

115TH CONGRESS
2D SESSION

H. R. 5333

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 HOUSE OF REPRESENTATIVES

MARCH 19, 2018

Mr. LATTA (for himself, Mr. BURGESS, Mr. GENE GREEN of Texas, Ms. DEGETTE, Mr. GUTHRIE, and Mrs. DINGELL) introduced the following bill; which was referred to the Committee on Energy and Commerce

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.**

4 This Act may be cited as the “Over-the-Counter
5 Monograph Safety, Innovation, and Reform Act of 2018”.

1 **TITLE I—OTC DRUG REVIEW**

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

5 (a) IN GENERAL.—Chapter V of the Federal Food,
6 Drug, and Cosmetic Act is amended by inserting after sec-
7 tion 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 NEW DRUG APPLICATION.**

11 “(a) NONPRESCRIPTION DRUGS MARKETED WITH-
12 OUT AN APPROVED APPLICATION.—Nonprescription
13 drugs marketed without an approved new drug application
14 under section 505, as of the date of the enactment of the
15 Over-the-Counter Monograph Safety, Innovation, and Re-
16 form Act of 2018, shall be treated in accordance with this
17 subsection.

18 “(1) DRUGS SUBJECT TO A FINAL MONOGRAPH;
19 CATEGORY I DRUGS SUBJECT TO A TENTATIVE
20 FINAL MONOGRAPH.—A drug is deemed to be gen-
21 erally recognized as safe and effective within the
22 meaning of section 201(p)(1), not a new drug under
23 section 201(p), and not subject to section 503(b)(1),
24 if—

25 “(A) the drug is—

1 “(i) in conformity with the require-
2 ments for nonprescription use of a final
3 monograph issued under part 330 of title
4 21, Code of Federal Regulations (except as
5 provided in paragraph (6)), the general re-
6 quirements for nonprescription drugs, and
7 requirements under subsections (b), (c),
8 and (k); and

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

18 “(B) the drug is—

19 “(i) classified in category I for safety
20 and effectiveness under a tentative final
21 monograph that is the most recently appli-
22 cable proposal or determination issued
23 under part 330 of title 21, Code of Federal
24 Regulations;

1 “(ii) in conformity with the proposed
2 requirements for nonprescription use of
3 such tentative final monograph, any appli-
4 cable subsequent determination by the Sec-
5 retary, the general requirements for non-
6 prescription drugs, and requirements under
7 subsections (b), (c), and (k); and

8 “(iii) except as permitted an order
9 issued under subsection (b) or, in the case
10 of a minor change in the drug, in con-
11 formity with an order issued under sub-
12 section (c), in a dosage form that, imme-
13 diately prior to the date of the enactment
14 of this section, has been used to a material
15 extent and for a material time within the
16 meaning of section 201(p)(2).

17 “(2) TREATMENT OF SUNSCREEN DRUGS.—

18 With respect to sunscreen drugs subject to this sec-
19 tion, the applicable requirements shall be those set
20 out at part 352 of title 21, Code of Federal Regula-
21 tions, as published at volume 64 page 27687 of the
22 Federal Register, except that the applicable require-
23 ments governing effectiveness and labeling shall be
24 those specified in section 201.327 of title 21, Code

1 of Federal Regulations, subject to the requirements
2 of subsections (b), (c), and (k)(2).

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

11 “(A) the drug is—

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

19 “(ii) in conformity with—

20 “(I) the conditions of use, includ-
21 ing indication and dosage strength, if
22 any, described for such category III
23 drug in such preamble or in an appli-
24 cable subsequent proposed rule;

1 “(II) the proposed requirements
2 for drugs classified in such tentative
3 final monograph in category I in the
4 most recently proposed rule estab-
5 lishing requirements related to such
6 tentative final monograph and in any
7 final rule establishing requirements
8 that are applicable to the drug; and

9 “(III) the general requirements
10 for nonprescription drugs and require-
11 ments under subsections (b) or (k);
12 and

13 “(iii) in a dosage form that, imme-
14 diately prior to the date of the enactment
15 of this section, was not required to have
16 satisfied the requirements of section
17 330.14 of title 21, Code of Federal Regula-
18 tions (as in effect at that time), in order
19 for such drug to be lawfully marketed
20 without an application approved under sec-
21 tion 505; or

22 “(B) the drug is—

23 “(i) classified in category I for safety
24 and effectiveness under a proposed mono-
25 graph or advance notice of proposed rule-

1 making that is the most recently applicable
2 proposal or determination for such drug
3 issued under part 330 of title 21, Code of
4 Federal Regulations;

5 “(ii) in conformity with the require-
6 ments for nonprescription use of such pro-
7 posed monograph or advance notice of pro-
8 posed rulemaking, any applicable subse-
9 quent determination by the Secretary, the
10 general requirements for nonprescription
11 drugs, and requirements under subsections
12 (b) or (k); and

13 “(iii) in a dosage form that, imme-
14 diately prior to the date of the enactment
15 of this section, has been used to a material
16 extent and for a material time within the
17 meaning of section 201(p)(2).

18 “(4) CATEGORY II DRUGS DEEMED NEW
19 DRUGS.—A drug that is classified in category II for
20 safety or effectiveness under a tentative final mono-
21 graph or that is subject to a determination to be not
22 safe or effective in a proposed rule that is the most
23 recently applicable proposal issued under part 330 of
24 title 21, Code of Federal Regulations, shall be
25 deemed to be a new drug within the meaning of sec-

1 tion 201(p), misbranded under section 502(ee), and
2 subject to the requirement for an approved new drug
3 application under section 505 beginning on the day
4 that is 180 calendar days after the date of the en-
5 actment of this section, unless, before such day, the
6 Secretary determines that it is in the interest of
7 public health to extend the period during which the
8 drug may be marketed without such an approved
9 new drug application.

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

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

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

5 “(b) ADMINISTRATIVE ORDERS.—

6 “(1) IN GENERAL.—

7 “(A) DETERMINATION.—The Secretary
8 may, on the initiative of the Secretary or at the
9 request of one or more requestors, issue admin-
10 istrative orders determining whether there are
11 conditions under which specific drugs, classes of
12 such drugs, or combinations of such drugs are
13 determined to be—

14 “(i) not subject to section 503(b)(1);
15 and

16 “(ii) generally recognized as safe and
17 effective within the meaning of section
18 201(p)(1).

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

23 “(i) is determined by the Secretary to
24 meet the conditions specified in clauses (i)
25 and (ii) of subparagraph (A);

1 “(ii) is marketed in conformity with
2 an administrative order under this sub-
3 section;

4 “(iii) meets the general requirements
5 for nonprescription drugs; and

6 “(iv) meets the requirements specified
7 in subsections (c) and (k).

8 “(C) STANDARD.—The Secretary shall find
9 that a drug is not generally recognized as safe
10 and effective within the meaning of section
11 201(p)(1) if—

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

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

20 “(2) ADMINISTRATIVE ORDERS INITIATED BY
21 THE SECRETARY.—

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

1 “(i) make reasonable efforts to notify
2 informally, not later than 2 business days
3 before the issuance of the proposed order,
4 sponsors of drugs that will be subject to
5 the administrative order;

6 “(ii) after any such reasonable efforts
7 of notification—

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

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

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

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

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

7 “(II) publish a notice of such
8 final administrative order in the Fed-
9 eral Register;

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

21 “(IV) except with respect to
22 drugs described in paragraph (3)(B),
23 upon completion of the formal dispute
24 resolution procedure, inform the per-
25 sons which sought such dispute reso-

1 lution of their right to request a hear-
2 ing.

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

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

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

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

21 “(ii) the Secretary shall provide for a
22 public comment period of no less than 180
23 calendar days with respect to such pro-
24 posed order, except when the Secretary de-
25 termines, for good cause, that a shorter pe-

1 riod is in the interests of public health;
2 and

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

13 “(3) HEARINGS; JUDICIAL REVIEW.—

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

1 ceiving notice of the final decision of the formal
2 dispute resolution procedure.

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

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

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

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

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

24 “(I) The term ‘human data stud-
25 ies’ means clinical trials of safety or

1 effectiveness (including actual use
2 studies), pharmacokinetics studies, or
3 bioavailability studies.

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

9 “(C) HEARING PROCEDURES.—

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

23 “(ii) SINGLE HEARING FOR MULTIPLE
24 RELATED REQUESTS.—If more than one
25 request for a hearing is submitted with re-

1 spect to the same administrative order
2 under subparagraph (A), the Secretary
3 may direct that a single hearing be con-
4 ducted in which all persons whose hearing
5 requests were granted may participate.

6 “(iii) PRESIDING OFFICER.—The pre-
7 siding officer of a hearing requested under
8 subparagraph (A) shall—

9 “(I) be designated by the Sec-
10 retary;

11 “(II) not be an employee of the
12 Center for Drug Evaluation and Re-
13 search; and

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

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

1 may require that cross-examination by par-
2 ties representing substantially the same in-
3 terests be consolidated to promote effi-
4 ciency and avoid duplication.

5 “(v) FINAL DECISION.—

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

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

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

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

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

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

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

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

19 “(III) the date on which a final
20 decision is made following a hearing
21 under subparagraph (C)(v); or

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

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

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

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

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

23 “(II) shall publish in the Federal
24 Register a notice of availability of any
25 such order; and

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

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

9 “(B) SAFETY LABELING CHANGES.—

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

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

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

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

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

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

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

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

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

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

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

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

1 ministrative order issued under paragraph
2 (2)(A)(iv).

3 “(F) TIMING.—Not later than 12 months
4 after the date on which an interim final order
5 is issued under subparagraph (A) or (B), the
6 Secretary shall issue a final order in accordance
7 with paragraph (1) and complete any required
8 hearing.

9 “(G) JUDICIAL REVIEW.—A final order
10 issued pursuant to subparagraph (F) shall be
11 subject to judicial review in accordance with
12 paragraph (3)(D).

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

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

20 “(i) the Secretary shall, after receiv-
21 ing a request under this subparagraph, de-
22 termine whether the request is sufficiently
23 complete and formatted to permit a sub-
24 stantive review;

1 “(ii) if the Secretary determines that
2 the request is sufficiently complete and for-
3 matted to permit a substantive review, the
4 Secretary shall—

5 “(I) file the request; and

6 “(II) initiate proceedings with re-
7 spect to issuing an administrative
8 order in accordance with paragraphs
9 (2) and (3); and

10 “(iii) except as provided in paragraph
11 (6), if the Secretary determines that a re-
12 quest does not meet the requirements for
13 filing or is not sufficiently complete and
14 formatted to permit a substantive review,
15 the requestor may demand that the request
16 be filed over protest, and the Secretary
17 shall initiate proceedings to review the re-
18 quest in accordance with paragraph (2)(A).

19 “(B) REQUEST TO INITIATE PRO-
20 CEEDINGS.—

21 “(i) IN GENERAL.—A requestor seek-
22 ing an administrative order under para-
23 graph (1) with respect to certain drugs,
24 classes of drugs, or combinations of drugs,
25 shall submit to the Secretary a request to

1 initiate proceedings for such order in the
2 form and manner as specified by the Sec-
3 retary. Such requestor may submit a re-
4 quest under this subparagraph for the
5 issuance of an administrative order—

6 “(I) determining whether a drug
7 is generally recognized as safe and ef-
8 fective within the meaning of section
9 201(p)(1), exempt from section
10 503(b)(1), and not required to be the
11 subject of an approved application
12 under section 505; or

13 “(II) determining whether a
14 change to a condition of use of a drug
15 is generally recognized as safe and ef-
16 fective within the meaning of section
17 201(p)(1), exempt from section
18 503(b)(1), and not required to be the
19 subject of an approved application
20 under section 505, if such drug is—

21 “(aa) absent such a changed
22 condition of use, generally recog-
23 nized as safe and effective within
24 the meaning of section 201(p)(1)
25 in accordance with subsection

1 (a)(1), (a)(2), or an order under
2 this subsection; or

3 “(bb) subject to subsection
4 (a)(3), but only if such requestor
5 initiates such request in conjunc-
6 tion with a request for the Sec-
7 retary to determine whether such
8 drug is generally recognized as
9 safe and effective within the
10 meaning of section 201(p)(1),
11 which is filed by the Secretary
12 under subparagraph (A)(ii).

13 “(ii) EXCEPTION.—The Secretary is
14 not required to complete review of a re-
15 quest for a change described in clause
16 (i)(II) if the Secretary determines that
17 there is an inadequate basis to find the
18 drug is generally recognized as safe and ef-
19 fective within the meaning of section
20 201(p)(1) under paragraph (1) and issues
21 a final order announcing that determina-
22 tion.

23 “(iii) WITHDRAWAL.—The requestor
24 may withdraw a request under this para-
25 graph, according to the procedures set

1 forth pursuant to subsection (d)(2)(B).
2 Notwithstanding any other provision of
3 this section, if such request is withdrawn,
4 the Secretary may cease proceedings under
5 this subparagraph.

6 “(C) EXCLUSIVITY.—

7 “(i) IN GENERAL.—A final adminis-
8 trative order issued in response to a re-
9 quest under this section shall have the ef-
10 fect of authorizing solely the order re-
11 questor (or the licensees, assignees, or suc-
12 cessors in interest of such requestor with
13 respect to the subject of such order), for a
14 period of 18 months following the effective
15 date of such final order, to market drugs—

16 “(I) incorporating changes de-
17 scribed in clause (ii);

18 “(II) beginning on the date the
19 requestor (or any such licensees, as-
20 signees, or successors in interest) may
21 lawfully market such drugs pursuant
22 to the order; and

23 “(III) subject to the limitations
24 under clause (iv).

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

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

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

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

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

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

23 “(III) subject to a final sun-
24 screen order (as defined in section
25 586(2)(A)); or

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

5 “(iv) LIMITATIONS ON EXCLU-
6 SIVITY.—

7 “(I) IN GENERAL.—Only one pe-
8 riod of exclusivity shall be granted,
9 under each order described in clause
10 (i), with respect to changes (to the
11 drug subject to such order) which are
12 either—

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

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

19 “(II) NO EXCLUSIVITY AL-
20 LOWED.—No exclusivity shall apply to
21 changes to a drug which are—

22 “(aa) the subject of a Tier 2
23 OTC monograph order request
24 (as defined in section 744N);

1 “(bb) safety-related changes,
2 as defined by the Secretary, or
3 any other changes the Secretary
4 considers necessary to assure
5 safe use; or

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

9 “(v) NEW HUMAN DATA STUDIES DE-
10 FINED.—In this subparagraph, the term
11 ‘new human data studies’ means clinical
12 trials of safety or effectiveness (including
13 actual use studies), pharmacokinetics stud-
14 ies, or bioavailability studies, the results of
15 which—

16 “(I) have not been relied on by
17 the Secretary to support—

18 “(aa) a proposed or final de-
19 termination that a drug described
20 in subclauses (I), (II), or (III) of
21 clause (iii) is generally recognized
22 as safe and effective within the
23 meaning of section 201(p)(1); or

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

1 505 (except for an approval
2 changing a drug from prescrip-
3 tion to nonprescription status);
4 and

5 “(II) do not duplicate the results
6 of another study that was relied on by
7 the Secretary to support—

8 “(aa) a proposed or final de-
9 termination that a drug described
10 in subclauses (I), (II), or (III) of
11 clause (iii) is generally recognized
12 as safe and effective within the
13 meaning of section 201(p)(1); or

14 “(bb) approval of a drug
15 that was approved under section
16 505 (except for an approval
17 changing a drug from prescrip-
18 tion to nonprescription status).

19 “(vi) EFFECTIVE DATE.—A final
20 order subject to clause (i) shall take effect
21 on the date when the order requestor (or
22 the licensees, assignees, or successors in
23 interest of such requestor with respect to
24 such order) submits updated drug listing
25 information under subsection (e) with re-

1 spect to the change which is permitted
2 under such order.

3 “(6) INFORMATION REGARDING SAFE NON-
4 PRESCRIPTION MARKETING AND USE AS CONDITION
5 FOR FILING A GENERALLY RECOGNIZED AS SAFE
6 AND EFFECTIVE REQUEST.—

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

11 “(i) may file such request, if the re-
12 quest includes information specified under
13 subparagraph (C) with respect to safe non-
14 prescription marketing and use of such
15 drug; or

16 “(ii) if the request fails to include in-
17 formation specified under subparagraph
18 (C), shall refuse to file such request and
19 require that nonprescription marketing of
20 the drug be pursuant to a new drug appli-
21 cation as described in subparagraph (D).

22 “(B) DRUG DESCRIBED.—A drug de-
23 scribed in this subparagraph is a nonprescrip-
24 tion drug which contains an active ingredient
25 not previously incorporated in a drug—

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

3 “(ii) subject to a final order under
4 this section; or

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

7 “(C) INFORMATION DEMONSTRATING
8 PRIMA FACIE SAFE NONPRESCRIPTION MAR-
9 KETING AND USE.—Information specified in
10 this subparagraph, with respect to a request de-
11 scribed in subparagraph (A)(i), is—

12 “(i) information sufficient for a prima
13 facie demonstration that the drug subject
14 to such request has a verifiable history of
15 being marketed and safely used by con-
16 sumers in the United States as a non-
17 prescription drug under comparable condi-
18 tions of use;

19 “(ii) if the drug has not been pre-
20 viously marketed in the United States as a
21 nonprescription drug, information suffi-
22 cient for a prima facie demonstration that
23 the drug was marketed and safely used
24 under comparable conditions of marketing
25 and use in a country listed in section

1 802(b)(1)(A) or designated by the Sec-
2 retary in accordance with section
3 802(b)(1)(B)—

4 “(I) for such period of time as
5 needed to provide reasonable assur-
6 ances concerning the safe nonprescrip-
7 tion use of the drug; and

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

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

22 “(D) MARKETING PURSUANT TO NEW
23 DRUG APPLICATION.—In the case of a request
24 described in subparagraph (A)(ii), the drug

1 subject to such request may be re-submitted for
2 filing only if—

3 “(i) the drug is marketed as a non-
4 prescription drug, under conditions of use
5 comparable to the conditions specified in
6 the request, for such period of time as the
7 Secretary determines appropriate (not to
8 exceed five consecutive years) pursuant to
9 an application approved under section 505;
10 and

11 “(ii) during such time period, one mil-
12 lion retail packages of the drug, or an
13 equivalent quantity as determined by the
14 Secretary, were distributed for retail sale,
15 as determined in such manner as the Sec-
16 retary finds appropriate.

17 “(E) RULE OF APPLICATION.—Except in
18 the case of a request involving a drug described
19 in section 586(9), as in effect on January 1,
20 2017, if the Secretary refuses to file a request
21 under this paragraph, the requestor may not
22 file such request over protest under paragraph
23 (5)(A)(iii).

24 “(7) PACKAGING.—An administrative order
25 issued under paragraph (2), (4)(A), or (5) may in-

1 clude requirements for the packaging of a drug to
2 encourage use in accordance with labeling. Such re-
3 quirements may include unit dose packaging, re-
4 quirements for products intended for use by chil-
5 dren, requirements to reduce risk of harm from un-
6 supervised ingestion, and other appropriate require-
7 ments. This paragraph does not authorize the Food
8 and Drug Administration to require standards or
9 testing procedures as described in part 1700 of title
10 16, Code of Federal Regulations.

11 “(8) FINAL AND TENTATIVE FINAL MONO-
12 GRAPHS FOR CATEGORY I DRUGS DEEMED FINAL
13 ADMINISTRATIVE ORDERS.—

14 “(A) IN GENERAL.—Subject to subpara-
15 graph (B), a final monograph or tentative final
16 monograph establishing conditions of use for a
17 drug described in subsection (a)(1), shall be
18 deemed to be a final administrative order under
19 this subsection and may be amended, revoked,
20 or otherwise modified in accordance with the
21 procedures of this subsection.

22 “(B) DEEMED ORDERS INCLUDE HARMO-
23 NIZING TECHNICAL AMENDMENTS.—The
24 deemed establishment of a final administrative
25 order under subparagraph (A) shall be con-

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

8 “(c) PROCEDURE FOR MINOR CHANGES.—

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

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

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

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

24 “(B) the change is in conformity with the
25 requirements of an applicable administrative

1 order issued by the Secretary under paragraph
2 (3).

3 “(2) ADDITIONAL INFORMATION.—

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

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

17 “(i) may so inform the sponsor of the
18 drug in writing; and

19 “(ii) provide the sponsor of the drug
20 with a reasonable opportunity to provide
21 additional information.

22 “(C) FAILURE TO SUBMIT SUFFICIENT IN-
23 FORMATION.—If the sponsor fails to provide
24 such additional information within the pre-
25 scribed time, or if the Secretary determines that

1 such additional information does not dem-
2 onstrate that the change does not affect the
3 safety or effectiveness of the drug or materially
4 affect the extent of absorption or other expo-
5 sure to the active ingredient, the drug as modi-
6 fied is a new drug within the meaning of sec-
7 tion 201(p) and shall be deemed to be mis-
8 branded under section 502(ee).

9 “(3) DETERMINING WHETHER A CHANGE WILL
10 AFFECT SAFETY OR EFFECTIVENESS.—

11 “(A) IN GENERAL.—The Secretary shall
12 issue one or more administrative orders speci-
13 fying requirements for determining whether a
14 minor change made by a sponsor pursuant to
15 this subsection will affect the safety or effective-
16 ness of a drug or materially affect the extent of
17 absorption or other exposure to an active ingre-
18 dient in the drug in comparison to a suitable
19 reference product, together with guidance for
20 applying those orders to specific dosage forms.

21 “(B) STANDARD PRACTICES.—The orders
22 and guidance issued by the Secretary under
23 subparagraph (A) shall take into account rel-
24 evant public standards and standard practices
25 for evaluating the quality of drugs, and may

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

3 “(d) CONFIDENTIALITY OF INFORMATION SUB-
4 MITTED BY REQUESTORS.—

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

16 “(2) PUBLIC AVAILABILITY.—Notwithstanding
17 paragraph (1), the Secretary shall make available to
18 the public any information (other than raw data
19 sets) submitted by a requestor in support of a re-
20 quest under subsection (b)(5)(A) as of the date on
21 which the proposed order is made public unless—

22 “(A) the information pertains to pharma-
23 ceutical quality information except to the extent
24 that specific information is necessary to estab-
25 lish standards under which a drug is generally

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

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

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

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

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

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

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

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

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

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

22 and

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

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

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

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

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

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

1 tions of general applicability contained in parts 201,
2 250, and 330 of title 21, Code of Federal Regula-
3 tions, or any successor regulations. The Secretary
4 shall establish or modify such regulations by means
5 of rulemaking in accordance with section 553 of title
6 5, United States Code.

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

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

14 “(B) Regulations in effect on the day be-
15 fore the date of the enactment of this section,
16 establishing requirements for specific non-
17 prescription drugs marketed pursuant to this
18 section (including such requirements in parts
19 201 and 250 of title 21, Code of Federal Regu-
20 lations), shall be deemed to be final orders
21 under subsection (b), only as they apply to
22 drugs subject to paragraphs (1), (2), (3), and
23 (6) of subsection (a).

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 and the proce-
24 dures for such proceedings where appropriate; 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 paragraphs (1), (2), (3), (4),
14 (5), or (6) 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 had de-

1 terminated in a proposed or final rule to be ineli-
2 gible for review under the OTC drug review (as
3 such phrase ‘OTC drug review’ was used in sec-
4 tion 330.14 of title 21, Code of Federal Regula-
5 tions, as in effect on the day before the date of
6 the 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 other provision of this Act.

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

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

21 “(o) INAPPLICABILITY OF NOTICE AND COMMENT
22 RULEMAKING AND OTHER REQUIREMENTS.—The re-
23 quirements of subsection (b) shall apply with respect to
24 orders issued under this section instead of the require-

1 ments of subchapter II of chapter 5 of title 5, United
2 States Code.

3 “(p) DEFINITIONS.—In this section:

4 “(1) The term ‘nonprescription drug’ refers to
5 a drug not subject to the requirements of section
6 503(b)(1).

7 “(2) The term ‘sponsor’ refers to any person
8 marketing, manufacturing, or processing a drug
9 that—

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

11 and

12 “(B) is or will be subject to an administra-
13 tive order of the Food and Drug Administra-
14 tion.

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

18 **SEC. 102. MISBRANDING.**

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

22 “(ee) If it is a nonprescription drug that is subject
23 to section 505G, not the subject of an application ap-
24 proved under section 505 or an exemption under section

1 505(i), and does not comply with the requirements under
2 section 505G.

3 “(ff) If it is a drug and it was manufactured, pre-
4 pared, propagated, compounded, or processed in a facility
5 for which fees have not been paid as required by section
6 744O.”.

7 **SEC. 103. DRUGS EXCLUDED FROM THE OVER-THE-**
8 **COUNTER DRUG REVIEW.**

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

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

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

21 (a) REVIEW OF NONPRESCRIPTION SUNSCREEN AC-
22 TIVE INGREDIENTS.—

23 (1) APPLICABILITY OF SECTION 505G FOR
24 PENDING SUBMISSIONS.—

1 (A) IN GENERAL.—A sponsor of a non-
2 prescription sunscreen active ingredient or com-
3 bination of nonprescription sunscreen active in-
4 gredients that, as of the date of enactment of
5 this Act, is subject to a proposed sunscreen
6 order under section 586C of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 360fff–3)
8 may elect, by means of giving written notifica-
9 tion to the Secretary of Health and Human
10 Services within 90 calendar days of the enact-
11 ment of this Act, to transition into the review
12 of such ingredient or combination of ingredients
13 pursuant to the process set out in section 505G
14 of the Federal Food, Drug, and Cosmetic Act,
15 as added by section 101 of this Act.

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

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

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

4 (C) ELECTION NOT EXERCISED.—A spon-
5 sor of a nonprescription sunscreen active ingre-
6 dient or combination of nonprescription sun-
7 screen active ingredients described in subpara-
8 graph (A) that does not elect for such ingre-
9 dient or combination of ingredients to be re-
10 viewed under section 505G of the Federal Food,
11 Drug, and Cosmetic Act, as added by section
12 101 of this Act, shall continue to have such in-
13 gredient or combination of ingredients reviewed
14 in accordance with section 586C of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C.
16 360fff-3) and may not subsequently elect to
17 transition into the review of such ingredient or
18 combination of ingredients pursuant to the
19 process set out in section 505G of such Act, as
20 added by section 101 of this Act.

21 (2) DEFINITIONS.—In this subsection, the
22 terms “sponsor”, “nonprescription”, “sunscreen ac-
23 tive ingredient”, and “proposed sunscreen order”
24 have the meanings given to those terms in section

1 586 of the Federal Food, Drug, and Cosmetic Act
2 (21 U.S.C. 360fff).

3 (b) AMENDMENTS TO SUNSCREEN PROVISIONS.—

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

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

11 (2) MEETINGS.—Paragraph (7) of section
12 586C(b) of the Federal Food, Drug, and Cosmetic
13 Act (21 U.S.C. 360fff–3(b)) is amended—

14 (A) by striking “A sponsor may request”
15 and inserting the following:

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

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

19 “(B) CONFIDENTIAL MEETINGS.—A spon-
20 sor may request one or more confidential meet-
21 ings with respect to a proposed sunscreen order,
22 including a letter deemed to be a proposed sun-
23 screen order under paragraph (3), to discuss
24 matters involving confidential commercial infor-
25 mation or trade secrets. The Secretary shall

1 convene a confidential meeting with such spon-
2 sor in a reasonable time period. If a sponsor re-
3 quests more than one confidential meeting for
4 the same proposed sunscreen order, the Sec-
5 retary may refuse to grant an additional con-
6 fidential meeting request if the Secretary deter-
7 mines that such additional confidential meeting
8 is not reasonably necessary for the sponsor to
9 advance its proposed sunscreen order, or if the
10 request for a confidential meeting fails to in-
11 clude sufficient information upon which to base
12 a substantive discussion. The Secretary shall
13 publish a post-meeting summary of each con-
14 fidential meeting under this subparagraph that
15 does not disclose confidential commercial infor-
16 mation or trade secrets.”.

17 (3) SUNSET PROVISION.—Subchapter I of chap-
18 ter V of the Federal Food, Drug, and Cosmetic Act
19 (21 U.S.C. 360fff et seq.) is amended by adding at
20 the end the following:

21 **“SEC. 586H. SUNSET.**

22 “This subchapter shall cease to be effective at the end
23 of fiscal year 2022.”.

24 (c) TREATMENT OF NON-SUNSCREEN TIME AND EX-
25 TENT APPLICATIONS.—

1 (1) IN GENERAL.—Any application described in
2 section 586F of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 360fff–6) that was submitted
4 to the Secretary of Health and Human Services pur-
5 suant to section 330.14 of title 21, Code of Federal
6 Regulations, as such provisions were in effect imme-
7 diately prior to the date of enactment date of this
8 Act, shall be extinguished as of such date of enact-
9 ment, subject to paragraph (2).

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

16 **SEC. 105. ANNUAL UPDATE TO CONGRESS ON APPRO-**
17 **PRIATE PEDIATRIC INDICATION FOR CER-**
18 **TAIN OTC COUGH AND COLD DRUGS.**

19 (a) IN GENERAL.—Subject to subsection (c), the Sec-
20 retary of Health and Human Services shall, beginning not
21 later than one year after the date of enactment of this
22 Act, annually submit to the Committee on Energy and
23 Commerce of the House of Representatives and the Com-
24 mittee on Health, Education, Labor, and Pensions of the

1 Senate a letter describing the progress of the Food and
2 Drug Administration—

3 (1) in evaluating the cough and cold monograph
4 described in subsection (b) with respect to children
5 under age 6; and

6 (2) as appropriate, revising such cough and cold
7 monograph to address such children through the
8 order process under section 505G(b) of the Federal
9 Food, Drug, and Cosmetic Act, as added by section
10 101 of this Act.

11 (b) COUGH AND COLD MONOGRAPH DESCRIBED.—

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

23 (c) DURATION OF AUTHORITY.—The requirement
24 under subsection (a) shall terminate as of the date of a
25 letter submitted by the Secretary of Health and Human

1 Services pursuant to such subsection in which the Sec-
2 retary indicates that the Food and Drug Administration
3 has completed its evaluation and revised, in a final order,
4 as applicable, the cough and cold monograph as described
5 in subsection (a)(2).

6 **TITLE II—USER FEES**

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

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

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

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

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

1 mittees, and costs related to such officers, em-
2 ployees, and committees and costs related to
3 contracts with such contractors;

4 “(B) management of information, and the
5 acquisition, maintenance, and repair of com-
6 puter resources;

7 “(C) leasing, maintenance, renovation, and
8 repair of facilities and acquisition, maintenance,
9 and repair of fixtures, furniture, scientific
10 equipment, and other necessary materials and
11 supplies; and

12 “(D) collecting fees under section 7440
13 and accounting for resources allocated for OTC
14 monograph drug activities.

15 “(4) The term ‘FDA establishment identifier’ is
16 the unique number automatically generated by Food
17 and Drug Administration’s Field Accomplishments
18 and Compliance Tracking System (FACTS) (or any
19 successor system).

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

24 “(6) The term ‘OTC monograph drug activities’
25 means activities of the Secretary associated with

1 OTC monograph drugs and inspection of facilities
2 associated with such products, including the fol-
3 lowing activities:

4 “(A) The activities necessary for review
5 and evaluation of OTC monographs and OTC
6 monograph order requests, including—

7 “(i) orders proposing or finalizing ap-
8 plicable conditions of use for OTC mono-
9 graph drugs;

10 “(ii) orders affecting status regarding
11 general recognition of safety and effective-
12 ness of an OTC monograph ingredient or
13 combination of ingredients under specified
14 conditions of use;

15 “(iii) all OTC monograph drug devel-
16 opment and review activities, including
17 intraagency collaboration;

18 “(iv) regulation and policy develop-
19 ment activities related to OTC monograph
20 drugs;

21 “(v) development of product standards
22 for products subject to review and evalua-
23 tion;

24 “(vi) meetings referred to in section
25 505G(i);

1 “(vii) review of labeling prior to
2 issuance of orders related to OTC mono-
3 graph drugs or conditions of use; and

4 “(viii) regulatory science activities re-
5 lated to OTC monograph drugs.

6 “(B) Inspections related to OTC mono-
7 graph drugs.

8 “(C) Monitoring of clinical and other re-
9 search conducted in connection with OTC
10 monograph drugs.

11 “(D) Safety activities with respect to OTC
12 monograph drugs, including—

13 “(i) collecting, developing, and review-
14 ing safety information on OTC monograph
15 drugs, including adverse event reports;

16 “(ii) developing and using improved
17 adverse event data-collection systems, in-
18 cluding information technology systems;
19 and

20 “(iii) developing and using improved
21 analytical tools to assess potential safety
22 risks, including access to external data-
23 bases.

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

1 “(7) The term ‘OTC monograph order request’
2 means a request for an order submitted under sec-
3 tion 505G(b)(6).

4 “(8) The term ‘Tier 1 OTC monograph order
5 request’ means any OTC monograph order request
6 not determined to be a Tier 2 OTC monograph
7 order request.

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

11 “(i) the reordering of existing information
12 in the drug facts label of an OTC monograph
13 drug;

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

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

23 “(iv) the standardization of the concentra-
24 tion or dose of a specific finalized ingredient
25 within a particular finalized monograph;

1 “(v) a change to ingredient nomenclature
2 to align with nomenclature of a standards-set-
3 ting organization; or

4 “(vi) addition of an interchangeable term
5 in accordance with section 330.1 of title 21,
6 Code of Federal Regulations (or any successor
7 regulations).

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

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

19 “(i) is—

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

22 “(II) at one geographic location or ad-
23 dress engaged in manufacturing or proc-
24 essing the finished dosage form of an OTC
25 monograph drug;

1 “(ii) includes a finished dosage form man-
2 ufacturer facility in a contractual relationship
3 with the sponsor of one or more OTC mono-
4 graph drugs to manufacture or process such
5 drugs; and

6 “(iii) does not include a business or other
7 entity whose only manufacturing or processing
8 activities are one or more of the following: pro-
9 duction of clinical research supplies, or testing.

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

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

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

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

23 “(C) If a business or other entity would meet
24 criteria specified in subparagraph (A), but for being
25 under multiple management, the business or other

1 entity is deemed to constitute multiple facilities, one
2 per management entity, for purposes of this para-
3 graph.

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

7 “(12) The term ‘person’ includes an affiliate of
8 a person.

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

11 **“SEC. 7440. AUTHORITY TO ASSESS AND USE OTC MONO-
12 GRAPH FEES.**

13 “(a) TYPES OF FEES.—Beginning with fiscal year
14 2019, the Secretary shall assess and collect fees in accord-
15 ance with this section as follows:

16 “(1) FACILITY FEE.—

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

24 “(B) EXCEPTIONS.—

1 “(i) A fee shall not be assessed under
2 subparagraph (A) if the identified OTC
3 monograph drug facility has ceased all ac-
4 tivities related to OTC monograph drugs
5 prior to the date specified in subparagraph
6 (D)(ii) and has updated its registration to
7 reflect such change under the requirements
8 for drug establishment registration set
9 forth in section 510.

10 “(ii) The amount of the fee for a con-
11 tract manufacturing organization facility
12 shall be equal to $\frac{2}{3}$ the amount of the fee
13 for an OTC monograph drug facility that
14 is not a contract manufacturing organiza-
15 tion facility.

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

19 “(D) DUE DATE.—

20 “(i) FOR FIRST PROGRAM YEAR.—For
21 fiscal year 2019, the facility fees required
22 under subparagraph (A) shall be due 45
23 calendar days after publication of the Fed-
24 eral Register notice provided for under
25 subsection (c)(4)(A).

1 “(ii) SUBSEQUENT FISCAL YEARS.—
2 For each fiscal year after fiscal year 2019,
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 infla-
24 tion 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.

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

20 “(G) REFUND OF FEE IF ORDER REQUEST
21 WITHDRAWN.—If an order request is withdrawn
22 after the order request was filed, the Secretary
23 may refund the fee or a portion of the fee if no
24 substantial work was performed on the order
25 request after the application was filed. The Sec-

1 retary shall have the sole discretion to refund a
2 fee or a portion of the fee under this subpara-
3 graph. A determination by the Secretary con-
4 cerning a refund under this subparagraph shall
5 not be reviewable.

6 “(3) REFUNDS.—

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

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

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

22 “(b) FEE REVENUE AMOUNTS.—

23 “(1) FISCAL YEAR 2019.—For fiscal year 2019,
24 fees under subsection (a)(1) shall be established to

1 generate a total facility fee revenue amount equal to
2 the sum of—

3 “(A) the annual base revenue for fiscal
4 year 2019 (as determined under paragraph (3));

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

9 “(C) additional direct cost adjustments (as
10 determined under subsection (c)(3)).

11 “(2) SUBSEQUENT FISCAL YEARS.—For each of
12 the fiscal years 2020 through 2023, fees under sub-
13 section (a)(1) shall be established to generate a total
14 facility fee revenue amount equal to the sum of—

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

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

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

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

1 “(E) additional dollar amounts for each
2 fiscal year as follows:

3 “(i) \$7,000,000 for fiscal year 2020.

4 “(ii) \$6,000,000 for fiscal year 2021.

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

6 “(iv) \$3,000,000 for fiscal year 2023.

7 “(3) ANNUAL BASE REVENUE.—For purposes
8 of paragraphs (1)(A) and (2)(A), the dollar amount
9 of the annual base revenue for a fiscal year shall
10 be—

11 “(A) for fiscal year 2019, \$8,000,000; and

12 “(B) for fiscal years 2020 through 2023,
13 the dollar amount of the total revenue amount
14 established under this subsection for the pre-
15 vious fiscal year, not including any adjustments
16 made under subsection (c)(2) or (c)(3).

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

18 “(1) INFLATION ADJUSTMENT.—

19 “(A) IN GENERAL.—For purposes of sub-
20 section (b)(2)(B), the dollar amount of the in-
21 flation adjustment to the annual base revenue
22 for fiscal year 2020 and each subsequent fiscal
23 year shall be equal to the product of—

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

1 “(ii) the inflation adjustment percent-
2 age under subparagraph (C).

3 “(B) OTC MONOGRAPH ORDER REQUEST
4 FEES.—For purposes of subsection (a)(2), the
5 dollar amount of the inflation adjustment to the
6 fee for OTC monograph order requests for fis-
7 cal year 2020 and each subsequent fiscal year
8 shall be equal to the product of—

9 “(i) the applicable fee under sub-
10 section (a)(2) for the preceding fiscal year;
11 and

12 “(ii) the inflation adjustment percent-
13 age under subparagraph (C).

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

18 “(i) for each of fiscal years 2020 and
19 2021, the average annual percent change
20 that occurred in the Consumer Price Index
21 for urban consumers (Washington-Balti-
22 more, DC–MD–VA–WV; Not Seasonally
23 Adjusted; All items; Annual Index) for the
24 first 3 years of the preceding 4 years of
25 available data; and

1 “(ii) for each of fiscal years 2022 and
2 2023, the sum of—

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

16 “(II) the average annual percent
17 change that occurred in the Consumer
18 Price Index for urban consumers
19 (Washington-Baltimore, DC–MD–VA–
20 WV; Not Seasonally Adjusted; All
21 items; Annual Index) for the first 3
22 years of the preceding 4 years of
23 available data multiplied by the pro-
24 portion of all costs other than per-
25 sonnel compensation and benefits

1 costs to total costs of OTC mono-
2 graph drug activities for the first 3
3 years of the preceding 4 fiscal years.

4 “(2) OPERATING RESERVE ADJUSTMENT.—

5 “(A) IN GENERAL.—For fiscal year 2019
6 and subsequent fiscal years, for purposes of
7 subsections (b)(1)(B) and (b)(2)(C), the Sec-
8 retary may, in addition to adjustments under
9 paragraph (1), further increase the fee revenue
10 and fees if such an adjustment is necessary to
11 provide operating reserves of carryover user
12 fees for OTC monograph drug activities for not
13 more than the number of weeks specified in
14 subparagraph (B).

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

17 “(i) 3 weeks for fiscal year 2019;

18 “(ii) 7 weeks for fiscal year 2020;

19 “(iii) 10 weeks for fiscal year 2021;

20 “(iv) 10 weeks for fiscal year 2022;

21 and

22 “(v) 10 weeks for fiscal year 2023.

23 “(C) DECREASE.—If the Secretary has
24 carryover balances for such process in excess of
25 10 weeks of the operating reserves referred to

1 in subparagraph (A), the Secretary shall de-
2 crease the fee revenue and fees referred to in
3 such subparagraph to provide for not more than
4 10 weeks of such operating reserves.

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

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

17 “(A) \$14,000,000 for fiscal year 2019;

18 “(B) \$7,000,000 for fiscal year 2020;

19 “(C) \$4,000,000 for fiscal year 2021;

20 “(D) \$3,000,000 for fiscal year 2022; and

21 “(E) \$3,000,000 for fiscal year 2023.

22 “(4) ANNUAL FEE SETTING.—

23 “(A) FISCAL YEAR 2019.—The Secretary
24 shall, not later than January 31, 2019—

1 “(i) establish OTC monograph drug
2 facility fees for fiscal year 2019 under sub-
3 section (a), based on the revenue amount
4 for such year under subsection (b) and the
5 adjustments provided under this sub-
6 section; and

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

10 “(B) SUBSEQUENT FISCAL YEARS.—The
11 Secretary shall, not later than January 31 of
12 each fiscal year that begins after September 30,
13 2019, establish for each such fiscal year, based
14 on the revenue amounts under subsection (b)
15 and the adjustments provided under this sub-
16 section—

17 “(i) OTC monograph drug facility fees
18 under subsection (a)(1);

19 “(ii) OTC monograph order request
20 fees under subsection (a)(2); and

21 “(iii) publish such fee revenue
22 amounts, facility fees, and OTC mono-
23 graph order request fees in the Federal
24 Register.

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

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

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

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

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

14 “(A) IN GENERAL.—Failure to pay the fee
15 under subsection (a)(1) within 20 calendar days
16 of the due date as specified in subparagraph
17 (D) of such subsection shall result in the fol-
18 lowing:

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

21 “(ii) All OTC monograph drugs man-
22 ufactured in such a facility or containing
23 an ingredient manufactured in such a facil-
24 ity shall be deemed misbranded under sec-
25 tion 502(a).

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

4 “(2) ORDER REQUESTS.—An OTC monograph
5 order request submitted by a person subject to fees
6 under subsection (a) shall be considered incomplete
7 and shall not be accepted for filing by the Secretary
8 until all fees owed by such person under this section
9 have been paid.

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

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

15 “(1) IN GENERAL.—Subject to paragraph
16 (2)(D), fees authorized under subsection (a) shall be
17 collected and available for obligation only to the ex-
18 tent and in the amount provided in advance in ap-
19 propriations Acts. Such fees are authorized to re-
20 main available until expended. Such sums as may be
21 necessary may be transferred from the Food and
22 Drug Administration salaries and expenses appro-
23 priation account without fiscal year limitation to
24 such appropriation account for salaries and expenses
25 with such fiscal year limitation. The sums trans-

1 ferred shall be available solely for OTC monograph
2 drug activities.

3 “(2) COLLECTIONS AND APPROPRIATION
4 ACTS.—

5 “(A) IN GENERAL.—Subject to subpara-
6 graphs (C) and (D), the fees authorized by this
7 section shall be collected and available in each
8 fiscal year in an amount not to exceed the
9 amount specified in appropriation Acts, or oth-
10 erwise made available for obligation, for such
11 fiscal year.

12 “(B) USE OF FEES AND LIMITATION.—
13 The fees authorized by this section shall be
14 available to defray increases in the costs of the
15 resources allocated for OTC monograph drug
16 activities (including increases in such costs for
17 an additional number of full-time equivalent po-
18 sitions in the Department of Health and
19 Human Services to be engaged in such activi-
20 ties), only if the Secretary allocates for such
21 purpose an amount for such fiscal year (exclud-
22 ing amounts from fees collected under this sec-
23 tion) no less than \$12,000,000, multiplied by
24 the adjustment factor applicable to the fiscal
25 year involved under subsection (c)(1).

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

8 “(D) FEE COLLECTION DURING FIRST
9 PROGRAM YEAR.—Until the date of the enact-
10 ment of an Act making appropriations and pro-
11 viding for the collection and obligation of fees
12 under this section through September 30, 2019,
13 for the salaries and expenses account of the
14 Food and Drug Administration, fees authorized
15 by this section for fiscal year 2019 may be col-
16 lected and shall be credited to such account and
17 remain available until expended.

18 “(E) PROVISION FOR EARLY PAYMENTS IN
19 SUBSEQUENT YEARS.—Payment of fees author-
20 ized under this section for a fiscal year (after
21 fiscal year 2019), prior to the due date for such
22 fees, may be accepted by the Secretary in ac-
23 cordance with authority provided in advance in
24 a prior year appropriations Act.

1 House of Representatives and the Committee on Health,
2 Education, Labor, and Pensions of the Senate a report
3 concerning the progress of the Food and Drug Adminis-
4 tration in achieving the goals identified in the letters de-
5 scribed in section 201(b) of the Over-the-Counter Mono-
6 graph Safety, Innovation, and Reform Act of 2018 during
7 such fiscal year and the future plans of the Food and
8 Drug Administration for meeting such goals.

9 “(b) FISCAL REPORT.—Not later than 120 calendar
10 days after the end of fiscal year 2019 and each subsequent
11 fiscal year for which fees are collected under this part,
12 the Secretary shall prepare and submit to the Committee
13 on Energy and Commerce of the House of Representatives
14 and the Committee on Health, Education, Labor, and
15 Pensions of the Senate a report on the implementation
16 of the authority for such fees during such fiscal year and
17 the use, by the Food and Drug Administration, of the fees
18 collected for such fiscal year.

19 “(c) PUBLIC AVAILABILITY.—The Secretary shall
20 make the reports required under subsections (a) and (b)
21 available to the public on the Internet website of the Food
22 and Drug Administration.

23 “(d) REAUTHORIZATION.—

24 “(1) CONSULTATION.—In developing rec-
25 ommendations to present to the Congress with re-

1 spect to the goals described in subsection (a), and
2 plans for meeting the goals, for OTC monograph
3 drug activities for the first 5 fiscal years after fiscal
4 year 2023, and for the reauthorization of this part
5 for such fiscal years, the Secretary shall consult
6 with—

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

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

11 “(C) scientific and academic experts;

12 “(D) health care professionals;

13 “(E) representatives of patient and con-
14 sumer advocacy groups; and

15 “(F) the regulated industry.

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

19 “(A) present the recommendations devel-
20 oped under paragraph (1) to the congressional
21 committees specified in such paragraph;

22 “(B) publish such recommendations in the
23 Federal Register;

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

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

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

10 “(3) TRANSMITTAL OF RECOMMENDATIONS.—
11 Not later than January 15, 2023, the Secretary
12 shall transmit to the Congress the revised rec-
13 ommendations under paragraph (2), a summary of
14 the views and comments received under such para-
15 graph, and any changes made to the recommenda-
16 tions in response to such views and comments.”.

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