secretary allocates for such
10 purpose an amount for such fiscal year (exclud-
11 ing amounts from fees collected under this sec-
12 tion) no less than \$12,000,000, multiplied by
13 the adjustment factor applicable to the fiscal
14 year involved under subsection (c)(1).

15 “(C) COMPLIANCE.—The Secretary shall

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

22 “(D) PROVISION FOR EARLY PAYMENTS IN

23 SUBSEQUENT YEARS.—Payment of fees author-
24 ized under this section for a fiscal year (after
25 fiscal year 2021), prior to the due date for such

1 fees, may be accepted by the Secretary in ac-
 2 cordance with authority provided in advance in
 3 a prior year appropriations Act.

4 “(3) AUTHORIZATION OF APPROPRIATIONS.—

5 For each of the fiscal years 2021 through 2025,
 6 there is authorized to be appropriated for fees under
 7 this section an amount equal to the total amount of
 8 fees assessed for such fiscal year under this section.

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

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

22 **“SEC. 744N. REAUTHORIZATION; REPORTING REQUIRE-**
 23 **MENTS.**

24 “(a) PERFORMANCE REPORT.—Beginning with fiscal
 25 year 2021, and not later than 120 calendar days after the

1 end of each fiscal year thereafter for which fees are col-
2 lected under this part, the Secretary shall prepare and
3 submit to the Committee on Energy and Commerce of the
4 House of Representatives and the Committee on Health,
5 Education, Labor, and Pensions of the Senate a report
6 concerning the progress of the Food and Drug Adminis-
7 tration in achieving the goals identified in the letters de-
8 scribed in section 201(b) of the Over-the-Counter Mono-
9 graph Safety, Innovation, and Reform Act of 2019 during
10 such fiscal year and the future plans of the Food and
11 Drug Administration for meeting such goals.

12 “(b) FISCAL REPORT.—Not later than 120 calendar
13 days after the end of fiscal year 2021 and each subsequent
14 fiscal year for which fees are collected under this part,
15 the Secretary shall prepare and submit to the Committee
16 on Energy and Commerce of the House of Representatives
17 and the Committee on Health, Education, Labor, and
18 Pensions of the Senate a report on the implementation
19 of the authority for such fees during such fiscal year and
20 the use, by the Food and Drug Administration, of the fees
21 collected for such fiscal year.

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

1 “(d) REAUTHORIZATION.—

2 “(1) CONSULTATION.—In developing rec-
3 ommendations to present to the Congress with re-
4 spect to the goals described in subsection (a), and
5 plans for meeting the goals, for OTC monograph
6 drug activities for the first 5 fiscal years after fiscal
7 year 2025, and for the reauthorization of this part
8 for such fiscal years, the Secretary shall consult
9 with—

10 “(A) the Committee on Energy and Com-
11 merce of the House of Representatives;

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

14 “(C) scientific and academic experts;

15 “(D) health care professionals;

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

18 “(F) the regulated industry.

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

22 “(A) present the recommendations devel-
23 oped under paragraph (1) to the congressional
24 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, 2025, the Secretary
14 shall transmit to the Congress the revised rec-
15 ommendations under paragraph (2), a summary of
16 the views and comments received under such para-
17 graph, and any changes made to the recommenda-
18 tions in response to such views and comments.”.

Calendar No. 290

116TH CONGRESS
1ST Session

S. 2740

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.

NOVEMBER 5, 2019

Reported without amendment