

115TH CONGRESS
1ST SESSION

H. R. _____

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

M. _____ introduced the following bill; which was referred to the Committee on _____

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 CURRENTLY MAR-
12 KETED WITHOUT AN APPROVED NEW DRUG APPLICA-
13 TION.—Drugs marketed without an approved new drug
14 application under section 505, as of the date of the enact-
15 ment of the Over-the-Counter Monograph Safety, Innova-
16 tion, and Reform Act of 2018, shall be treated in accord-
17 ance with this 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 admin-
10 istrative order issued under subsection (b)
11 or, in the case of a minor change in the
12 drug, in conformity with an order issued
13 under subsection (c), in a dosage form
14 that, immediately prior to the date of the
15 enactment of this section, has been used to
16 a material extent and for a material time
17 within the 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 by an ad-
9 ministrative order issued under subsection
10 (b) or, in the case of a minor change in the
11 drug, in conformity with an order issued
12 under subsection (c), in a dosage form
13 that, immediately prior to the date of the
14 enactment of this section, has been used to
15 a material extent and for a material time
16 within the meaning of section 201(p)(2).

17 “(2) DRUGS SUBJECT TO A FINAL ADMINISTRA-
18 TIVE ORDER.—A drug is deemed to be generally rec-
19 ognized as safe and effective within the meaning of
20 section 201(p)(1), not a new drug under section
21 201(p), and not subject to section 503(b)(1), if the
22 drug is in conformity with—

23 “(A) the requirements of a final adminis-
24 trative order issued under subsection (b) deter-
25 mining that such drug is generally recognized

1 as safe and effective within the meaning of sec-
2 tion 201(p)(1);

3 “(B) the general requirements for non-
4 prescription drugs; and

5 “(C) any requirements under subsections
6 (b), (c), and (k).

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

15 “(A) the drug is—

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

23 “(ii) in conformity with—

24 “(I) the conditions of use, includ-
25 ing indication and dosage strength, if

1 any, described for such category III
2 drug in such preamble or in an appli-
3 cable subsequent proposed rule;

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

12 “(III) the general requirements
13 for nonprescription drugs and require-
14 ments under subsections (b) or (k);
15 and

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

25 “(B) the drug is—

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

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

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

21 “(4) CATEGORY II DRUGS DEEMED NEW
22 DRUGS.—A drug that is classified in category II for
23 safety or effectiveness in a preamble of a proposed
24 rule establishing a tentative final monograph that is
25 the most recently applicable proposal issued under

1 part 330 of title 21, Code of Federal Regulations,
2 shall be deemed to be a new drug within the mean-
3 ing of section 201(p), misbranded under section
4 502(ee), and subject to the requirement for an ap-
5 proved new drug application under section 505 be-
6 ginning on the day that is 180 calendar days after
7 the date of the enactment of this section, unless, be-
8 fore such day, the Secretary determines that it is in
9 the interest of public health to extend the period
10 during which the drug may be marketed without
11 such an approved new drug application.

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

22 “(6) TREATMENT OF SUNSCREEN DRUGS.—
23 With respect to sunscreen drugs subject to this sec-
24 tion, the applicable requirements shall be those set
25 out at part 352 of title 21, Code of Federal Regula-

1 tions, as published at volume 64 page 27687 of the
2 Federal Register, except that the applicable require-
3 ments governing effectiveness and labeling shall be
4 those specified in section 201.327 of title 21, Code
5 of Federal Regulations, subject to any changes to
6 such requirements under subsections (b) or (k)(2).

7 “(7) OTHER DRUGS DEEMED NEW DRUGS.—
8 Except as provided in subsection (m), a drug is
9 deemed to be a new drug within the meaning of sec-
10 tion 201(p) and misbranded under section 502(ee) if
11 the drug—

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

13 and

14 “(B) is not described in paragraphs (1),
15 (2), (3), (4), (5), or (6).

16 “(b) ADMINISTRATIVE ORDERS.—

17 “(1) IN GENERAL.—

18 “(A) DETERMINATION.—The Secretary
19 may, on the initiative of the Secretary or at the
20 request of one or more requestors, issue admin-
21 istrative orders determining whether there are
22 conditions under which specific drugs, classes of
23 such drugs, or combinations of such drugs are
24 determined to be—

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

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

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

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

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

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

18 “(2) ADMINISTRATIVE ORDERS INITIATED BY
19 THE SECRETARY.—

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

23 “(i) make reasonable efforts to notify
24 informally, not later than 2 business days
25 before the issuance of the proposed order,

1 sponsors of drugs that will be subject to
2 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 within
6 the meaning of section 201(p)(1), the Secretary
7 shall follow the procedures in subparagraph
8 (A), except that—

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

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

17 “(II) the format for submissions
18 by interested persons;

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

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

11 “(3) HEARINGS; JUDICIAL REVIEW.—

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

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

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

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

11 “(II) with respect to which no
12 human or non-human data relevant to
13 the safety or effectiveness of such
14 drug have been submitted to the ad-
15 ministrative record since the issuance
16 of the most recent tentative final
17 monograph relating to such drug.

18 “(ii) HUMAN AND NON-HUMAN DATA
19 DEFINED.—In this subparagraph:

20 “(I) The term ‘human data’
21 means data from any testing with
22 human subjects, including clinical
23 trials of safety or effectiveness (in-
24 cluding actual use studies), pharmaco-
25 kinetics, bioavailability, label com-

1 prehension studies (including self-se-
2 lection studies), or human factors.

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

8 “(C) HEARING PROCEDURES.—

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

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

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

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

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

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

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

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

1 ties representing substantially the same in-
2 terests be consolidated to promote effi-
3 ciency and avoid duplication.

4 “(v) FINAL DECISION.—

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

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

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

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

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

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

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

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

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

21 “(IV) if no hearing is requested,
22 the date on which the time for re-
23 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) generally recognized
22 as safe and effective within the
23 meaning of section 201(p)(1)
24 under subsection (a)(1) or (a)(2);
25 or

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

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

21 “(iii) WITHDRAWAL.—The requestor
22 may withdraw a request under this para-
23 graph, according to the procedures set
24 forth pursuant to subsection (d)(2)(B).
25 Notwithstanding any other provision of

1 this section, if such request is withdrawn,
2 the Secretary may cease proceedings under
3 this subparagraph.

4 “(C) EXCLUSIVITY.—

5 “(i) IN GENERAL.—A final adminis-
6 trative order issued in response to a re-
7 quest under this section shall have the ef-
8 fect of authorizing solely the order re-
9 questor (or the licensees, assignees, or suc-
10 cessors in interest of such requestor with
11 respect to the subject of such order), for a
12 period of **[24 months]**, to market drugs
13 under this section—

14 “(I) incorporating changes de-
15 scribed in clause (ii);

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

21 “(III) subject to the limitations
22 under clause (iv).

23 “(ii) CHANGES DESCRIBED.—A
24 change described in this clause is a change

1 subject to an order specified in clause (i),
2 which—

3 “(I) provides for a drug to con-
4 tain an active ingredient not pre-
5 viously incorporated in a marketed
6 drug listed in clause (iii); or

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

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

17 “(I) marketed in accordance with
18 a final monograph issued under part
19 330 of title 21, Code of Federal Regu-
20 lations (including conditions of use
21 thereunder), as in effect as of the date
22 of the enactment of this section;

23 “(II) marketed as category I or
24 III in accordance with a tentative
25 final monograph issued under part

1 330 of title 21, Code of Federal Regu-
2 lations (including conditions of use
3 and any applicable subsequent deter-
4 minations thereunder), as in effect on
5 such date of enactment;

6 “(III) marketed as category I in
7 accordance with an advance notice of
8 proposed rulemaking issued under
9 part 330 of title 21, Code of Federal
10 Regulations (including conditions of
11 use and any applicable subsequent de-
12 terminations thereunder), as in effect
13 on such date of enactment;

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

17 “(V) marketed in accordance
18 with a final sunscreen order (as de-
19 fined in section 586(2)(A)) as of the
20 date of enactment of this section; or

21 “(VI) described in subsection
22 (m)(1), other than drugs subject to an
23 active enforcement action under chap-
24 ter III of this Act.

1 “(iv) LIMITATIONS ON EXCLU-
2 SIVITY.—

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

9 “(aa) changes described in
10 clause (ii)(I), relating to active
11 ingredients; or

12 “(bb) changes described in
13 clause (ii)(II), relating to condi-
14 tions of use.

15 “(II) NO EXCLUSIVITY AL-
16 LOWED.—No exclusivity shall apply to
17 changes to a drug which are—

18 “(aa) the subject of a Tier 2
19 OTC monograph order request
20 (as defined in section 744N);

21 “(bb) safety-related changes,
22 as defined by the Secretary, or
23 any other changes the Secretary
24 considers necessary to assure
25 safe use; or

1 “(cc) changes related to
2 methods of testing safety or effi-
3 cacy.

4 “(v) HUMAN DATA DEFINED.—In this
5 subparagraph, the term ‘human data’
6 means data from clinical trials of safety or
7 effectiveness (including actual use studies),
8 pharmacokinetics, or bioavailability stud-
9 ies.

10 “(6) INFORMATION REGARDING SAFE NON-
11 PRESCRIPTION MARKETING AND USE AS CONDITION
12 FOR FILING A GENERALLY RECOGNIZED AS SAFE
13 AND EFFECTIVE REQUEST.—

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

18 “(i) may file such request, if the re-
19 quest includes information specified under
20 subparagraph (C) with respect to safe non-
21 prescription marketing and use of such
22 drug; or

23 “(ii) if the request fails to include in-
24 formation specified under subparagraph
25 (C), shall refuse to file such request and

1 require that nonprescription marketing of
2 the drug be pursuant to a new drug appli-
3 cation as described in subparagraph (D).

4 “(B) DRUG DESCRIBED.—A drug de-
5 scribed in this subparagraph is a nonprescrip-
6 tion drug which contains an active ingredient
7 not previously incorporated—

8 “(i) in a drug marketed in accordance
9 with a final monograph issued under part
10 330 of title 21, Code of Federal Regula-
11 tions (including conditions of use there-
12 under), as in effect on the day before the
13 date of the enactment of this section;

14 “(ii) in a drug marketed as category
15 I in accordance with a tentative final
16 monograph issued under part 330 of title
17 21, Code of Federal Regulations (including
18 conditions of use and any applicable subse-
19 quent determinations thereunder), as in ef-
20 fect on such day; or

21 “(iii) in a drug marketed in accord-
22 ance with a final order issued under this
23 section.

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 of time as
22 needed to provide reasonable assur-
23 ances concerning the safe nonprescrip-
24 tion use 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 clauses (i) or (ii)
10 is 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 re-submitted 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 of time as the
24 Secretary determines appropriate (not to
25 exceed five consecutive years) pursuant to

1 an application approved under section 505;
2 and

3 “(ii) during such time period, one mil-
4 lion retail packages of the drug, or an
5 equivalent quantity as determined by the
6 Secretary, were distributed for retail sale,
7 as 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 chil-
22 dren, requirements to reduce risk of harm from un-
23 supervised ingestion, and other appropriate require-
24 ments. This paragraph does not authorize the Food
25 and Drug Administration to require standards or

1 testing procedures as described in part 1700 of title
2 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.—Subject to subpara-
7 graph (B), a final monograph or tentative final
8 monograph establishing conditions of use for a
9 drug described in subsection (a)(1), shall be
10 deemed to be a final administrative order under
11 this subsection and may be amended, revoked,
12 or otherwise modified in accordance with the
13 procedures of this subsection.

14 “(B) DEEMED ORDERS INCLUDE HARMO-
15 NIZING TECHNICAL AMENDMENTS.—The
16 deemed establishment of a final administrative
17 order under subparagraph (A) shall be con-
18 strued to include any technical amendments to
19 such order as the Secretary determines nec-
20 essary to ensure that such order is appro-
21 priately harmonized, in terms of terminology or
22 cross-references, with the applicable provisions
23 of this Act (and regulations thereunder) and
24 any other orders issued under this section.

25 “(c) PROCEDURE FOR MINOR CHANGES.—

1 “(1) IN GENERAL.—Minor changes in the dos-
2 age form of a drug that is described in paragraph
3 (1) or (2) of subsection (a) may be made by a re-
4 questor without the issuance of an administrative
5 order under subsection (b) if—

6 “(A) the requestor maintains such infor-
7 mation as is necessary to demonstrate that the
8 change—

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

11 “(ii) will not materially affect the ex-
12 tent of absorption or other exposure to the
13 active ingredient in comparison to a suit-
14 able reference product; and

15 “(B) the change is in conformity with the
16 requirements of an applicable administrative
17 order issued by the Secretary under paragraph
18 (3).

19 “(2) ADDITIONAL INFORMATION.—

20 “(A) ACCESS TO RECORDS.—A sponsor
21 shall submit records requested by the Secretary
22 relating to such a minor change under section
23 704(a)(4), within 15 business days of receiving
24 such a request, or such longer period as the
25 Secretary may provide.

1 “(B) INSUFFICIENT INFORMATION.—If the
2 Secretary determines that the information con-
3 tained in such records is not sufficient to dem-
4 onstrate that the change does not affect the
5 safety or effectiveness of the drug or materially
6 affect the extent of absorption or other expo-
7 sure to the active ingredient, the Secretary—

8 “(i) may so inform the sponsor of the
9 drug in writing; and

10 “(ii) provide the sponsor of the drug
11 with a reasonable opportunity to provide
12 additional information.

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

1 “(3) DETERMINING WHETHER A CHANGE WILL
2 AFFECT SAFETY OR EFFECTIVENESS.—

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

13 “(B) STANDARD PRACTICES.—The orders
14 and guidance issued by the Secretary under
15 subparagraph (A) shall take into account rel-
16 evant public standards and standard practices
17 for evaluating the quality of drugs, and may
18 take into account the special needs of popu-
19 lations, including children.

20 “(d) CONFIDENTIALITY OF INFORMATION SUB-
21 MITTED BY REQUESTORS.—

22 “(1) IN GENERAL.—Subject to paragraph (2),
23 any information, including reports of testing con-
24 ducted on the drug or drugs involved, that is sub-
25 mitted by a requestor in connection with proceedings

1 on an administrative order under this section (or
2 any minor change under subsection (c)) and is a
3 trade secret or confidential information subject to
4 section 552(b)(4) of title 5, United States Code, or
5 section 1905 of title 18, United States Code, shall
6 not be disclosed to the public unless the requestor
7 consents to that disclosure.

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

14 “(A) the information pertains to pharma-
15 ceutical quality information which is necessary
16 to establish standards under which a drug is
17 generally recognized as safe and effective within
18 the meaning of section 201(p)(1);

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

1 “(C) the Secretary obtains the information
2 under subsection (c).

3 “(e) UPDATES TO DRUG LISTING INFORMATION.—
4 A sponsor who makes a change to a drug subject to this
5 section shall submit updated drug listing information for
6 the drug in accordance with the requirements of section
7 510(j) within 30 calendar days of the date the drug is
8 first introduced or delivered for introduction into inter-
9 state commerce with the change.

10 “(f) APPROVALS UNDER SECTION 505.—The provi-
11 sions of this section shall not be construed to preclude a
12 person from seeking or maintaining the approval of a drug
13 under sections 505(b)(1), 505(b)(2), and 505(j). A deter-
14 mination under this section that a drug is not subject to
15 section 503(b)(1), is generally recognized as safe and ef-
16 fective within the meaning of section 201(p)(1), and is not
17 a new drug under section 201(p) shall constitute a finding
18 that the drug is safe and effective that may be relied upon
19 for purposes of an application under section 505(b)(2), so
20 that the applicant shall be required to submit for purposes
21 of such application only information needed to support any
22 modification of the drug that is not covered by such deter-
23 mination under this section.

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

1 (as determined necessary by the Secretary but no less fre-
2 quently than annually), and make publicly available, with
3 respect to administrative orders issued under this sec-
4 tion—

5 “(1) a repository of each final administrative
6 order and interim final order in effect, including the
7 complete text of the administrative order; and

8 “(2) a listing of all administrative orders pro-
9 posed and under development under subsection
10 (b)(2), including—

11 “(A) a brief description of each such ad-
12 ministrative order; and

13 “(B) the Secretary’s expectations, if re-
14 sources permit, for issuance of proposed admin-
15 istrative orders over a three-year period.

16 “(h) DEVELOPMENT ADVICE TO SPONSORS OR RE-
17 QUESTORS.—The Secretary shall establish procedures
18 under which sponsors or requestors may meet with appro-
19 priate officials of the Food and Drug Administration to
20 obtain advice on the studies and other information nec-
21 essary to support submissions under this section and other
22 matters relevant to the regulation of nonprescription
23 drugs and the development of new nonprescription drugs
24 under this section.

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

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

10 “(k) EFFECT ON EXISTING REGULATIONS GOV-
11 ERNING NONPRESCRIPTION DRUGS.—

12 “(1) REGULATIONS OF GENERAL APPLICA-
13 BILITY TO NONPRESCRIPTION DRUGS.—Except as
14 provided in this subsection, nothing in this section
15 supersedes regulations establishing general require-
16 ments for nonprescription drugs, including regula-
17 tions of general applicability contained in parts 201,
18 250, and 330 of title 21, Code of Federal Regula-
19 tions, or any successor regulations. The Secretary
20 shall establish or modify such regulations by means
21 of rulemaking in accordance with section 553 of title
22 5, United States Code.

23 “(2) REGULATIONS ESTABLISHING REQUIRE-
24 MENTS FOR SPECIFIC NONPRESCRIPTION DRUGS.—

1 “(A) The provisions of section 310.545 of
2 title 21, Code of Federal Regulations, as in ef-
3 fect on the date of the enactment of this sec-
4 tion, shall be deemed to be a final administra-
5 tive order under subsection (b).

6 “(B) Regulations in effect on the date im-
7 mediately before the date of the enactment of
8 this section, establishing requirements for spe-
9 cific nonprescription drugs marketed pursuant
10 to this section (including such requirements in
11 parts 201 and 250 of title 21, Code of Federal
12 Regulations), shall be deemed to be final ad-
13 ministrative orders under subsection (b), only
14 as they apply to drugs subject to paragraphs
15 (1), (2), (3), and (6) of subsection (a).

16 “(3) WITHDRAWAL OF REGULATIONS.—The
17 Secretary shall withdraw regulations establishing
18 final monographs and the procedures governing the
19 over-the-counter drug review under part 330 and
20 other relevant parts of title 21, Code of Federal
21 Regulations (as in effect on the day preceding the
22 date of the enactment of this section) or make tech-
23 nical changes to such regulations to ensure con-
24 formity with appropriate terminology and cross ref-
25 erences. Notwithstanding subchapter II of chapter 5

1 of title 5, United States Code, any such withdrawal
2 or technical changes shall be made without public
3 notice and comment and shall be effective upon pub-
4 lication through notice in the Federal Register (or
5 upon such date as specified in such notice).

6 “(l) GUIDANCE.—The Secretary shall issue guidance
7 that specifies—

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

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

13 “(3) the format of electronic submissions to the
14 Secretary under this section;

15 “(4) consolidated proceedings and the proce-
16 dures for such proceedings where appropriate; and

17 “(5) for minor changes in drugs, recommenda-
18 tions on how to comply with the requirements in ad-
19 ministrative orders issued under subsection (c)(3).

20 “(m) RULE OF CONSTRUCTION.—

21 “(1) IN GENERAL.—This section shall not af-
22 fect the treatment or status of a nonprescription
23 drug—

1 “(A) that is marketed without an applica-
2 tion approved under section 505 as of the date
3 of the enactment of this section;

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

6 “(C) to which paragraphs (1), (2), (3), (4),
7 (5), or (6) of subsection (a) do not apply.

8 “(2) TREATMENT OF PRODUCTS PREVIOUSLY
9 FOUND TO BE SUBJECT TO TIME AND EXTENT RE-
10 QUIREMENTS.—

11 “(A) Notwithstanding subsection (a), a
12 drug described in subparagraph (B) may only
13 be lawfully marketed, without an application
14 approved under section 505, pursuant to an
15 order issued under this section.

16 “(B) A drug described in this subpara-
17 graph is a drug which, prior to the date of the
18 enactment of this section, the Secretary had de-
19 termined in a proposed or final rule to be ineli-
20 gible for review under the OTC drug review (as
21 such phrase ‘OTC drug review’ was used in sec-
22 tion 330.14 of title 21, Code of Federal Regula-
23 tions, as in effect on the day before the date of
24 the enactment of this section).

25 “(3) PRESERVATION OF AUTHORITY.—

1 “(A) Nothing in this subsection shall be
2 construed to preclude or limit the applicability
3 of any other provision of this Act.

4 “(B) Nothing in this subsection shall be
5 construed to prohibit the Secretary from issuing
6 an order under this section finding a drug to be
7 not generally recognized as safe and effective
8 within the meaning of section 201(p)(1), as the
9 Secretary determines appropriate.

10 “(n) INAPPLICABILITY OF PAPERWORK REDUCTION
11 ACT.—Chapter 35 of title 44, United States Code, shall
12 not apply to collections of information made under this
13 section.

14 “(o) INAPPLICABILITY OF NOTICE AND COMMENT
15 RULEMAKING REQUIREMENTS.—The requirements of
16 subsection (b) shall apply with respect to administrative
17 orders issued under this section instead of the require-
18 ments of subchapter II of chapter 5 of title 5, United
19 States Code.

20 “(p) DEFINITIONS.—In this section:

21 “(1) The term ‘nonprescription drug’ refers to
22 a drug not subject to the requirements of section
23 503(b)(1).

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

4 “(A) is listed pursuant to section 510(j);
5 and

6 “(B) is or will be subject to an administra-
7 tive order of the Food and Drug Administra-
8 tion.

9 “(3) the term ‘requestor’ refers to any person
10 or group of persons marketing, manufacturing, proc-
11 essing, or developing a drug.”.

12 **SEC. 102. MISBRANDING.**

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

16 “(ee) If it is a nonprescription drug that is subject
17 to section 505G, 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 7440.”.

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 which was excluded by the Food and
6 Drug Administration from the Over-the-Counter Drug Re-
7 view in accordance with the statement set out at page
8 9466 of volume 37 of the Federal Register, published on
9 May 11, 1972.

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

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

15 (a) REVIEW OF NONPRESCRIPTION SUNSCREEN AC-
16 TIVE INGREDIENTS.—

17 (1) APPLICABILITY OF SECTION 505G FOR
18 PENDING SUBMISSIONS.—

19 (A) IN GENERAL.—A sponsor of a non-
20 prescription sunscreen active ingredient or com-
21 bination of nonprescription sunscreen active in-
22 gredients that, as of the date of enactment of
23 this Act, is subject to a proposed sunscreen
24 order may elect, by means of giving notification
25 to the Secretary of Health and Human Serv-
26 ices, to transition into the review of such ingre-

1 dient or combination of ingredients pursuant to
2 the process set out in section 505G of such Act,
3 as added by section 101 of this Act.

4 (B) ELECTION EXERCISED.—Upon receipt
5 by the Secretary of Health and Human Services
6 of a notification under subparagraph (A)—

7 (i) the proposed sunscreen order in-
8 volved is deemed to be a request for an ad-
9 ministrative order under subsection (b) of
10 section 505G of the Federal Food, Drug,
11 and Cosmetic Act, as added by section 101
12 of this Act; and

13 (ii) such administrative order is
14 deemed to have been accepted for filing
15 under subsection (b)(6)(A)(i) of such sec-
16 tion 505G.

17 (C) ELECTION NOT EXERCISED.—A spon-
18 sor of a nonprescription sunscreen active ingre-
19 dient or combination of nonprescription sun-
20 screen active ingredients described in subpara-
21 graph (A) that does not elect for such ingre-
22 dient or combination of ingredients to be re-
23 viewed under section 505G of the Federal Food,
24 Drug, and Cosmetic Act, as added by section
25 101 of this Act, shall continue to have such in-

1 ingredient or combination of ingredients reviewed
2 in accordance with section 586C of such Act
3 (21 U.S.C. 360fff-3).

4 (2) DEFINITIONS.—In this subsection, the
5 terms “sponsor”, “nonprescription”, “sunscreen ac-
6 tive ingredient”, and “proposed sunscreen order”
7 have the meanings given to those terms in section
8 586 of the Federal Food, Drug, and Cosmetic Act
9 (21 U.S.C. 360fff).

10 (b) AMENDMENTS TO SUNSCREEN PROVISIONS.—

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

15 “(3) RELATIONSHIP TO ORDERS UNDER SEC-
16 TION 505G.—A final sunscreen order shall be deemed
17 to be a final administrative order under section
18 505G.”.

19 【(2) MEETINGS.—Paragraph (7) of section
20 586C(b) of the Federal Food, Drug, and Cosmetic
21 Act (21 U.S.C. 360fff-3(b)) is amended—】

22 【(A) by striking “A sponsor may request”
23 and inserting the following:】

24 【“(A) IN GENERAL.—A sponsor may re-
25 quest”; and】

1 [(B) by adding at the end the following:]

2 [“(B) CONFIDENTIAL MEETINGS.—[A
3 sponsor may request one or more confidential
4 meetings with respect to a proposed sunscreen
5 order, including a letter deemed to be a pro-
6 posed sunscreen order under paragraph (3), to
7 discuss matters involving confidential commer-
8 cial information or trade secrets. The Secretary
9 shall convene a confidential meeting with such
10 sponsor in a reasonable time period. If a spon-
11 sor requests more than one confidential meeting
12 for the same proposed sunscreen order, the Sec-
13 retary may refuse to grant an additional con-
14 fidential meeting request if the Secretary deter-
15 mines that such additional confidential meeting
16 is not reasonably necessary for the sponsor to
17 advance such proposed sunscreen order. The
18 Secretary shall publish a post-meeting summary
19 of each confidential meeting under this sub-
20 paragraph that does not disclose confidential
21 commercial information or trade secrets.]”.]

22 (3) SUNSET PROVISION.—Subchapter I of chap-
23 ter V of the Federal Food, Drug, and Cosmetic Act
24 (21 U.S.C. 360fff et seq.) is amended by adding at
25 the end the following:

1 **“SEC. 586H. SUNSET.**

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

4 (c) TREATMENT OF NON-SUNSCREEN TIME AND EX-
5 TENT APPLICATIONS.—

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

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

21 **SEC. 105. ANNUAL UPDATE TO CONGRESS ON APPRO-**
22 **PRIATE PEDIATRIC INDICATION FOR CER-**
23 **TAIN OTC COUGH AND COLD DRUGS.**

24 (a) IN GENERAL.—Subject to subsection (c), the Sec-
25 retary of Health and Human Services shall, beginning not
26 later than one year after the date of enactment of this

1 Act, annually submit to the Committee on Energy and
2 Commerce of the House of Representatives and the Com-
3 mittee on Health, Education, Labor, and Pensions of the
4 Senate a letter describing the progress of the Food and
5 Drug Administration—

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

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

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

1 (c) DURATION OF AUTHORITY.—The requirement
2 under subsection (a) shall terminate as of the date of a
3 letter submitted by the Secretary of Health and Human
4 Services pursuant to such subsection in which the Sec-
5 retary indicates that the Food and Drug Administration
6 has completed its evaluation and revised, in a final admin-
7 istrative order, as applicable, the cough and cold mono-
8 graph as described in subsection (a)(2).

9 **TITLE II—USER FEES**

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

11 (a) SHORT TITLE.—This title may be cited as the
12 “Over-the-Counter Monograph User Fee Act of 2017”.

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

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

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

5 **“PART 10—FEES RELATING TO OVER-THE-**
6 **COUNTER DRUGS.**

7 **“SEC. 744N. DEFINITIONS.**

8 “In this part:

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

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

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

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

24 “(3) The term ‘costs of resources allocated for
25 OTC monograph drug activities’ means the expenses

1 in connection with OTC monograph drug activities
2 for—

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

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

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

17 “(D) collecting fees under section 744O
18 and accounting for resources allocated for OTC
19 monograph drug activities.

20 “(4) The term ‘FDA establishment identifier’ is
21 the unique number automatically generated by Food
22 and Drug Administration’s Field Accomplishments
23 and Compliance Tracking System (FACTS) (or any
24 successor system).

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

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

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

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

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

21 “(iii) all OTC monograph drug devel-
22 opment and review activities, including
23 intraagency 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 cluding 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 administrative order sub-
11 mitted under section 505G(b)(6).

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 infor-
20 mation in the drug facts label of an OTC
21 monograph drug;

22 “(ii) the addition of information to
23 the other information section of the drug
24 facts label of an OTC monograph drug, as
25 limited by section 201.66(c)(7) of title 21,

1 Code of Federal Regulations (or any suc-
2 cessor regulations);

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

8 “(iv) the standardization of the con-
9 centration or dose of a specific finalized in-
10 gredient within a particular finalized
11 monograph;

12 “(v) a change to ingredient nomen-
13 clature to align with nomenclature of a
14 standards-setting organization; or

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

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

20 “(B) For purposes of subparagraph (A)(i)(II),
21 separate buildings or locations within close proximity
22 are considered to be at one geographic location or
23 address if the activities conducted in such buildings
24 or locations are—

1 “(i) closely related to the same business
2 enterprise;

3 “(ii) under the supervision of the same
4 local management; and

5 “(iii) under a single FDA establishment
6 identifier and capable of being inspected by the
7 Food and Drug Administration during a single
8 inspection.

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

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

18 “(12) The term ‘person’ includes an affiliate of
19 a person.

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

1 **“SEC. 7440. AUTHORITY TO ASSESS AND USE OTC MONO-**
2 **GRAPH FEES.**

3 “(a) TYPES OF FEES.—Beginning with fiscal year
4 2018, the Secretary shall assess and collect fees in accord-
5 ance with this section as follows:

6 “(1) FACILITY FEE.—

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

14 “(B) EXCEPTIONS.—

15 “(i) A fee shall not be assessed under
16 subparagraph (A) if the identified OTC
17 monograph drug facility has ceased all ac-
18 tivities related to OTC monograph drugs
19 prior to the date specified in subparagraph
20 (D)(ii) and has updated its registration to
21 reflect such change under the requirements
22 for drug establishment registration set
23 forth in section 510.

24 “(ii) The amount of the fee for a con-
25 tract manufacturing organization facility
26 shall be equal to $\frac{2}{3}$ the amount of the fee

1 for an OTC monograph drug facility that
2 is not a contract manufacturing organiza-
3 tion facility.

4 “(C) AMOUNT.—The amount of fees estab-
5 lished under subparagraph (A) shall be estab-
6 lished under subsection (c).

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

10 “(i) the first business day of April of
11 such year; and

12 “(ii) the first business day after the
13 enactment of an appropriations Act pro-
14 viding for the collection and obligation of
15 fees under this section for such year.

16 “(2) OTC MONOGRAPH ORDER REQUEST
17 FEE.—

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

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

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

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

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

17 “(i) a contraindication, warning, or
18 precaution;

19 “(ii) a statement about risk associated
20 with misuse or abuse; or

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

24 “(D) REFUND OF FEE IF ORDER REQUEST
25 IS RECATEGORIZED AS A TIER 2 OTC MONO-

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

11 “(E) REFUND OF FEE IF ORDER REQUEST
12 REFUSED FOR FILING OR WITHDRAWN BEFORE
13 FILING.—The Secretary shall refund 75 percent
14 of the fee paid under subparagraph (B) for any
15 order request which is refused for filing.

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

24 “(G) REFUND OF FEE IF ORDER REQUEST
25 WITHDRAWN.—If an order request is withdrawn

1 after the order request was filed, the Secretary
2 may refund the fee or a portion of the fee if no
3 substantial work was performed on the order
4 request after the application was filed. The Sec-
5 retary shall have the sole discretion to refund a
6 fee or a portion of the fee under this subpara-
7 graph. A determination by the Secretary con-
8 cerning a refund under this subparagraph shall
9 not be reviewable.

10 “(3) REFUNDS.—

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

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

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

1 “(b) FEE REVENUE AMOUNTS.—

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

6 “(A) the annual base revenue for fiscal
7 year 2018 (as determined under paragraph (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 2019 through 2022, 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 2019;

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

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

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

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 2018, \$8,000,000; and

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

1 for fiscal year 2019 and each subsequent fiscal
2 year shall be equal to the product of—

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

5 “(ii) the inflation adjustment percent-
6 age under subparagraph (C).

7 “(B) OTC MONOGRAPH ORDER REQUEST
8 FEES.—For purposes of subsection (a)(2), the
9 dollar amount of the inflation adjustment to the
10 fee for OTC monograph order requests for fis-
11 cal year 2019 and each subsequent fiscal year
12 shall be equal to the product of—

13 “(i) the applicable fee under sub-
14 section (a)(2) for the preceding fiscal year;
15 and

16 “(ii) the inflation adjustment percent-
17 age under subparagraph (C).

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

22 “(i) for each of fiscal years 2019 and
23 2020, the average annual percent change
24 that occurred in the Consumer Price Index
25 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 2021 and
6 2022, 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

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

8 “(2) OPERATING RESERVE ADJUSTMENT.—

9 “(A) IN GENERAL.—For fiscal year 2018
10 and subsequent fiscal years, for purposes of
11 subsections (b)(1)(B) and (b)(2)(C), the Sec-
12 retary may, in addition to adjustments under
13 paragraph (1), further increase the fee revenue
14 and fees if such an adjustment is necessary to
15 provide operating reserves of carryover user
16 fees for OTC monograph drug activities for not
17 more than the number of weeks specified in
18 subparagraph (B).

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

21 “(i) 3 weeks for fiscal year 2018;

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

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

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

25 and

1 “(v) 10 weeks for fiscal year 2022.

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 2018;

22 “(B) \$7,000,000 for fiscal year 2019;

23 “(C) \$4,000,000 for fiscal year 2020;

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

25 “(E) \$3,000,000 for fiscal year 2022.

1 “(4) ANNUAL FEE SETTING.—

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

4 “(i) establish OTC monograph drug
5 facility fees for fiscal year 2018 under sub-
6 section (a), based on the revenue amount
7 for such year under subsection (b) and the
8 adjustments provided under this sub-
9 section; and

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

13 “(B) SUBSEQUENT FISCAL YEARS.—The
14 Secretary shall, not later than January 31 of
15 each fiscal year that begins after September 30,
16 2018, establish for each such fiscal year, based
17 on the revenue amounts under subsection (b)
18 and the adjustments provided under this sub-
19 section—

20 “(i) OTC monograph drug facility fees
21 under subsection (a)(1);

22 “(ii) OTC monograph order request
23 fees under subsection (a)(2); and

24 “(iii) publish such fee revenue
25 amounts, facility fees, and OTC mono-

1 graph order request fees in the Federal
2 Register.

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

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

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

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

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

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

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

23 “(ii) All OTC monograph drugs man-
24 ufactured in such a facility or containing
25 an ingredient manufactured in such a facil-

1 ity shall be deemed misbranded under sec-
2 tion 502(a).

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

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

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

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

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

1 such appropriation account for salaries and expenses
2 with such fiscal year limitation. The sums trans-
3 ferred shall be available solely for OTC monograph
4 drug activities.

5 “(2) COLLECTIONS AND APPROPRIATION
6 ACTS.—

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

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

1 the adjustment factor applicable to the fiscal
2 year involved under subsection (e)(1).

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

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

20 “(E) PROVISION FOR EARLY PAYMENTS IN
21 SUBSEQUENT YEARS.—Payment of fees author-
22 ized under this section for a fiscal year (after
23 fiscal year 2018), prior to the due date for such
24 fees, may be accepted by the Secretary in ac-

1 cordance with authority provided in advance in
2 a prior year appropriations Act.

3 “(3) AUTHORIZATION OF APPROPRIATIONS.—

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

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

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

21 **“SEC. 744P. REAUTHORIZATION; REPORTING REQUIRE-**
22 **MENTS.**

23 “(a) PERFORMANCE REPORT.—Beginning with fiscal
24 year 2018, and not later than 120 calendar days after the
25 end of each fiscal year thereafter for which fees are col-

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

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

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

25 “(d) REAUTHORIZATION.—

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

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

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

13 “(C) scientific and academic experts;

14 “(D) health care professionals;

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

17 “(F) the regulated industry.

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

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

24 “(B) publish such recommendations in the
25 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, 2022, 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.”.