

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

A BILL

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

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

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

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Over-the-Counter Monograph Safety, Innovation, and
6 Reform Act of 2019”.

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

Sec. 1. Short title; table of contents.

TITLE I—OTC DRUG REVIEW

Sec. 101. Regulation of certain nonprescription drugs that are marketed without 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.

1 **TITLE I—OTC DRUG REVIEW**

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

5 (a) IN GENERAL.—Chapter V of the Federal Food,
6 Drug, and Cosmetic Act is amended by inserting after section 505F of such Act (21 U.S.C. 355g) the following:

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

11 “(a) NONPRESCRIPTION DRUGS MARKETED WITH-
12 OUT AN APPROVED APPLICATION.—Nonprescription
13 drugs marketed without an approved drug application
14 under section 505, as of the date of the enactment of this
15 section, shall be treated in accordance with this sub-
16 section.

17 “(1) DRUGS SUBJECT TO A FINAL MONOGRAPH;
18 CATEGORY I DRUGS SUBJECT TO A TENTATIVE

1 FINAL MONOGRAPH.—A drug is deemed to be gen-
2 erally recognized as safe and effective under section
3 201(p)(1), not a new drug under section 201(p), and
4 not subject to section 503(b)(1), if—

5 “(A) the drug is—

6 “(i) in conformity with the require-
7 ments for nonprescription use of a final
8 monograph issued under part 330 of title
9 21, Code of Federal Regulations (except as
10 provided in paragraph (2)), the general re-
11 quirements for nonprescription drugs, and
12 conditions or requirements under sub-
13 sections (b), (c), and (k); and

14 “(ii) except as permitted by an order
15 issued under subsection (b) or, in the case
16 of a minor change in the drug, in con-
17 formity with an order issued under sub-
18 section (c), in a dosage form that, imme-
19 diately prior to the date of the enactment
20 of this section, has been used to a material
21 extent and for a material time under sec-
22 tion 201(p)(2); or

23 “(B) the drug is—

24 “(i) classified in category I for safety
25 and effectiveness under a tentative final

monograph that is the most recently applicable proposal or determination issued under part 330 of title 21, Code of Federal Regulations;

“(ii) in conformity with the proposed requirements for nonprescription use of such tentative final monograph, any applicable subsequent determination by the Secretary, the general requirements for nonprescription drugs, and conditions or requirements under subsections (b), (c), and (k); and

“(iii) except as permitted by an order issued under subsection (b) or, in the case of a minor change in the drug, in conformity with an order issued under subsection (c), in a dosage form that, immediately prior to the date of the enactment of this section, has been used to a material extent and for a material time under section 201(p)(2).

“(2) TREATMENT OF SUNSCREEN DRUGS.—

With respect to sunscreen drugs subject to this section, the applicable requirements in terms of conformity with a final monograph, for purposes of

1 paragraph (1)(A)(i), shall be the requirements speci-
2 fied in part 352 of title 21, Code of Federal Regula-
3 tions, as published on May 21, 1999, beginning on
4 page 27687 of volume 64 of the Federal Register,
5 except that the applicable requirements governing ef-
6 fectiveness and labeling shall be those specified in
7 section 201.327 of title 21, Code of Federal Regula-
8 tions.

9 “(3) CATEGORY III DRUGS SUBJECT TO A TEN-
10 TATIVE FINAL MONOGRAPH; CATEGORY I DRUGS
11 SUBJECT TO PROPOSED MONOGRAPH OR ADVANCE
12 NOTICE OF PROPOSED RULEMAKING.—A drug that
13 is not described in paragraph (1), (2), or (4) is not
14 required to be the subject of an application approved
15 under section 505, and is not subject to section
16 503(b)(1), if—

17 “(A) the drug is—

18 “(i) classified in category III for safe-
19 ty or effectiveness in the preamble of a
20 proposed rule establishing a tentative final
21 monograph that is the most recently appli-
22 cable proposal or determination for such
23 drug issued under part 330 of title 21,
24 Code of Federal Regulations;

25 “(ii) in conformity with—

1 “(I) the conditions of use, includ-
2 ing indication and dosage strength, if
3 any, described for such category III
4 drug in such preamble or in an appli-
5 cable subsequent proposed rule;

6 “(II) the proposed requirements
7 for drugs classified in such tentative
8 final monograph in category I in the
9 most recently proposed rule estab-
10 lishing requirements related to such
11 tentative final monograph and in any
12 final rule establishing requirements
13 that are applicable to the drug; and

14 “(III) the general requirements
15 for nonprescription drugs and condi-
16 tions or requirements under sub-
17 section (b) or (k); and

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

23 “(B) the drug is—

24 “(i) classified in category I for safety
25 and effectiveness under a proposed mono-

graph or advance notice of proposed rulemaking that is the most recently applicable proposal or determination for such drug issued under part 330 of title 21, Code of Federal Regulations;

“(ii) in conformity with the requirements for nonprescription use of such proposed monograph or advance notice of proposed rulemaking, any applicable subsequent determination by the Secretary, the general requirements for nonprescription drugs, and conditions or requirements under subsection (b) or (k); and

“(iii) in a dosage form that, immediately prior to the date of the enactment of this section, has been used to a material extent and for a material time under section 201(p)(2).

“(4) CATEGORY II DRUGS DEEMED NEW DRUGS.—A drug that is classified in category II for safety or effectiveness under a tentative final monograph or that is subject to a determination to be not generally recognized as safe and effective in a proposed rule that is the most recently applicable proposal issued under part 330 of title 21, Code of Fed-

1 eral Regulations, shall be deemed to be a new drug
 2 under section 201(p), misbranded under section
 3 502(ee), and subject to the requirement for an ap-
 4 proved new drug application under section 505 be-
 5 ginning on the day that is 180 calendar days after
 6 the date of the enactment of this section, unless, be-
 7 fore such day, the Secretary determines that it is in
 8 the interest of public health to extend the period
 9 during which the drug may be marketed without
 10 such an approved new drug application.

11 “(5) DRUGS NOT GRASE DEEMED NEW
 12 DRUGS.—A drug that the Secretary has determined
 13 not to be generally recognized as safe and effective
 14 under section 201(p)(1) under a final determination
 15 issued under part 330 of title 21, Code of Federal
 16 Regulations, shall be deemed to be a new drug under
 17 section 201(p), misbranded under section 502(ee),
 18 and subject to the requirement for an approved new
 19 drug application under section 505.

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

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

25 and

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

3 “(b) ADMINISTRATIVE ORDERS.—

4 “(1) IN GENERAL.—

5 “(A) DETERMINATION.—The Secretary
 6 may, on the initiative of the Secretary or at the
 7 request of one or more requestors, issue an ad-
 8 ministrative order determining whether there
 9 are conditions under which a specific drug, a
 10 class of drugs, or a combination of drugs, is de-
 11 termined to be—

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

13 and

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

16 “(B) EFFECT.—A drug or combination of
 17 drugs shall be deemed to not require approval
 18 under section 505 if such drug or combination
 19 of drugs—

20 “(i) is determined by the Secretary to
 21 meet the conditions specified in clauses (i)
 22 and (ii) of subparagraph (A);

23 “(ii) is marketed in conformity with
 24 an administrative order under this sub-
 25 section;

1 “(iii) meets the general requirements
2 for nonprescription drugs; and

3 “(iv) meets the requirements under
4 subsections (c) and (k).

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

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

11 “(ii) the evidence is inadequate to
12 show that the drug is generally recognized
13 as safe and effective under section
14 201(p)(1).

15 “(2) ADMINISTRATIVE ORDERS INITIATED BY
16 THE SECRETARY.—

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

20 “(i) make reasonable efforts to notify
21 informally, not later than 2 business days
22 before the issuance of the proposed order,
23 the sponsors of drugs who have a listing in
24 effect under section 510(j) for the drugs or

1 combination of drugs that will be subject
2 to the administrative order;

3 “(ii) after any such reasonable efforts
4 of notification—

5 “(I) issue a proposed administra-
6 tive order by publishing it on the
7 website of the Food and Drug Admin-
8 istration and include in such order the
9 reasons for the issuance of such order;
10 and

11 “(II) publish a notice of avail-
12 ability of such proposed order in the
13 Federal Register;

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

18 “(iv) if, after completion of the pro-
19 ceedings specified in clauses (i) through
20 (iii), the Secretary determines that it is ap-
21 propriate to issue a final administrative
22 order—

23 “(I) issue the final administrative
24 order, together with a detailed state-
25 ment of reasons, which order shall not

1 take effect until the time for request-
2 ing judicial review under paragraph
3 (3)(D)(ii) has expired;

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

7 “(III) afford requestors of drugs
8 that will be subject to such order the
9 opportunity for formal dispute resolu-
10 tion up to the level of the Director of
11 the Center for Drug Evaluation and
12 Research, which initially must be re-
13 quested within 45 calendar days of
14 the issuance of the order, and, for
15 subsequent levels of appeal, within 30
16 calendar days of the prior decision;
17 and

18 “(IV) except with respect to
19 drugs described in paragraph (3)(B),
20 upon completion of the formal dispute
21 resolution procedure, inform the per-
22 sons which sought such dispute reso-
23 lution of their right to request a hear-
24 ing.

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

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

10 “(I) the general categories of
11 data the Secretary has determined
12 necessary to establish that the drug is
13 generally recognized as safe and effec-
14 tive under section 201(p)(1); and

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

17 “(ii) the Secretary shall provide for a
18 public comment period of no less than 180
19 calendar days with respect to such pro-
20 posed order, except when the Secretary de-
21 termines, for good cause, that a shorter pe-
22 riod is in the interest of public health; and

23 “(iii) any person who submits data in
24 such comment period shall include a cer-
25 tification that the person has submitted all

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

7 “(3) HEARINGS; JUDICIAL REVIEW.—

8 “(A) IN GENERAL.—Only a person who
9 participated in each stage of formal dispute res-
10 olution under subclause (III) of paragraph
11 (2)(A)(iv) of an administrative order with re-
12 spect to a drug may request a hearing con-
13 cerning a final administrative order issued
14 under such paragraph with respect to such
15 drug. If a hearing is sought, such person must
16 submit a request for a hearing, which shall be
17 based solely on information in the administra-
18 tive record, to the Secretary not later than 30
19 calendar days after receiving notice of the final
20 decision of the formal dispute resolution proce-
21 dure.

22 “(B) NO HEARING REQUIRED WITH RE-
23 SPECT TO ORDERS RELATING TO CERTAIN
24 DRUGS.—

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

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

8 “(II) with respect to which no
9 human or non-human data studies rel-
10 evant to the safety or effectiveness of
11 such drug have been submitted to the
12 administrative record since the
13 issuance of the most recent tentative
14 final monograph relating to such
15 drug.

16 “(ii) HUMAN DATA STUDIES AND
17 NON-HUMAN DATA DEFINED.—In this sub-
18 paragraph:

19 “(I) The term ‘human data stud-
20 ies’ means clinical trials of safety or
21 effectiveness (including actual use
22 studies), pharmacokinetics studies, or
23 bioavailability studies.

24 “(II) The term ‘non-human data’
25 means data from testing other than

1 with human subjects which provides
2 information concerning safety or ef-
3 fectiveness.

4 “(C) HEARING PROCEDURES.—

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

18 “(ii) SINGLE HEARING FOR MULTIPLE
19 RELATED REQUESTS.—If more than one
20 request for a hearing is submitted with re-
21 spect to the same administrative order
22 under subparagraph (A), the Secretary
23 may direct that a single hearing be con-
24 ducted in which all persons whose hearing
25 requests were granted may participate.

1 “(iii) PRESIDING OFFICER.—The pre-
2 siding officer of a hearing requested under
3 subparagraph (A) shall—

4 “(I) be designated by the Sec-
5 retary;

6 “(II) not be an employee of the
7 Center for Drug Evaluation and Re-
8 search; and

9 “(III) not have been previously
10 involved in the development of the ad-
11 ministrative order involved or pro-
12 ceedings relating to that administra-
13 tive order.

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

25 “(v) FINAL DECISION.—

1 “(I) At the conclusion of a hear-
2 ing requested under subparagraph
3 (A), the presiding officer of the hear-
4 ing shall issue a decision containing
5 findings of fact and conclusions of
6 law. The decision of the presiding offi-
7 cer shall be final.

8 “(II) The final decision may not
9 take effect until the period under sub-
10 paragraph (D)(ii) for submitting a re-
11 quest for judicial review of such deci-
12 sion expires.

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

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

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

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

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

14 “(III) the date on which a final
 15 decision is made following a hearing
 16 under subparagraph (C)(v); or

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

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

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

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

12 “(I) may issue an interim final
13 administrative order for such drug,
14 class of drugs, or combination of
15 drugs under paragraph (1), together
16 with a detailed statement of the rea-
17 sons for such order;

18 “(II) shall publish in the Federal
19 Register a notice of availability of any
20 such order; and

21 “(III) shall provide for a public
22 comment period of at least 45 cal-
23 endar days with respect to such in-
24 terim final order.

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

5 “(B) SAFETY LABELING CHANGES.—

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

14 “(I) make reasonable efforts to
15 notify informally, not later than 48
16 hours before the issuance of the in-
17 terim final order, the sponsors of
18 drugs who have a listing in effect
19 under section 510(j) for such drug or
20 combination of drugs;

21 “(II) after reasonable efforts of
22 notification, issue an interim final ad-
23 ministrative order in accordance with
24 paragraph (1) to require such change,

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

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

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

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

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

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

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

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

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

13 “(E) HEARINGS.—A sponsor of a drug
14 subject to a final order issued under subpara-
15 graph (D) and that participated in each stage
16 of formal dispute resolution under clause (iii) of
17 such subparagraph may request a hearing on
18 such order. The provisions of subparagraphs
19 (A), (B), and (C) of paragraph (3), other than
20 paragraph (3)(C)(v)(II), shall apply with re-
21 spect to a hearing on such order in the same
22 manner and to the same extent as such provi-
23 sions apply with respect to a hearing on an ad-
24 ministrative order issued under paragraph
25 (2)(A)(iv).

1 “(F) TIMING.—

2 “(i) FINAL ORDER AND HEARING.—

3 The Secretary shall—

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

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

13 “(ii) DISPUTE RESOLUTION RE-
14 QUEST.—The Secretary shall specify in an
15 interim final order issued under subpara-
16 graph (A) or (B) such shorter periods for
17 requesting dispute resolution under sub-
18 paragraph (D)(iii) as are necessary to
19 meet the requirements of this subpara-
20 graph.

21 “(G) JUDICIAL REVIEW.—A final order
22 issued pursuant to subparagraph (F) shall be
23 subject to judicial review in accordance with
24 paragraph (3)(D).

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

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

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

13 “(ii) if the Secretary determines that
14 the request is sufficiently complete and for-
15 matted to permit a substantive review, the
16 Secretary shall—

17 “(I) file the request; and

18 “(II) initiate proceedings with re-
19 spect to issuing an administrative
20 order in accordance with paragraphs
21 (2) and (3); and

22 “(iii) except as provided in paragraph
23 (6), if the Secretary determines that a re-
24 quest does not meet the requirements for
25 filing or is not sufficiently complete and

1 formatted to permit a substantive review,
2 the requestor may demand that the request
3 be filed over protest, and the Secretary
4 shall initiate proceedings to review the re-
5 quest in accordance with paragraph (2)(A).

6 “(B) REQUEST TO INITIATE PRO-
7 CEEDINGS.—

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

18 “(I) determining whether a drug
19 is generally recognized as safe and ef-
20 fective under section 201(p)(1), ex-
21 empt from section 503(b)(1), and not
22 required to be the subject of an ap-
23 proved application under section 505;
24 or

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

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

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

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

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

18 “(C) EXCLUSIVITY.—

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

1 period of 18 months following the effective
2 date of such final order and beginning on
3 the date the requestor may lawfully market
4 such drugs pursuant to the order, to mar-
5 ket drugs—

6 “(I) incorporating changes de-
7 scribed in clause (ii); and

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

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

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

19 “(II) provides for a change in the
20 conditions of use of a drug, for which
21 new human data studies conducted or
22 sponsored by the requestor (or for
23 which the requestor has an exclusive
24 right of reference) were essential to
25 the issuance of such order.

1 “(iii) DRUGS DESCRIBED.—The drugs
2 described in this clause are drugs—

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

5 “(II) subject to a final order
6 issued under this section;

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

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

14 “(iv) LIMITATIONS ON EXCLU-
15 SIVITY.—

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

22 “(aa) changes described in
23 clause (ii)(I), relating to active
24 ingredients; or

1 “(bb) changes described in
2 clause (ii)(II), relating to condi-
3 tions of use.

4 “(II) NO EXCLUSIVITY AL-
5 LOWED.—No exclusivity shall apply to
6 changes to a drug which are—

7 “(aa) the subject of a Tier 2
8 OTC monograph order request
9 (as defined in section 744L);

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

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

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

1 “(I) have not been relied on by
2 the Secretary to support—

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

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

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

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

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

24 “(vi) NOTIFICATION OF DRUG NOT
25 AVAILABLE FOR SALE.—A requestor that

1 is granted exclusivity with respect to a
2 drug under this subparagraph shall notify
3 the Secretary in writing within 1 year of
4 the issuance of the final administrative
5 order if the drug that is the subject of
6 such order will not be available for sale
7 within 1 year of the date of issuance of
8 such order. The requestor shall include
9 with such notice the—

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

13 “(II) strength of the drug;

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

17 “(IV) reason for not marketing
18 the drug after issuance of the order.

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

23 “(A) IN GENERAL.—In response to a re-
24 quest under this section that a drug described

1 in subparagraph (B) be generally recognized as
 2 safe and effective, the Secretary—

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

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

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

18 “(i) specified in subsection (a)(1),
 19 (a)(2), or (a)(3);

20 “(ii) subject to a final order under
 21 this section; or

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

24 “(C) INFORMATION DEMONSTRATING
 25 PRIMA FACIE SAFE NONPRESCRIPTION MAR-

1 KETING AND USE.—Information specified in
2 this subparagraph, with respect to a request de-
3 scribed in subparagraph (A)(i), is—

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

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

21 “(I) for such period as needed to
22 provide reasonable assurances con-
23 cerning the safe nonprescription use
24 of the drug; and

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

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

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

20 “(i) the drug is marketed as a non-
21 prescription drug, under conditions of use
22 comparable to the conditions specified in
23 the request, for such period as the Sec-
24 retary determines appropriate (not to ex-
25 ceed 5 consecutive years) pursuant to an

1 application approved under section 505;
2 and

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

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

16 “(7) PACKAGING.—An administrative order
17 issued under paragraph (2), (4)(A), or (5) may in-
18 clude requirements for the packaging of a drug to
19 encourage use in accordance with labeling. Such re-
20 quirements may include unit dose packaging, re-
21 quirements for products intended for use by pedi-
22 atric populations, requirements to reduce risk of
23 harm from unsupervised ingestion, and other appro-
24 priate requirements. This paragraph does not au-
25 thorize the Food and Drug Administration to re-

1 quire standards or testing procedures as described in
2 part 1700 of title 16, Code of Federal Regulations.

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

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

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

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

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

24 “(C) DEEMED ORDERS INCLUDE HARMO-
25 NIZING TECHNICAL AMENDMENTS.—The

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

10 “(c) PROCEDURE FOR MINOR CHANGES.—

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

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

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

22 “(ii) will not materially affect the ex-
 23 tent of absorption or other exposure to the
 24 active ingredient in comparison to a suit-
 25 able reference product; and

1 “(B) the change is in conformity with the
2 requirements of an applicable administrative
3 order issued by the Secretary under paragraph
4 (3).

5 “(2) ADDITIONAL INFORMATION.—

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

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

19 “(i) may so inform the sponsor of the
20 drug in writing; and

21 “(ii) if the Secretary so informs the
22 sponsor, shall provide the sponsor of the
23 drug with a reasonable opportunity to pro-
24 vide additional information.

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

7 “(i) affect the safety or effectiveness
8 of the drug; or

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

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

16 “(3) DETERMINING WHETHER A CHANGE WILL
17 AFFECT SAFETY OR EFFECTIVENESS.—

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

1 reference product, together with guidance for
2 applying those orders to specific dosage forms.

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

10 “(d) CONFIDENTIALITY OF INFORMATION SUB-
11 MITTED TO THE SECRETARY.—

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

23 “(2) PUBLIC AVAILABILITY.—

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

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

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

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

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

20 “(ii) the information is submitted in a
21 requestor-initiated request, but the re-
22 questor withdraws such request, in accord-
23 ance with withdrawal procedures estab-
24 lished by the Secretary, before the Sec-
25 retary issues the proposed order;

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

6 “(iv) the information is of the type
7 contained in raw datasets.

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

19 “(f) APPROVALS UNDER SECTION 505.—The provi-
20 sions of this section shall not be construed to preclude a
21 person from seeking or maintaining the approval of an ap-
22 plication for a drug under sections 505(b)(1), 505(b)(2),
23 and 505(j). A determination under this section that a drug
24 is not subject to section 503(b)(1), is generally recognized
25 as safe and effective under section 201(p)(1), and is not

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

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

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

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

18 “(A) a brief description of each such order;

19 and

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

23 “(h) DEVELOPMENT ADVICE TO SPONSORS OR RE-
 24 QUESTORS.—The Secretary shall establish procedures
 25 under which sponsors or requestors may meet with appro-

1 priate officials of the Food and Drug Administration to
 2 obtain advice on the studies and other information nec-
 3 essary to support submissions under this section and other
 4 matters relevant to the regulation of nonprescription
 5 drugs and the development of new nonprescription drugs
 6 under this section.

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

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

16 “(k) EFFECT ON EXISTING REGULATIONS GOV-
 17 ERNING NONPRESCRIPTION DRUGS.—

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

1 shall establish or modify such regulations by means
 2 of rulemaking in accordance with section 553 of title
 3 5, United States Code.

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

6 “(A) The provisions of section 310.545 of
 7 title 21, Code of Federal Regulations, as in ef-
 8 fect on the day before the date of the enact-
 9 ment of this section, shall be deemed to be a
 10 final order under subsection (b).

11 “(B) Regulations in effect on the day be-
 12 fore the date of the enactment of this section,
 13 establishing requirements for specific non-
 14 prescription drugs marketed pursuant to this
 15 section (including such requirements in parts
 16 201 and 250 of title 21, Code of Federal Regu-
 17 lations), shall be deemed to be final orders
 18 under subsection (b), only as they apply to
 19 drugs—

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

22 “(ii) otherwise subject to an order
 23 under this section.

24 “(3) WITHDRAWAL OF REGULATIONS.—The
 25 Secretary shall withdraw regulations establishing

1 final monographs and the procedures governing the
2 over-the-counter drug review under part 330 and
3 other relevant parts of title 21, Code of Federal
4 Regulations (as in effect on the day before the date
5 of the enactment of this section), or make technical
6 changes to such regulations to ensure conformity
7 with appropriate terminology and cross references.
8 Notwithstanding subchapter II of chapter 5 of title
9 5, United States Code, any such withdrawal or tech-
10 nical changes shall be made without public notice
11 and comment and shall be effective upon publication
12 through notice in the Federal Register (or upon such
13 date as specified in such notice).

14 “(1) GUIDANCE.—The Secretary shall issue guidance
15 that specifies—

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

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

21 “(3) the format of electronic submissions to the
22 Secretary under this section;

23 “(4) consolidated proceedings for appeal and
24 the procedures for such proceedings where appro-
25 priate; and

1 “(5) for minor changes in drugs, recommenda-
 2 tions on how to comply with the requirements in or-
 3 ders issued under subsection (c)(3).

4 “(m) RULE OF CONSTRUCTION.—

5 “(1) IN GENERAL.—This section shall not af-
 6 fect the treatment or status of a nonprescription
 7 drug—

8 “(A) that is marketed without an applica-
 9 tion approved under section 505 as of the date
 10 of the enactment of this section;

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

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

15 “(2) TREATMENT OF PRODUCTS PREVIOUSLY
 16 FOUND TO BE SUBJECT TO TIME AND EXTENT RE-
 17 QUIREMENTS.—

18 “(A) Notwithstanding subsection (a), a
 19 drug described in subparagraph (B) may only
 20 be lawfully marketed, without an application
 21 approved under section 505, pursuant to an
 22 order issued under this section.

23 “(B) A drug described in this subpara-
 24 graph is a drug which, prior to the date of the
 25 enactment of this section, the Secretary deter-

1 mined in a proposed or final rule to be ineligible
2 for review under the OTC drug review (as such
3 phrase ‘OTC drug review’ was used in section
4 330.14 of title 21, Code of Federal Regulations,
5 as in effect on the day before the date of the
6 enactment of this section).

7 “(3) PRESERVATION OF AUTHORITY.—

8 “(A) Nothing in paragraph (1) shall be
9 construed to preclude or limit the applicability
10 of any provision of this Act other than this sec-
11 tion.

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

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

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

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

7 “(q) DEFINITIONS.—In this section:

8 “(1) The term ‘nonprescription drug’ refers to
 9 a drug not subject to the requirements of section
 10 503(b)(1).

11 “(2) The term ‘sponsor’ refers to any person
 12 marketing, manufacturing, or processing a drug
 13 that—

14 “(A) is listed pursuant to section 510(j);
 15 and

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

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

22 (b) GAO STUDY.—Not later than 4 years after the
 23 date of enactment of this Act, the Comptroller General
 24 of the United States shall submit a study to the Com-
 25 mittee on Energy and Commerce of the House of Rep-

1 representatives and the Committee on Health, Education,
 2 Labor, and Pensions of the Senate addressing the effec-
 3 tiveness and overall impact of exclusivity under section
 4 505G of the Federal Food, Drug, and Cosmetic Act, as
 5 added by subsection (a), and section 586C of such Act
 6 (21 U.S.C. 360fff-3), including the impact of such exclu-
 7 sivity on consumer access. Such study shall include—

8 (1) an analysis of the impact of exclusivity
 9 under such section 505G for nonprescription drug
 10 products, including—

11 (A) the number of nonprescription drug
 12 products that were granted exclusivity and the
 13 indication for which the nonprescription drug
 14 products were determined to be generally recog-
 15 nized as safe and effective;

16 (B) whether the exclusivity for such drug
 17 products was granted for—

18 (i) a new active ingredient (including
 19 any ester or salt of the active ingredient);
 20 or

21 (ii) changes in the conditions of use of
 22 a drug, for which new human data studies
 23 conducted or sponsored by the requestor
 24 were essential;

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

4 (D) an analysis of the implementation of
5 the exclusivity provision in such section 505G,
6 including—

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

9 (ii) the impact of such provision on
10 innovation, as well as research and devel-
11 opment in the nonprescription drug mar-
12 ket;

13 (iii) the impact of such provision on
14 competition in the nonprescription drug
15 market;

16 (iv) the impact of such provision on
17 consumer access to nonprescription drug
18 products;

19 (v) the impact of such provision on
20 the prices of nonprescription drug prod-
21 ucts; and

22 (vi) whether the administrative orders
23 initiated by requestors under such section
24 505G have been sufficient to encourage the
25 development of nonprescription drug prod-

1 ucts that would likely not be otherwise de-
2 veloped, or developed in as timely a man-
3 ner; and

4 (E) whether the administrative orders ini-
5 tiated by requestors under such section 505G
6 have been sufficient incentive to encourage in-
7 novation in the nonprescription drug market;
8 and

9 (2) an analysis of the impact of exclusivity
10 under such section 586C for sunscreen ingredients,
11 including—

12 (A) the number of sunscreen ingredients
13 that were granted exclusivity and the specific
14 ingredient that was determined to be generally
15 recognized as safe and effective;

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

19 (C) whether, and to what extent, the sun-
20 screen ingredient granted exclusivity had pre-
21 viously been available outside of the United
22 States;

23 (D) an analysis of the implementation of
24 the exclusivity provision in such section 586C,
25 including—

- 1 (i) the resources used by the Food
2 and Drug Administration;
- 3 (ii) the impact of such provision on
4 innovation, as well as research and devel-
5 opment in the sunscreen market;
- 6 (iii) the impact of such provision on
7 competition in the sunscreen market;
- 8 (iv) the impact of such provision on
9 consumer access to sunscreen products;
- 10 (v) the impact of such provision on
11 the prices of sunscreen products; and
- 12 (vi) whether the administrative orders
13 initiated by requestors under such section
14 505G have been utilized by sunscreen in-
15 gredient sponsors and whether such proc-
16 ess has been sufficient to encourage the
17 development of sunscreen ingredients that
18 would likely not be otherwise developed, or
19 developed in as timely a manner; and
- 20 (E) whether the administrative orders ini-
21 tiated by requestors under such section 586C
22 have been sufficient incentive to encourage in-
23 novation in the sunscreen market.

1 (c) CONFORMING AMENDMENT.—Section 751(d)(1)
 2 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 3 379r(d)(1)) is amended—

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

5 (A) by striking “final regulation promul-
 6 gated” and inserting “final order under section
 7 505G”; and

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

9 (2) in subparagraph (A), by striking “regula-
 10 tion in effect” and inserting “regulation or order in
 11 effect”.

12 **SEC. 102. MISBRANDING.**

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

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

20 “(ff) If it is a drug and it was manufactured, pre-
 21 pared, propagated, compounded, or processed in a facility
 22 for which fees have not been paid as required by section
 23 744M.”.

1 **SEC. 103. DRUGS EXCLUDED FROM THE OVER-THE-**
2 **COUNTER DRUG REVIEW.**

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

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

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

17 (a) REVIEW OF NONPRESCRIPTION SUNSCREEN AC-
18 TIVE INGREDIENTS.—

19 (1) APPLICABILITY OF SECTION 505G FOR
20 PENDING SUBMISSIONS.—

21 (A) IN GENERAL.—A sponsor of a non-
22 prescription sunscreen active ingredient or com-
23 bination of nonprescription sunscreen active in-
24 gredients that, as of the date of enactment of
25 this Act, is subject to a proposed sunscreen
26 order under section 586C of the Federal Food,

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

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

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

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

23 (C) ELECTION NOT EXERCISED.—If a noti-
24 fication under subparagraph (A) is not received
25 by the Secretary of Health and Human Services

1 within 180 calendar days of the date of enact-
 2 ment of this Act, the review of the proposed
 3 sunscreen order described in subparagraph
 4 (A)—

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

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

11 (2) DEFINITIONS.—In this subsection, the
 12 terms “sponsor”, “nonprescription”, “sunscreen ac-
 13 tive ingredient”, and “proposed sunscreen order”
 14 have the meanings given to those terms in section
 15 586 of the Federal Food, Drug, and Cosmetic Act
 16 (21 U.S.C. 360fff).

17 (b) AMENDMENTS TO SUNSCREEN PROVISIONS.—

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

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

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

4 (A) by striking “A sponsor may request”
5 and inserting the following:

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

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

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

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

14 (3) EXCLUSIVITY.—Section 586C of the Fed-
 15 eral Food, Drug, and Cosmetic Act (21 U.S.C.
 16 360fff–3) is amended by adding at the end the fol-
 17 lowing:

18 “(f) EXCLUSIVITY.—

19 “(1) IN GENERAL.—A final sunscreen order
 20 shall have the effect of authorizing solely the order
 21 requestor (or the licensees, assignees, or successors
 22 in interest of such requestor with respect to the sub-
 23 ject of such request and listed under paragraph (5))
 24 for a period of 18 months, to market a sunscreen in-
 25 gredient under this section incorporating changes

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

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

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

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

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

1 “(4) LIMITATIONS ON EXCLUSIVITY.—Only one
2 18-month period may be granted per ingredient
3 under paragraph (1).

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

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

15 **“SEC. 586H. SUNSET.**

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

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

22 (c) TREATMENT OF AUTHORITY REGARDING FINAL-
23 IZATION OF SUNSCREEN MONOGRAPH.—

24 (1) IN GENERAL.—

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

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

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

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

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

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

17 (d) TREATMENT OF NON-SUNSCREEN TIME AND EX-
 18 TENT APPLICATIONS.—

19 (1) IN GENERAL.—Any application described in
 20 section 586F of the Federal Food, Drug, and Cos-
 21 metic Act (21 U.S.C. 360fff–6) that was submitted
 22 to the Secretary pursuant to section 330.14 of title
 23 21, Code of Federal Regulations, as such provisions
 24 were in effect immediately prior to the date of enact-

1 ment date of this Act, shall be extinguished as of
2 such date of enactment, subject to paragraph (2).

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

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

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

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

23 (2) as appropriate, revising such cough and cold
24 monograph to address such children through the
25 order process under section 505G(b) of the Federal

1 Food, Drug, and Cosmetic Act, as added by section
2 101 of this Act.

3 (b) COUGH AND COLD MONOGRAPH DESCRIBED.—

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

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

23 **SEC. 106. TECHNICAL CORRECTIONS.**

24 (a) IMPORTS AND EXPORTS.—Section
25 801(e)(4)(E)(iii) of the Federal Food, Drug, and Cosmetic

1 Act (21 U.S.C. 381(e)(4)(E)(iii)) is amended by striking
 2 “subparagraph” each place such term appears and insert-
 3 ing “paragraph”.

4 (b) FDA REAUTHORIZATION ACT OF 2017.—

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

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

13 **TITLE II—USER FEES**

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

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

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

1 of the House of Representatives, as set forth in the Con-
 2 gressional Record.

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

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

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

9 **“SEC. 744L. DEFINITIONS.**

10 “In this part:

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

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

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

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

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

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

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

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

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

22 “(4) The term ‘FDA establishment identifier’ is
23 the unique number automatically generated by Food
24 and Drug Administration’s Field Accomplishments

1 and Compliance Tracking System (FACTS) (or any
2 successor system).

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

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

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

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

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

23 “(iii) all OTC monograph drug devel-
24 opment and review activities, including
25 intra-agency collaboration;

1 “(iv) regulation and policy develop-
2 ment activities related to OTC monograph
3 drugs;

4 “(v) development of product standards
5 for products subject to review and evalua-
6 tion;

7 “(vi) meetings referred to in section
8 505G(i);

9 “(vii) review of labeling prior to
10 issuance of orders related to OTC mono-
11 graph drugs or conditions of use; and

12 “(viii) regulatory science activities re-
13 lated to OTC monograph drugs.

14 “(B) Inspections related to OTC mono-
15 graph drugs.

16 “(C) Monitoring of clinical and other re-
17 search conducted in connection with OTC
18 monograph drugs.

19 “(D) Safety activities with respect to OTC
20 monograph drugs, including—

21 “(i) collecting, developing, and review-
22 ing safety information on OTC monograph
23 drugs, including adverse event reports;

24 “(ii) developing and using improved
25 adverse event data-collection systems, in-

1 including information technology systems;
2 and

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

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

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

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

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

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

22 “(ii) the addition of information to the
23 other information section of the drug facts label
24 of an OTC monograph drug, as limited by sec-

1 tion 201.66(c)(7) of title 21, Code of Federal
2 Regulations (or any successor regulations);

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

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

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

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

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

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

4 “(i) is—

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

7 “(II) at one geographic location or ad-
8 dress engaged in manufacturing or proc-
9 essing the finished dosage form of an OTC
10 monograph drug;

11 “(ii) includes a finished dosage form man-
12 ufacturer facility in a contractual relationship
13 with the sponsor of one or more OTC mono-
14 graph drugs to manufacture or process such
15 drugs; and

16 “(iii) does not include a business or other
17 entity whose only manufacturing or processing
18 activities are one or more of the following: pro-
19 duction of clinical research supplies, testing, or
20 placement of outer packaging on packages con-
21 taining multiple products, for such purposes as
22 creating multipacks, when each monograph
23 drug product contained within the overpack-
24 aging is already in a final packaged form prior
25 to placement in the outer overpackaging.

1 “(B) For purposes of subparagraph (A)(i)(II),
2 separate buildings or locations within close proximity
3 are considered to be at one geographic location or
4 address if the activities conducted in such buildings
5 or locations are—

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

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

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

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

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

23 “(12) The term ‘person’ includes an affiliate of
24 a person.

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

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

5 “(a) TYPES OF FEES.—Beginning with fiscal year
6 2021, the Secretary shall assess and collect fees in accord-
7 ance with this section as follows:

8 “(1) FACILITY FEE.—

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

16 “(B) EXCEPTIONS.—

17 “(i) FACILITIES THAT CEASE ACTIVI-
18 TIES.—A fee shall not be assessed under
19 subparagraph (A) if the identified OTC
20 monograph drug facility—

21 “(I) has ceased all activities re-
22 lated to OTC monograph drugs prior
23 to December 31 of the year imme-
24 diately preceding the applicable fiscal
25 year; and

1 “(II) has updated its registration
2 to reflect such change under the re-
3 quirements for drug establishment
4 registration set forth in section 510.

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

12 “(C) AMOUNT.—The amount of fees estab-
13 lished under subparagraph (A) shall be estab-
14 lished under subsection (c).

15 “(D) DUE DATE.—

16 “(i) FOR FIRST PROGRAM YEAR.—For
17 fiscal year 2021, the facility fees required
18 under subparagraph (A) shall be due on
19 the later of—

20 “(I) the first business day of
21 June of 2020; or

22 “(II) 45 calendar days after pub-
23 lication of the Federal Register notice
24 provided for under subsection
25 (c)(4)(A).

1 “(ii) SUBSEQUENT FISCAL YEARS.—

2 For each fiscal year after fiscal year 2021,
3 the facility fees required under subpara-
4 graph (A) shall be due on the later of—

5 “(I) the first business day of
6 June of such year; or

7 “(II) the first business day after
8 the enactment of an appropriations
9 Act providing for the collection and
10 obligation of fees under this section
11 for such year.

12 “(2) OTC MONOGRAPH ORDER REQUEST
13 FEE.—

14 “(A) IN GENERAL.—Each person that sub-
15 mits an OTC monograph order request shall be
16 subject to a fee for an OTC monograph order
17 request. The amount of such fee shall be—

18 “(i) for a Tier 1 OTC monograph
19 order request, \$500,000, adjusted for in-
20 flation for the fiscal year (as determined
21 under subsection (c)(1)(B)); and

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

1 “(B) DUE DATE.—The OTC monograph
2 order request fees required under subparagraph
3 (A) shall be due on the date of submission of
4 the OTC monograph order request.

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

13 “(i) a contraindication, warning, or
14 precaution;

15 “(ii) a statement about risk associated
16 with misuse or abuse; or

17 “(iii) an instruction about dosage and
18 administration that is intended to increase
19 the safe use of the OTC monograph drug.

20 “(D) REFUND OF FEE IF ORDER REQUEST
21 IS RECATEGORIZED AS A TIER 2 OTC MONO-
22 GRAPH ORDER REQUEST.—If the Secretary de-
23 termines that an OTC monograph request ini-
24 tially characterized as Tier 1 shall be re-charac-
25 terized as a Tier 2 OTC monograph order re-

1 quest, and the requestor has paid a Tier 1 fee
2 in accordance with subparagraph (A)(i), the
3 Secretary shall refund the requestor the dif-
4 ference between the Tier 1 and Tier 2 fees de-
5 termined under subparagraphs (A)(i) and
6 (A)(ii), respectively.

7 “(E) REFUND OF FEE IF ORDER REQUEST
8 REFUSED FOR FILING OR WITHDRAWN BEFORE
9 FILING.—The Secretary shall refund 75 percent
10 of the fee paid under subparagraph (B) for any
11 order request which is refused for filing or was
12 withdrawn before being accepted or refused for
13 filing.

14 “(F) FEES FOR ORDER REQUESTS PRE-
15 VIOUSLY REFUSED FOR FILING OR WITHDRAWN
16 BEFORE FILING.—An OTC monograph order
17 request that was submitted but was refused for
18 filing, or was withdrawn before being accepted
19 or refused for filing, shall be subject to the full
20 fee under subparagraph (A) upon being resub-
21 mitted or filed over protest.

22 “(G) REFUND OF FEE IF ORDER REQUEST
23 WITHDRAWN.—If an order request is withdrawn
24 after the order request was filed, the Secretary
25 may refund the fee or a portion of the fee if no

1 substantial work was performed on the order
2 request after the application was filed. The Sec-
3 retary shall have the sole discretion to refund a
4 fee or a portion of the fee under this subpara-
5 graph. A determination by the Secretary con-
6 cerning a refund under this subparagraph shall
7 not be reviewable.

8 “(3) REFUNDS.—

9 “(A) IN GENERAL.—Other than refunds
10 provided pursuant to any of subparagraphs (D)
11 through (G) of paragraph (2), the Secretary
12 shall not refund any fee paid under paragraph
13 (1) except as provided in subparagraph (B).

14 “(B) DISPUTES CONCERNING FEES.—To
15 qualify for the return of a fee claimed to have
16 been paid in error under paragraph (1) or (2),
17 a person shall submit to the Secretary a written
18 request justifying such return within 180 cal-
19 endar days after such fee was paid.

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

24 “(b) FEE REVENUE AMOUNTS.—

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

5 “(A) the annual base revenue for fiscal
6 year 2021 (as determined under paragraph
7 (3));

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

12 “(C) additional direct cost adjustments (as
13 determined under subsection (c)(3)).

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

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

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

23 “(C) the dollar amount equal to the oper-
24 ating reserve adjustment for the fiscal year, if

1 applicable (as determined under subsection
2 (c)(2));

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

5 “(E) additional dollar amounts for each
6 fiscal year as follows:

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

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

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

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

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

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

16 “(B) for fiscal years 2022 through 2025,
17 the dollar amount of the total revenue amount
18 established under this subsection for the pre-
19 vious fiscal year, not including any adjustments
20 made under subsection (c)(2) or (c)(3).

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

22 “(1) INFLATION ADJUSTMENT.—

23 “(A) IN GENERAL.—For purposes of sub-
24 section (b)(2)(B), the dollar amount of the in-
25 flation adjustment to the annual base revenue

for fiscal year 2022 and each subsequent fiscal year shall be equal to the product of—

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

“(ii) the inflation adjustment percentage under subparagraph (C).

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

“(i) the applicable fee under subsection (a)(2) for the preceding fiscal year; and

“(ii) the inflation adjustment percentage under subparagraph (C).

“(C) INFLATION ADJUSTMENT PERCENTAGE.—The inflation adjustment percentage under this subparagraph for a fiscal year is equal to—

“(i) for each of fiscal years 2022 and 2023, the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Balti-

1 more, DC–MD–VA–WV; Not Seasonally
2 Adjusted; All items; Annual Index) for the
3 first 3 years of the preceding 4 years of
4 available data; and

5 “(ii) for each of fiscal years 2024 and
6 2025, the sum of—

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

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

years of the preceding 4 years of
 available data multiplied by the pro-
 portion of all costs other than per-
 sonnel compensation and benefits
 costs to total costs of OTC mono-
 graph drug activities for the first 3
 years of the preceding 4 fiscal years.

“(2) OPERATING RESERVE ADJUSTMENT.—

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

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

“(i) 3 weeks for fiscal year 2021;

“(ii) 7 weeks for fiscal year 2022;

“(iii) 10 weeks for fiscal year 2023;

“(iv) 10 weeks for fiscal year 2024;

and

1 “(v) 10 weeks for fiscal year 2025.

2 “(C) DECREASE.—If the Secretary has
3 carryover balances for such process in excess of
4 10 weeks of the operating reserves referred to
5 in subparagraph (A), the Secretary shall de-
6 crease the fee revenue and fees referred to in
7 such subparagraph to provide for not more than
8 10 weeks of such operating reserves.

9 “(D) RATIONALE FOR ADJUSTMENT.—If
10 an adjustment under this paragraph is made,
11 the rationale for the amount of the increase or
12 decrease (as applicable) in fee revenue and fees
13 shall be contained in the annual Federal Reg-
14 ister notice under paragraph (4) establishing
15 fee revenue and fees for the fiscal year involved.

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

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

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

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

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

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

1 “(4) ANNUAL FEE SETTING.—

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

5 “(i) establish OTC monograph drug
6 facility fees for fiscal year 2021 under sub-
7 section (a), based on the revenue amount
8 for such year under subsection (b) and the
9 adjustments provided under this sub-
10 section; and

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

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

19 “(i) establish for such fiscal year,
20 based on the revenue amounts under sub-
21 section (b) and the adjustments provided
22 under this subsection—

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

1 “(II) OTC monograph order re-
 2 quest fees under subsection (a)(2);
 3 and

4 “(ii) publish such fee revenue
 5 amounts, facility fees, and OTC mono-
 6 graph order request fees in the Federal
 7 Register.

8 “(d) IDENTIFICATION OF FACILITIES.—Each person
 9 that owns an OTC monograph drug facility shall submit
 10 to the Secretary the information required under this sub-
 11 section each year. Such information shall, for each fiscal
 12 year—

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

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

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

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

21 “(A) IN GENERAL.—Failure to pay the fee
 22 under subsection (a)(1) within 20 calendar days
 23 of the due date as specified in subparagraph
 24 (D) of such subsection shall result in the fol-
 25 lowing:

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

3 “(ii) All OTC monograph drugs man-
4 ufactured in such a facility or containing
5 an ingredient manufactured in such a facil-
6 ity shall be deemed misbranded under sec-
7 tion 502(ff).

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

11 “(2) ORDER REQUESTS.—An OTC monograph
12 order request submitted by a person subject to fees
13 under subsection (a) shall be considered incomplete
14 and shall not be accepted for filing by the Secretary
15 until all fees owed by such person under this section
16 have been paid.

17 “(3) MEETINGS.—A person subject to fees
18 under this section shall be considered ineligible for
19 OTC monograph drug meetings until all such fees
20 owed by such person have been paid.

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

22 “(1) IN GENERAL.—Fees authorized under sub-
23 section (a) shall be collected and available for obliga-
24 tion only to the extent and in the amount provided
25 in advance in appropriations Acts. Such fees are au-

1 thorized to remain available until expended. Such
 2 sums as may be necessary may be transferred from
 3 the Food and Drug Administration salaries and ex-
 4 penses appropriation account without fiscal year lim-
 5 itation to such appropriation account for salaries
 6 and expenses with such fiscal year limitation. The
 7 sums transferred shall be available solely for OTC
 8 monograph drug activities.

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

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

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

ties), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than \$12,000,000, multiplied by the adjustment factor applicable to the fiscal year involved under subsection (c)(1).

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

“(D) PROVISION FOR EARLY PAYMENTS IN SUBSEQUENT YEARS.—Payment of fees authorized under this section for a fiscal year (after fiscal year 2021), prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

“(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2021 through 2025, there is authorized to be appropriated for fees under this section an amount equal to the total amount of fees assessed for such fiscal year under this section.

14 “SEC. 744N. REAUTHORIZATION; REPORTING REQUIRE-
15 MENTS.

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1 graph Safety, Innovation, and Reform Act of 2019 during
2 such fiscal year and the future plans of the Food and
3 Drug Administration for meeting such goals.

4 “(b) FISCAL REPORT.—Not later than 120 calendar
5 days after the end of fiscal year 2021 and each subsequent
6 fiscal year for which fees are collected under this part,
7 the Secretary shall prepare and submit to the Committee
8 on Energy and Commerce of the House of Representatives
9 and the Committee on Health, Education, Labor, and
10 Pensions of the Senate a report on the implementation
11 of the authority for such fees during such fiscal year and
12 the use, by the Food and Drug Administration, of the fees
13 collected for such fiscal year.

14 “(c) PUBLIC AVAILABILITY.—The Secretary shall
15 make the reports required under subsections (a) and (b)
16 available to the public on the internet website of the Food
17 and Drug Administration.

18 “(d) REAUTHORIZATION.—

19 “(1) CONSULTATION.—In developing rec-
20 ommendations to present to the Congress with re-
21 spect to the goals described in subsection (a), and
22 plans for meeting the goals, for OTC monograph
23 drug activities for the first 5 fiscal years after fiscal
24 year 2025, and for the reauthorization of this part

1 for such fiscal years, the Secretary shall consult
2 with—

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

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

7 “(C) scientific and academic experts;

8 “(D) health care professionals;

9 “(E) representatives of patient and con-
10 sumer advocacy groups; and

11 “(F) the regulated industry.

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

15 “(A) present the recommendations devel-
16 oped under paragraph (1) to the congressional
17 committees specified in such paragraph;

18 “(B) publish such recommendations in the
19 Federal Register;

20 “(C) provide for a period of 30 calendar
21 days for the public to provide written comments
22 on such recommendations;

23 “(D) hold a meeting at which the public
24 may present its views on such recommenda-
25 tions; and

1 “(E) after consideration of such public
2 views and comments, revise such recommenda-
3 tions as necessary.

4 “(3) TRANSMITTAL OF RECOMMENDATIONS.—
5 Not later than January 15, 2025, the Secretary
6 shall transmit to the Congress the revised rec-
7 ommendations under paragraph (2), a summary of
8 the views and comments received under such para-
9 graph, and any changes made to the recommenda-
10 tions in response to such views and comments.”.

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