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115TH CONGRESS
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H. R. 5333

IN THE SENATE OF THE UNITED STATES

JULY 17, 2018

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AN ACT

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 (2)), 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 by 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 the re-
20 quirements specified in part 352 of title 21, Code of
21 Federal Regulations, as published on May 21, 1999,
22 beginning on page 27687 of volume 64 of the Fed-
23 eral Register, except that the applicable require-
24 ments governing effectiveness and labeling shall be
25 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).

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 under
7 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 the sponsors of drugs who have a listing in
5 effect under section 510(j) for the drugs or
6 combination of drugs that will be subject
7 to the administrative order;

8 “(ii) after any such reasonable efforts
9 of notification—

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

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

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

23 “(iv) if, after completion of the pro-
24 ceedings specified in clauses (i) through
25 (iii), the Secretary determines that it is ap-

1 appropriate to issue a final administrative
2 order—

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

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

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

23 “(IV) except with respect to
24 drugs described in paragraph (3)(B),
25 upon completion of the formal dispute

1 resolution procedure, inform the per-
2 sons which sought such dispute reso-
3 lution of their right to request a hear-
4 ing.

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

13 “(i) the proposed order shall include
14 notice of—

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

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

23 “(ii) the Secretary shall provide for a
24 public comment period of no less than 180
25 calendar days with respect to such pro-

1 posed order, except when the Secretary de-
2 termines, for good cause, that a shorter pe-
3 riod is in the interests of public health;
4 and

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

15 “(3) HEARINGS; JUDICIAL REVIEW.—

16 “(A) IN GENERAL.—Only a person who
17 participated in each stage of formal dispute res-
18 olution under subclause (III) of paragraph
19 (2)(A)(iv) of an administrative order with re-
20 spect to a drug may request a hearing con-
21 cerning a final administrative order issued
22 under such paragraph with respect to such
23 drug. Such person must submit a request for a
24 hearing, which shall be based solely on informa-
25 tion in the administrative record, to the Sec-

1 retary not later than 30 calendar days after re-
2 ceiving notice of the final decision of the formal
3 dispute resolution procedure.

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

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

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

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

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

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

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

11 “(C) HEARING PROCEDURES.—

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

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

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

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

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

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

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

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

8 “(v) FINAL DECISION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12 “(B) SAFETY LABELING CHANGES.—

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

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

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

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

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

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

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

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

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

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

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

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

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

1 spect to a hearing on such order in the same
2 manner and to the same extent as such provi-
3 sions apply with respect to a hearing on an ad-
4 ministrative order issued under paragraph
5 (2)(A)(iv).

6 “(F) TIMING.—

7 “(i) FINAL ORDER AND HEARING.—

8 The Secretary shall—

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

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

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

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

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

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

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

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

21 “(I) file the request; and

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

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

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

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

22 “(I) determining whether a drug
23 is generally recognized as safe and ef-
24 fective within the meaning of section
25 201(p)(1), exempt from section

1 503(b)(1), and not required to be the
2 subject of an approved application
3 under section 505; or

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

14 “(aa) generally recognized
15 as safe and effective within the
16 meaning of section 201(p)(1) in
17 accordance with subsection
18 (a)(1), (a)(2), or an order under
19 this subsection; or

20 “(bb) subject to subsection
21 (a)(3), but only if such requestor
22 initiates such request in conjunc-
23 tion with a request for the Sec-
24 retary to determine whether such
25 drug is generally recognized as

1 safe and effective within the
2 meaning of section 201(p)(1),
3 which is filed by the Secretary
4 under subparagraph (A)(ii).

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

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

23 “(C) EXCLUSIVITY.—

24 “(i) IN GENERAL.—A final adminis-
25 trative order issued in response to a re-

1 quest under this section shall have the ef-
2 fect of authorizing solely the order re-
3 questor (or the licensees, assignees, or suc-
4 cessors in interest of such requestor with
5 respect to the subject of such order), for a
6 period of 18 months following the effective
7 date of such final order, to market drugs—

8 “(I) incorporating changes de-
9 scribed in clause (ii);

10 “(II) beginning on the date the
11 requestor (or any such licensees, as-
12 signees, or successors in interest) may
13 lawfully market such drugs pursuant
14 to the order; and

15 “(III) subject to the limitations
16 under clause (iv).

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

21 “(I) provides for a drug to con-
22 tain an active ingredient (including
23 any ester or salt of the active ingre-
24 dient) not previously incorporated in a
25 drug described in clause (iii); or

1 “(II) provides for a change in the
2 conditions of use of a drug, for which
3 new human data studies conducted or
4 sponsored by the requestor (or for
5 which the requestor has an exclusive
6 right of reference) were essential to
7 the issuance of such order.

8 “(iii) DRUGS DESCRIBED.—The drugs
9 described in this clause are drugs—

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

12 “(II) subject to a final order
13 issued under this section;

14 “(III) subject to a final sun-
15 screen order (as defined in section
16 586(2)(A)); or

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

21 “(iv) LIMITATIONS ON EXCLU-
22 SIVITY.—

23 “(I) IN GENERAL.—Only one pe-
24 riod of exclusivity shall be granted,
25 under each order described in clause

1 (i), with respect to changes (to the
2 drug subject to such order) which are
3 either—

4 “(aa) changes described in
5 clause (ii)(I), relating to active
6 ingredients; or

7 “(bb) changes described in
8 clause (ii)(II), relating to condi-
9 tions of use.

10 “(II) NO EXCLUSIVITY AL-
11 LOWED.—No exclusivity shall apply to
12 changes to a drug which are—

13 “(aa) the subject of a Tier 2
14 OTC monograph order request
15 (as defined in section 744N);

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

21 “(cc) changes related to
22 methods of testing safety or effi-
23 cacy.

24 “(v) NEW HUMAN DATA STUDIES DE-
25 FINED.—In this subparagraph, the term

1 ‘new human data studies’ means clinical
2 trials of safety or effectiveness (including
3 actual use studies), pharmacokinetics stud-
4 ies, or bioavailability studies, the results of
5 which—

6 “(I) have not been 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; and

17 “(II) do not duplicate the results
18 of another study that was relied on by
19 the Secretary to support—

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

1 “(bb) approval of a drug
2 that was approved under section
3 505.

4 “(vi) EFFECTIVE DATE.—A final
5 order subject to clause (i) shall take effect
6 on the date when the order requestor (or
7 the licensees, assignees, or successors in
8 interest of such requestor with respect to
9 such order) submits updated drug listing
10 information under subsection (e) with re-
11 spect to the change which is permitted
12 under such order.

13 “(vii) GAO STUDY.—Not later than 4
14 years after the date of enactment of the
15 Over-the-Counter Monograph, Safety, In-
16 novation, and Reform Act of 2018, the
17 Comptroller General of the United States
18 shall submit a study to the Committee on
19 Energy and Commerce of the House of
20 Representatives and the Committee on
21 Health, Education, Labor, and Pensions of
22 the Senate addressing the effectiveness and
23 overall impact of exclusivity under this sec-
24 tion, including its impact on consumer ac-
25 cess. Such study shall include—

1 “(I) the number of nonprescrip-
2 tion drug products that were granted
3 exclusivity and the indication for
4 which the nonprescription drug prod-
5 ucts were determined to be generally
6 recognized as safe and effective;

7 “(II) whether the exclusivity for
8 such drug products was granted for—

9 “(aa) a new active ingre-
10 dient (including any ester or salt
11 of the active ingredient); or

12 “(bb) changes in the condi-
13 tions of use of a drug, for which
14 new human data studies con-
15 ducted or sponsored by the re-
16 questor were essential;

17 “(III) whether, and to what ex-
18 tent, the exclusivity impacted the re-
19 questor’s or sponsor’s decision to de-
20 velop the drug product;

21 “(IV) an analysis of the imple-
22 mentation of the exclusivity provision
23 in this subparagraph, including—

1 “(aa) the resources used by
2 the Food and Drug Administra-
3 tion;

4 “(bb) the impact of such
5 provision on innovation, as well
6 as research and development in
7 the nonprescription drug market;

8 “(cc) the impact of such
9 provision on competition in the
10 nonprescription drug market;

11 “(dd) the impact of such
12 provision on consumer access to
13 nonprescription drug products;

14 “(ee) the impact of such
15 provision on the prices of non-
16 prescription drug products; and

17 “(ff) whether the adminis-
18 trative orders initiated by request-
19 tors under this section have been
20 sufficient to encourage the devel-
21 opment of nonprescription drug
22 products that would likely not be
23 otherwise developed, or developed
24 in as timely a manner; and

1 “(V) whether the administrative
2 orders initiated by requestors under
3 this section have been sufficient incen-
4 tive to encourage innovation in the
5 nonprescription drug market.

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

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

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

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

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

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

7 “(ii) subject to a final order under
8 this section; or

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

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

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

23 “(ii) if the drug has not been pre-
24 viously marketed in the United States as a
25 nonprescription drug, information suffi-

1 cient for a prima facie demonstration that
2 the drug was marketed and safely used
3 under comparable conditions of marketing
4 and use in a country listed in section
5 802(b)(1)(A) or designated by the Sec-
6 retary in accordance with section
7 802(b)(1)(B)—

8 “(I) for such period of time as
9 needed to provide reasonable assur-
10 ances concerning the safe nonprescrip-
11 tion use of the drug; and

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

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

1 “(D) MARKETING PURSUANT TO NEW
2 DRUG APPLICATION.—In the case of a request
3 described in subparagraph (A)(ii), the drug
4 subject to such request may be re-submitted for
5 filing only if—

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

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

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

1 file such request over protest under paragraph
2 (5)(A)(iii).

3 “(7) PACKAGING.—An administrative order
4 issued under paragraph (2), (4)(A), or (5) may in-
5 clude requirements for the packaging of a drug to
6 encourage use in accordance with labeling. Such re-
7 quirements may include unit dose packaging, re-
8 quirements for products intended for use by chil-
9 dren, requirements to reduce risk of harm from un-
10 supervised ingestion, and other appropriate require-
11 ments. This paragraph does not authorize the Food
12 and Drug Administration to require standards or
13 testing procedures as described in part 1700 of title
14 16, Code of Federal Regulations.

15 “(8) FINAL AND TENTATIVE FINAL MONO-
16 GRAPHS FOR CATEGORY I DRUGS DEEMED FINAL
17 ADMINISTRATIVE ORDERS.—

18 “(A) IN GENERAL.—A final monograph or
19 tentative final monograph described in subpara-
20 graph (B) shall be deemed to be a final admin-
21 istrative order under this subsection and may
22 be amended, revoked, or otherwise modified in
23 accordance with the procedures of this sub-
24 section.

1 “(B) MONOGRAPHS DESCRIBED.—For pur-
2 poses of subparagraph (A), a final monograph
3 or tentative final monograph is described in this
4 subparagraph if it—

5 “(i) establishes conditions of use for a
6 drug described in paragraph (1) or (2) of
7 subsection (a); and

8 “(ii) represents the most recently pro-
9 mulgated version of such conditions, in-
10 cluding as modified, in whole or in part, by
11 any proposed or final rule.

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

23 “(c) PROCEDURE FOR MINOR CHANGES.—

24 “(1) IN GENERAL.—Minor changes in the dos-
25 age form of a drug that is described in paragraph

1 (1) or (2) of subsection (a) or the subject of an
2 order issued under subsection (b) may be made by
3 a requestor without the issuance of an order under
4 subsection (b) if—

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

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

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

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

18 “(2) ADDITIONAL INFORMATION.—

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

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

8 “(2) PUBLIC AVAILABILITY.—

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

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

16 “(ii) make any information submitted
17 by any other person with respect to an
18 order requested (or initiated by the Sec-
19 retary) under subsection (b), available to
20 the public upon such submission.

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

24 “(i) the information pertains to phar-
25 maceutical quality information, unless such

1 information is necessary to establish stand-
2 ards under which a drug is generally rec-
3 ognized as safe and effective within the
4 meaning of section 201(p)(1);

5 “(ii) the information is submitted in a
6 requestor-initiated request, but the re-
7 questor withdraws such request, in accord-
8 ance with withdrawal procedures estab-
9 lished by the Secretary, before the Sec-
10 retary issues the proposed order;

11 “(iii) the Secretary requests and ob-
12 tains the information under subsection (c)
13 and such information is not submitted in
14 relation to an order under subsection (b);
15 or

16 “(iv) the information is of the type
17 contained in raw datasets.

18 “(e) UPDATES TO DRUG LISTING INFORMATION.—
19 A sponsor who makes a change to a drug subject to this
20 section shall submit updated drug listing information for
21 the drug in accordance with section 510(j) within 30 cal-
22 endar days of the date when the drug is first commercially
23 marketed, except that a sponsor who was the order re-
24 questor with respect to an order subject to subsection
25 (b)(5)(C) (or a licensee, assignee, or successor in interest

1 of such requestor) shall submit updated drug listing infor-
2 mation on or before the date when the drug is first com-
3 mercially marketed.

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

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

23 “(1) a repository of each final order and in-
24 terim final order in effect, including the complete
25 text of the order; and

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

3 “(A) a brief description of each such order;
4 and

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

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

17 “(i) PARTICIPATION OF MULTIPLE SPONSORS OR RE-
18 QUESTORS.—The Secretary shall establish procedures to
19 facilitate efficient participation by multiple sponsors or re-
20 questors in proceedings under this section, including provi-
21 sion for joint meetings with multiple sponsors or reques-
22 tors or with organizations nominated by sponsors or re-
23 questors to represent their interests in a proceeding.

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

1 “(k) EFFECT ON EXISTING REGULATIONS GOV-
2 ERNING NONPRESCRIPTION DRUGS.—

3 “(1) REGULATIONS OF GENERAL APPLICA-
4 BILITY TO NONPRESCRIPTION DRUGS.—Except as
5 provided in this subsection, nothing in this section
6 supersedes regulations establishing general require-
7 ments for nonprescription drugs, including regula-
8 tions of general applicability contained in parts 201,
9 250, and 330 of title 21, Code of Federal Regula-
10 tions, or any successor regulations. The Secretary
11 shall establish or modify such regulations by means
12 of rulemaking in accordance with section 553 of title
13 5, United States Code.

14 “(2) REGULATIONS ESTABLISHING REQUIRE-
15 MENTS FOR SPECIFIC NONPRESCRIPTION DRUGS.—

16 “(A) The provisions of section 310.545 of
17 title 21, Code of Federal Regulations, as in ef-
18 fect on the day before the date of the enact-
19 ment of this section, shall be deemed to be a
20 final order under subsection (b).

21 “(B) Regulations in effect on the day be-
22 fore the date of the enactment of this section,
23 establishing requirements for specific non-
24 prescription drugs marketed pursuant to this
25 section (including such requirements in parts

1 201 and 250 of title 21, Code of Federal Regu-
2 lations), shall be deemed to be final orders
3 under subsection (b), only as they apply to
4 drugs—

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

7 “(ii) otherwise subject to an order
8 under this section.

9 “(3) WITHDRAWAL OF REGULATIONS.—The
10 Secretary shall withdraw regulations establishing
11 final monographs and the procedures governing the
12 over-the-counter drug review under part 330 and
13 other relevant parts of title 21, Code of Federal
14 Regulations (as in effect on the day before the date
15 of the enactment of this section), or make technical
16 changes to such regulations to ensure conformity
17 with appropriate terminology and cross references.
18 Notwithstanding subchapter II of chapter 5 of title
19 5, United States Code, any such withdrawal or tech-
20 nical changes shall be made without public notice
21 and comment and shall be effective upon publication
22 through notice in the Federal Register (or upon such
23 date as specified in such notice).

24 “(l) GUIDANCE.—The Secretary shall issue guidance
25 that specifies—

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

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

6 “(3) the format of electronic submissions to the
7 Secretary under this section;

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

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

13 “(m) RULE OF CONSTRUCTION.—

14 “(1) IN GENERAL.—This section shall not af-
15 fect the treatment or status of a nonprescription
16 drug—

17 “(A) that is marketed without an applica-
18 tion approved under section 505 as of the date
19 of the enactment of this section;

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

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

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

4 “(A) Notwithstanding subsection (a), a
5 drug described in subparagraph (B) may only
6 be lawfully marketed, without an application
7 approved under section 505, pursuant to an
8 order issued under this section.

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

18 “(3) PRESERVATION OF AUTHORITY.—

19 “(A) Nothing in paragraph (1) shall be
20 construed to preclude or limit the applicability
21 of any other provision of this Act.

22 “(B) Nothing in subsection (a) shall be
23 construed to prohibit the Secretary from issuing
24 an order under this section finding a drug to be
25 not generally recognized as safe and effective

1 within the meaning of section 201(p)(1), as the
2 Secretary determines appropriate.

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

6 “(o) INAPPLICABILITY OF PAPERWORK REDUCTION
7 ACT.—Chapter 35 of title 44, United States Code, shall
8 not apply to collections of information made under this
9 section.

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

16 “(q) DEFINITIONS.—In this section:

17 “(1) The term ‘nonprescription drug’ refers to
18 a drug not subject to the requirements of section
19 503(b)(1).

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

23 “(A) is listed pursuant to section 510(j);
24 and

1 “(B) is or will be subject to an administra-
2 tive order of the Food and Drug Administra-
3 tion.

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

7 **SEC. 102. MISBRANDING.**

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

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

15 “(ff) If it is a drug and it was manufactured, pre-
16 pared, propagated, compounded, or processed in a facility
17 for which fees have not been paid as required by section
18 744O.”.

19 **SEC. 103. DRUGS EXCLUDED FROM THE OVER-THE-**
20 **COUNTER DRUG REVIEW.**

21 (a) IN GENERAL.—Nothing in this Act (or the
22 amendments made by this Act) shall apply to any non-
23 prescription drug which was excluded by the Food and
24 Drug Administration from the Over-the-Counter Drug Re-
25 view in accordance with the statement set out at page

1 9466 of volume 37 of the Federal Register, published on
2 May 11, 1972.

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

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

8 (a) REVIEW OF NONPRESCRIPTION SUNSCREEN AC-
9 TIVE INGREDIENTS.—

10 (1) APPLICABILITY OF SECTION 505G FOR
11 PENDING SUBMISSIONS.—

12 (A) IN GENERAL.—A sponsor of a non-
13 prescription sunscreen active ingredient or com-
14 bination of nonprescription sunscreen active in-
15 gredients that, as of the date of enactment of
16 this Act, is subject to a proposed sunscreen
17 order under section 586C of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 360fff–3)
19 may elect, by means of giving written notifica-
20 tion to the Secretary of Health and Human
21 Services within 180 calendar days of the enact-
22 ment of this Act, to transition into the review
23 of such ingredient or combination of ingredients
24 pursuant to the process set out in section 505G

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

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

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

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

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

1 in accordance with section 586C of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C.
3 360fff–3) and may not subsequently elect to
4 transition into the review of such ingredient or
5 combination of ingredients pursuant to the
6 process set out in section 505G of such Act, as
7 added by section 101 of this Act.

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

14 (b) AMENDMENTS TO SUNSCREEN PROVISIONS.—

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

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

22 (2) MEETINGS.—Paragraph (7) of section
23 586C(b) of the Federal Food, Drug, and Cosmetic
24 Act (21 U.S.C. 360fff–3(b)) is amended—

1 (A) by striking “A sponsor may request”
2 and inserting the following:

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

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

6 “(B) CONFIDENTIAL MEETINGS.—A spon-
7 sor may request one or more confidential meet-
8 ings with respect to a proposed sunscreen order,
9 including a letter deemed to be a proposed sun-
10 screen order under paragraph (3), to discuss
11 matters involving confidential commercial infor-
12 mation or trade secrets. The Secretary shall
13 convene a confidential meeting with such spon-
14 sor in a reasonable time period. If a sponsor re-
15 quests more than one confidential meeting for
16 the same proposed sunscreen order, the Sec-
17 retary may refuse to grant an additional con-
18 fidential meeting request if the Secretary deter-
19 mines that such additional confidential meeting
20 is not reasonably necessary for the sponsor to
21 advance its proposed sunscreen order, or if the
22 request for a confidential meeting fails to in-
23 clude sufficient information upon which to base
24 a substantive discussion. The Secretary shall
25 publish a post-meeting summary of each con-

1 fidential meeting under this subparagraph that
2 does not disclose confidential commercial infor-
3 mation or trade secrets.”.

4 (3) SUNSET PROVISION.—Subchapter I of chap-
5 ter V of the Federal Food, Drug, and Cosmetic Act
6 (21 U.S.C. 360fff et seq.) is amended by adding at
7 the end the following:

8 **“SEC. 586H. SUNSET.**

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

11 (4) TREATMENT OF FINAL SUNSCREEN
12 ORDER.—The Federal Food, Drug, and Cosmetic
13 Act is amended by striking section 586E of such Act
14 (21 U.S.C. 360fff–5).

15 (c) TREATMENT OF NON-SUNSCREEN TIME AND EX-
16 TENT APPLICATIONS.—

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

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

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

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

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

21 (2) as appropriate, revising such cough and cold
22 monograph to address such children through the
23 order process under section 505G(b) of the Federal
24 Food, Drug, and Cosmetic Act, as added by section
25 101 of this Act.

1 (b) COUGH AND COLD MONOGRAPH DESCRIBED.—

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

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

21 **TITLE II—USER FEES**

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

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

1 (b) FINDING.—The Congress finds that the fees au-
 2 thorized by the amendments made in this title will be dedi-
 3 cated to OTC monograph drug activities, as set forth in
 4 the goals identified for purposes of part 10 of subchapter
 5 C of chapter VII of the Federal Food, Drug, and Cosmetic
 6 Act, in the letters from the Secretary of Health and
 7 Human Services to the Chairman of the Committee on
 8 Health, Education, Labor, and Pensions of the Senate and
 9 the Chairman of the Committee on Energy and Commerce
 10 of the House of Representatives, as set forth in the Con-
 11 gressional Record.

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

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

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

18 **“SEC. 744N. DEFINITIONS.**

19 “In this part:

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

23 “(A) one business entity controls, or has
 24 the power to control, the other business entity;
 25 or

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

3 “(2) The term ‘contract manufacturing organi-
4 zation facility’ means an OTC monograph drug facil-
5 ity where neither the owner of such manufacturing
6 facility nor any affiliate of such owner or facility
7 sells the OTC monograph drug produced at such fa-
8 cility directly to wholesalers, retailers, or consumers
9 in the United States.

10 “(3) The term ‘costs of resources allocated for
11 OTC monograph drug activities’ means the expenses
12 in connection with OTC monograph drug activities
13 for—

14 “(A) officers and employees of the Food
15 and Drug Administration, contractors of the
16 Food and Drug Administration, advisory com-
17 mittees, and costs related to such officers, em-
18 ployees, and committees and costs related to
19 contracts with such contractors;

20 “(B) management of information, and the
21 acquisition, maintenance, and repair of com-
22 puter resources;

23 “(C) leasing, maintenance, renovation, and
24 repair of facilities and acquisition, maintenance,
25 and repair of fixtures, furniture, scientific

1 equipment, and other necessary materials and
2 supplies; and

3 “(D) collecting fees under section 744O
4 and accounting for resources allocated for OTC
5 monograph drug activities.

6 “(4) The term ‘FDA establishment identifier’ is
7 the unique number automatically generated by Food
8 and Drug Administration’s Field Accomplishments
9 and Compliance Tracking System (FACTS) (or any
10 successor system).

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

15 “(6) The term ‘OTC monograph drug activities’
16 means activities of the Secretary associated with
17 OTC monograph drugs and inspection of facilities
18 associated with such products, including the fol-
19 lowing activities:

20 “(A) The activities necessary for review
21 and evaluation of OTC monographs and OTC
22 monograph order requests, including—

23 “(i) orders proposing or finalizing ap-
24 plicable conditions of use for OTC mono-
25 graph drugs;

1 “(ii) orders affecting status regarding
2 general recognition of safety and effective-
3 ness of an OTC monograph ingredient or
4 combination of ingredients under specified
5 conditions of use;

6 “(iii) all OTC monograph drug devel-
7 opment and review activities, including
8 intraagency collaboration;

9 “(iv) regulation and policy develop-
10 ment activities related to OTC monograph
11 drugs;

12 “(v) development of product standards
13 for products subject to review and evalua-
14 tion;

15 “(vi) meetings referred to in section
16 505G(i);

17 “(vii) review of labeling prior to
18 issuance of orders related to OTC mono-
19 graph drugs or conditions of use; and

20 “(viii) regulatory science activities re-
21 lated to OTC monograph drugs.

22 “(B) Inspections related to OTC mono-
23 graph drugs.

1 “(C) Monitoring of clinical and other re-
2 search conducted in connection with OTC
3 monograph drugs.

4 “(D) Safety activities with respect to OTC
5 monograph drugs, including—

6 “(i) collecting, developing, and review-
7 ing safety information on OTC monograph
8 drugs, including adverse event reports;

9 “(ii) developing and using improved
10 adverse event data-collection systems, in-
11 cluding information technology systems;
12 and

13 “(iii) developing and using improved
14 analytical tools to assess potential safety
15 risks, including access to external data-
16 bases.

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

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

22 “(8) The term ‘Tier 1 OTC monograph order
23 request’ means any OTC monograph order request
24 not determined to be a Tier 2 OTC monograph
25 order request.

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

4 “(i) the reordering of existing information
5 in the drug facts label of an OTC monograph
6 drug;

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

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

16 “(iv) the standardization of the concentra-
17 tion or dose of a specific finalized ingredient
18 within a particular finalized monograph;

19 “(v) a change to ingredient nomenclature
20 to align with nomenclature of a standards-set-
21 ting organization; or

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

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

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

12 “(i) is—

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

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

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

24 “(iii) does not include a business or other
25 entity whose only manufacturing or processing

1 activities are one or more of the following: pro-
2 duction of clinical research supplies, or testing.

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

8 “(i) closely related to the same business
9 enterprise;

10 “(ii) under the supervision of the same
11 local management; and

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

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

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

1 “(12) The term ‘person’ includes an affiliate of
2 a person.

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

5 **“SEC. 7440. AUTHORITY TO ASSESS AND USE OTC MONO-**
6 **GRAPH FEES.**

7 “(a) TYPES OF FEES.—Beginning with fiscal year
8 2019, the Secretary shall assess and collect fees in accord-
9 ance with this section as follows:

10 “(1) FACILITY FEE.—

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

18 “(B) EXCEPTIONS.—

19 “(i) A fee shall not be assessed under
20 subparagraph (A) if the identified OTC
21 monograph drug facility has ceased all ac-
22 tivities related to OTC monograph drugs
23 prior to the date specified in subparagraph
24 (D)(ii) and has updated its registration to
25 reflect such change under the requirements

1 for drug establishment registration set
2 forth in section 510.

3 “(ii) The amount of the fee for a con-
4 tract manufacturing organization facility
5 shall be equal to $\frac{2}{3}$ the amount of the fee
6 for an OTC monograph drug facility that
7 is not a contract manufacturing organiza-
8 tion facility.

9 “(C) AMOUNT.—The amount of fees estab-
10 lished under subparagraph (A) shall be estab-
11 lished under subsection (c).

12 “(D) DUE DATE.—

13 “(i) FOR FIRST PROGRAM YEAR.—For
14 fiscal year 2019, the facility fees required
15 under subparagraph (A) shall be due 45
16 calendar days after publication of the Fed-
17 eral Register notice provided for under
18 subsection (c)(4)(A).

19 “(ii) SUBSEQUENT FISCAL YEARS.—
20 For each fiscal year after fiscal year 2019,
21 the facility fees required under subpara-
22 graph (A) shall be due on the later of—

23 “(I) the first business day of
24 June of such year; or

1 “(II) the first business day after
2 the enactment of an appropriations
3 Act providing for the collection and
4 obligation of fees under this section
5 for such year.

6 “(2) OTC MONOGRAPH ORDER REQUEST
7 FEE.—

8 “(A) IN GENERAL.—Each person that sub-
9 mits an OTC monograph order request shall be
10 subject to a fee for an OTC monograph order
11 request. The amount of such fee shall be—

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

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

20 “(B) DUE DATE.—The OTC monograph
21 order request fees required under subparagraph
22 (A) shall be due on the date of submission of
23 the OTC monograph order request.

24 “(C) EXCEPTION FOR CERTAIN SAFETY
25 CHANGES.—A person who is named as the re-

1 requestor in an OTC monograph order shall not
2 be subject to a fee under subparagraph (A) if
3 the Secretary finds that the OTC monograph
4 order request seeks to change the drug facts la-
5 beling of an OTC monograph drug in a way
6 that would add to or strengthen—

7 “(i) a contraindication, warning, or
8 precaution;

9 “(ii) a statement about risk associated
10 with misuse or abuse; or

11 “(iii) an instruction about dosage and
12 administration that is intended to increase
13 the safe use of the OTC monograph drug.

14 “(D) REFUND OF FEE IF ORDER REQUEST
15 IS RECATEGORIZED AS A TIER 2 OTC MONO-
16 GRAPH ORDER REQUEST.—If the Secretary de-
17 termines that an OTC monograph request ini-
18 tially characterized as Tier 1 shall be re-charac-
19 terized as a Tier 2 OTC monograph order re-
20 quest, and the requestor has paid a Tier 1 fee
21 in accordance with subparagraph (A)(i), the
22 Secretary shall refund the requestor the dif-
23 ference between the Tier 1 and Tier 2 fees de-
24 termined under subparagraphs (A)(i) and
25 (A)(ii), respectively.

1 “(E) REFUND OF FEE IF ORDER REQUEST
2 REFUSED FOR FILING OR WITHDRAWN BEFORE
3 FILING.—The Secretary shall refund 75 percent
4 of the fee paid under subparagraph (B) for any
5 order request which is refused for filing or was
6 withdrawn before being accepted or refused for
7 filing.

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

16 “(G) REFUND OF FEE IF ORDER REQUEST
17 WITHDRAWN.—If an order request is withdrawn
18 after the order request was filed, the Secretary
19 may refund the fee or a portion of the fee if no
20 substantial work was performed on the order
21 request after the application was filed. The Sec-
22 retary shall have the sole discretion to refund a
23 fee or a portion of the fee under this subpara-
24 graph. A determination by the Secretary con-

1 cerning a refund under this subparagraph shall
2 not be reviewable.

3 “(3) REFUNDS.—

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

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

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

19 “(b) FEE REVENUE AMOUNTS.—

20 “(1) FISCAL YEAR 2019.—For fiscal year 2019,
21 fees under subsection (a)(1) shall be established to
22 generate a total facility fee revenue amount equal to
23 the sum of—

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

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

5 “(C) additional direct cost adjustments (as
6 determined under subsection (c)(3)).

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

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

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

16 “(C) the dollar amount equal to the oper-
17 ating reserve adjustment for the fiscal year, if
18 applicable (as determined under subsection
19 (c)(2));

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

22 “(E) additional dollar amounts for each
23 fiscal year as follows:

24 “(i) \$7 million for fiscal year 2020.

25 “(ii) \$6 million for fiscal year 2021.

1 “(iii) \$7 million for fiscal year 2022.

2 “(iv) \$3 million for fiscal year 2023.

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

7 “(A) for fiscal year 2019, \$8 million; and

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

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

14 “(1) INFLATION ADJUSTMENT.—

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

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

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

24 “(B) OTC MONOGRAPH ORDER REQUEST
25 FEES.—For purposes of subsection (a)(2), the

1 dollar amount of the inflation adjustment to the
2 fee for OTC monograph order requests for fis-
3 cal year 2020 and each subsequent fiscal year
4 shall be equal to the product of—

5 “(i) the applicable fee under sub-
6 section (a)(2) for the preceding fiscal year;
7 and

8 “(ii) the inflation adjustment percent-
9 age under subparagraph (C).

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

14 “(i) for each of fiscal years 2020 and
15 2021, the average annual percent change
16 that occurred in the Consumer Price Index
17 for urban consumers (Washington-Balti-
18 more, DC–MD–VA–WV; Not Seasonally
19 Adjusted; All items; Annual Index) for the
20 first 3 years of the preceding 4 years of
21 available data; and

22 “(ii) for each of fiscal years 2022 and
23 2023, the sum of—

24 “(I) the average annual percent
25 change in the cost, per full-time equiv-

1 alent position of the Food and Drug
2 Administration, of all personnel com-
3 pensation and benefits paid with re-
4 spect to such positions for the first 3
5 years of the preceding 4 fiscal years,
6 multiplied by the proportion of per-
7 sonnel compensation and benefits
8 costs to total costs of OTC mono-
9 graph drug activities for the first 3
10 years of the preceding 4 fiscal years;
11 and

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

25 “(2) OPERATING RESERVE ADJUSTMENT.—

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

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

13 “(i) 3 weeks for fiscal year 2019;

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

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

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

17 and

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

19 “(C) DECREASE.—If the Secretary has
20 carryover balances for such process in excess of
21 10 weeks of the operating reserves referred to
22 in subparagraph (A), the Secretary shall de-
23 crease the fee revenue and fees referred to in
24 such subparagraph to provide for not more than
25 10 weeks of such operating reserves.

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

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

13 “(A) \$14 million for fiscal year 2019;

14 “(B) \$7 million for fiscal year 2020;

15 “(C) \$4 million for fiscal year 2021;

16 “(D) \$3 million for fiscal year 2022; and

17 “(E) \$3 million for fiscal year 2023.

18 “(4) ANNUAL FEE SETTING.—

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

21 “(i) establish OTC monograph drug
 22 facility fees for fiscal year 2019 under sub-
 23 section (a), based on the revenue amount
 24 for such year under subsection (b) and the

1 adjustments provided under this sub-
2 section; and

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

6 “(B) SUBSEQUENT FISCAL YEARS.—The
7 Secretary shall, not later than January 31 of
8 each fiscal year that begins after September 30,
9 2019, establish for each such fiscal year, based
10 on the revenue amounts under subsection (b)
11 and the adjustments provided under this sub-
12 section—

13 “(i) OTC monograph drug facility fees
14 under subsection (a)(1);

15 “(ii) OTC monograph order request
16 fees under subsection (a)(2); and

17 “(iii) publish such fee revenue
18 amounts, facility fees, and OTC mono-
19 graph order request fees in the Federal
20 Register.

21 “(d) IDENTIFICATION OF FACILITIES.—Each person
22 that owns an OTC monograph drug facility shall submit
23 to the Secretary the information required under this sub-
24 section each year. Such information shall, for each fiscal
25 year—

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

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

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

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

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

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

16 “(ii) All OTC monograph drugs man-
17 ufactured in such a facility or containing
18 an ingredient manufactured in such a facil-
19 ity shall be deemed misbranded under sec-
20 tion 502(a).

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

24 “(2) ORDER REQUESTS.—An OTC monograph
25 order request submitted by a person subject to fees

1 under subsection (a) shall be considered incomplete
2 and shall not be accepted for filing by the Secretary
3 until all fees owed by such person under this section
4 have been paid.

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

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

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

22 “(2) COLLECTIONS AND APPROPRIATION
23 ACTS.—

24 “(A) IN GENERAL.—Subject to subpara-
25 graph (C), the fees authorized by this section

1 shall be collected and available in each fiscal
2 year in an amount not to exceed the amount
3 specified in appropriation Acts, or otherwise
4 made available for obligation, for such fiscal
5 year.

6 “(B) USE OF FEES AND LIMITATION.—

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

20 “(C) COMPLIANCE.—The Secretary shall

21 be considered to have met the requirements of
22 subparagraph (B) in any fiscal year if the costs
23 funded by appropriations and allocated for OTC
24 monograph drug activities are not more than 15

1 percent below the level specified in such sub-
2 paragraph.

3 “(D) PROVISION FOR EARLY PAYMENTS IN
4 SUBSEQUENT YEARS.—Payment of fees author-
5 ized under this section for a fiscal year (after
6 fiscal year 2019), prior to the due date for such
7 fees, may be accepted by the Secretary in ac-
8 cordance with authority provided in advance in
9 a prior year appropriations Act.

10 “(3) AUTHORIZATION OF APPROPRIATIONS.—
11 For each of the fiscal years 2019 through 2023,
12 there is authorized to be appropriated for fees under
13 this section an amount equal to the total amount of
14 fees assessed for such fiscal year under this section.

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

21 “(h) CONSTRUCTION.—This section may not be con-
22 strued to require that the number of full-time equivalent
23 positions in the Department of Health and Human Serv-
24 ices, for officers, employers, and advisory committees not
25 engaged in OTC monograph drug activities, be reduced

1 to offset the number of officers, employees, and advisory
2 committees so engaged.

3 **“SEC. 744P. REAUTHORIZATION; REPORTING REQUIRE-**
4 **MENTS.**

5 “(a) PERFORMANCE REPORT.—Beginning with fiscal
6 year 2019, and not later than 120 calendar days after the
7 end of each fiscal year thereafter for which fees are col-
8 lected under this part, the Secretary shall prepare and
9 submit to the Committee on Energy and Commerce of the
10 House of Representatives and the Committee on Health,
11 Education, Labor, and Pensions of the Senate a report
12 concerning the progress of the Food and Drug Adminis-
13 tration in achieving the goals identified in the letters de-
14 scribed in section 201(b) of the Over-the-Counter Mono-
15 graph Safety, Innovation, and Reform Act of 2018 during
16 such fiscal year and the future plans of the Food and
17 Drug Administration for meeting such goals.

18 “(b) FISCAL REPORT.—Not later than 120 calendar
19 days after the end of fiscal year 2019 and each subsequent
20 fiscal year for which fees are collected under this part,
21 the Secretary shall prepare and submit to the Committee
22 on Energy and Commerce of the House of Representatives
23 and the Committee on Health, Education, Labor, and
24 Pensions of the Senate a report on the implementation
25 of the authority for such fees during such fiscal year and

1 the use, by the Food and Drug Administration, of the fees
2 collected for such fiscal year.

3 “(c) PUBLIC AVAILABILITY.—The Secretary shall
4 make the reports required under subsections (a) and (b)
5 available to the public on the Internet website of the Food
6 and Drug Administration.

7 “(d) REAUTHORIZATION.—

8 “(1) CONSULTATION.—In developing rec-
9 ommendations to present to the Congress with re-
10 spect to the goals described in subsection (a), and
11 plans for meeting the goals, for OTC monograph
12 drug activities for the first 5 fiscal years after fiscal
13 year 2023, and for the reauthorization of this part
14 for such fiscal years, the Secretary shall consult
15 with—

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

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

20 “(C) scientific and academic experts;

21 “(D) health care professionals;

22 “(E) representatives of patient and con-
23 sumer advocacy groups; and

24 “(F) the regulated industry.

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

4 “(A) present the recommendations devel-
5 oped under paragraph (1) to the congressional
6 committees specified in such paragraph;

7 “(B) publish such recommendations in the
8 Federal Register;

9 “(C) provide for a period of 30 calendar
10 days for the public to provide written comments
11 on such recommendations;

12 “(D) hold a meeting at which the public
13 may present its views on such recommenda-
14 tions; and

15 “(E) after consideration of such public
16 views and comments, revise such recommenda-
17 tions as necessary.

18 “(3) TRANSMITTAL OF RECOMMENDATIONS.—
19 Not later than January 15, 2023, the Secretary
20 shall transmit to the Congress the revised rec-
21 ommendations under paragraph (2), a summary of
22 the views and comments received under such para-

1 graph, and any changes made to the recommenda-
 2 tions in response to such views and comments.”.

Passed the House of Representatives July 16, 2018.

Attest: KAREN L. HAAS,
Clerk.

Calendar No. 518

115TH CONGRESS
2^D Session

H. R. 5333

AN ACT

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.

JULY 17, 2018

Received; read twice and placed on the calendar