

115TH CONGRESS
2D 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.

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

1 **SECTION 1. SHORT TITLE.**

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

4 **TITLE I—OTC DRUG REVIEW**

5 **SEC. 101. REGULATION OF CERTAIN NONPRESCRIPTION**

6 **DRUGS THAT ARE MARKETED WITHOUT AN**

7 **APPROVED NEW DRUG APPLICATION.**

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

11 **“SEC. 505G. REGULATION OF CERTAIN NONPRESCRIPTION**

12 **DRUGS THAT ARE MARKETED WITHOUT AN**

13 **APPROVED NEW DRUG APPLICATION.**

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

21 “(1) DRUGS SUBJECT TO A FINAL MONOGRAPH;

22 CATEGORY I DRUGS SUBJECT TO A TENTATIVE

23 FINAL MONOGRAPH.—A drug is deemed to be gen-

24 erally recognized as safe and effective within the

25 meaning of section 201(p)(1), not a new drug under

1 section 201(p), and not subject to section 503(b)(1),
2 if—

3 “(A) the drug is—

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

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

21 “(B) the drug is—

22 “(i) classified in category I for safety
23 and effectiveness under a tentative final
24 monograph that is the most recently appli-
25 cable proposal or determination issued

1 under part 330 of title 21, Code of Federal
2 Regulations;

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

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

19 “(2) TREATMENT OF SUNSCREEN DRUGS.—

20 With respect to sunscreen drugs subject to this sec-
21 tion, the applicable requirements shall be the re-
22 quirements specified in part 352 of title 21, Code of
23 Federal Regulations, as published on May 21, 1999,
24 beginning on page 27687 of volume 64 of the Fed-
25 eral Register, except that the applicable require-

1 ments governing effectiveness and labeling shall be
2 those specified in section 201.327 of title 21, Code
3 of Federal Regulations, subject to the requirements
4 of subsections (b), (c), and (k).

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

13 “(A) the drug is—

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

21 “(ii) in conformity with—

22 “(I) the conditions of use, includ-
23 ing indication and dosage strength, if
24 any, described for such category III

1 drug in such preamble or in an appli-
2 cable subsequent proposed rule;

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

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

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

24 “(B) the drug is—

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

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

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

21 “(4) CATEGORY II DRUGS DEEMED NEW
22 DRUGS.—A drug that is classified in category II for
23 safety or effectiveness under a tentative final mono-
24 graph or that is subject to a determination to be not
25 safe or effective in a proposed rule that is the most

1 recently applicable proposal issued under part 330 of
2 title 21, Code of Federal Regulations, shall be
3 deemed to be a new drug within the meaning of sec-
4 tion 201(p), misbranded under section 502(ee), and
5 subject to the requirement for an approved new drug
6 application under section 505 beginning on the day
7 that is 180 calendar days after the date of the en-
8 actment of this section, unless, before such day, the
9 Secretary determines that it is in the interest of
10 public health to extend the period during which the
11 drug may be marketed without such an approved
12 new drug application.

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

23 “(6) OTHER DRUGS DEEMED NEW DRUGS.—
24 Except as provided in subsection (m), a drug is
25 deemed to be a new drug within the meaning of sec-

tion 201(p) and misbranded under section 502(ee) if
the drug—

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

and

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

“(b) ADMINISTRATIVE ORDERS.—

“(1) IN GENERAL.—

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

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

and

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

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

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

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

7 “(iii) meets the general requirements
8 for nonprescription drugs; and

9 “(iv) meets the requirements under
10 subsections (c) and (k).

11 “(C) STANDARD.—The Secretary shall find
12 that a drug is not generally recognized as safe
13 and effective within the meaning of section
14 201(p)(1) if—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18 “(I) the general categories of
19 data the Secretary has determined
20 necessary to establish that the drug is
21 generally recognized as safe and effec-
22 tive within the meaning of section
23 201(p)(1); and

24 “(II) the format for submissions
25 by interested persons;

1 “(ii) the Secretary shall provide for a
2 public comment period of no less than 180
3 calendar days with respect to such pro-
4 posed order, except when the Secretary de-
5 termines, for good cause, that a shorter pe-
6 riod is in the interests of public health;
7 and

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

18 “(3) HEARINGS; JUDICIAL REVIEW.—

19 “(A) IN GENERAL.—Only a person who
20 participated in each stage of formal dispute res-
21 olution under subclause (III) of paragraph
22 (2)(A)(iv) of an administrative order with re-
23 spect to a drug may request a hearing con-
24 cerning a final administrative order issued
25 under such paragraph with respect to such

1 drug. Such person must submit a request for a
2 hearing, which shall be based solely on informa-
3 tion in the administrative record, to the Sec-
4 retary not later than 30 calendar days after re-
5 ceiving notice of the final decision of the formal
6 dispute resolution procedure.

7 “(B) NO HEARING REQUIRED WITH RE-
8 SPECT TO ORDERS RELATING TO CERTAIN
9 DRUGS.—

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

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

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

1 “(ii) HUMAN DATA STUDIES AND
2 NON-HUMAN DATA DEFINED.—In this sub-
3 paragraph:

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

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

14 “(C) HEARING PROCEDURES.—

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

1 are based on relevant and reliable scientific
2 principles and methodologies.

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

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

14 “(I) be designated by the Sec-
15 retary;

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

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

24 “(iv) RIGHTS OF PARTIES TO HEAR-
25 ING.—The parties to a hearing requested

1 under subparagraph (A) shall have the
2 right to present testimony, including testi-
3 mony of expert witnesses, and to cross-ex-
4 amine witnesses presented by other parties.
5 Where appropriate, the presiding officer
6 may require that cross-examination by par-
7 ties representing substantially the same in-
8 terests be consolidated to promote effi-
9 ciency and avoid duplication.

10 “(v) FINAL DECISION.—

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

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

23 “(D) JUDICIAL REVIEW OF FINAL ADMIN-
24 ISTRATIVE ORDER.—

1 “(i) IN GENERAL.—The procedures
2 described in section 505(h) shall apply
3 with respect to judicial review of final ad-
4 ministrative orders issued under this sub-
5 section in the same manner and to the
6 same extent as such section applies to an
7 order described in such section except that
8 the judicial review shall be taken by filing
9 in an appropriate district court of the
10 United States in lieu of the appellate
11 courts specified in such section.

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

20 “(I) the date on which notice of
21 such order is published;

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

1 “(III) the date on which a final
2 decision is made following a hearing
3 under subparagraph (C)(v); or

4 “(IV) if no hearing is requested,
5 the date on which the time for re-
6 questing a hearing expires.

7 “(4) EXPEDITED PROCEDURE WITH RESPECT
8 TO ADMINISTRATIVE ORDERS INITIATED BY THE
9 SECRETARY.—

10 “(A) IMMINENT HAZARD TO THE PUBLIC
11 HEALTH.—

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

23 “(I) may issue an interim final
24 administrative order for such drug,
25 class of drugs, or combination of

1 drugs under paragraph (1), together
2 with a detailed statement of the rea-
3 sons for such order;

4 “(II) shall publish in the Federal
5 Register a notice of availability of any
6 such order; and

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

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

15 “(B) SAFETY LABELING CHANGES.—

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

24 “(I) make reasonable efforts to
25 notify informally, not later than 48

1 hours before the issuance of the in-
2 terim final order, the sponsors of
3 drugs who have a listing in effect
4 under section 510(j) for such drug or
5 combination of drugs;

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

12 “(III) publish in the Federal
13 Register a notice of availability of
14 such order; and

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

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

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

4 “(D) FINAL ORDER.—After the completion
5 of the proceedings in subparagraph (A) or (B),
6 the Secretary shall—

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

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

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

21 “(E) HEARINGS.—A sponsor of a drug
22 subject to a final order issued under subpara-
23 graph (D) and that participated in each stage
24 of formal dispute resolution under clause (iii) of
25 such subparagraph may request a hearing on

1 such order. The provisions of subparagraphs
2 (A), (B), and (C) of paragraph (3), other than
3 paragraph (3)(C)(v)(II), shall apply with re-
4 spect to a hearing on such order in the same
5 manner and to the same extent as such provi-
6 sions apply with respect to a hearing on an ad-
7 ministrative order issued under paragraph
8 (2)(A)(iv).

9 “(F) TIMING.—

10 “(i) FINAL ORDER AND HEARING.—

11 The Secretary shall—

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

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

21 “(ii) DISPUTE RESOLUTION RE-
22 QUEST.—The Secretary shall specify in an
23 interim final order issued under subpara-
24 graph (A) or (B) such shorter periods for
25 requesting dispute resolution under sub-

1 paragraph (D)(iii) as are necessary to
2 meet the requirements of this subpara-
3 graph.

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

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

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

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

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

24 “(I) file the request; and

1 “(II) initiate proceedings with re-
2 spect to issuing an administrative
3 order in accordance with paragraphs
4 (2) and (3); and

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

14 “(B) REQUEST TO INITIATE PRO-
15 CEEDINGS.—

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

1 “(I) determining whether a drug
2 is generally recognized as safe and ef-
3 fective within the meaning of section
4 201(p)(1), exempt from section
5 503(b)(1), and not required to be the
6 subject of an approved application
7 under section 505; or

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

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

24 “(bb) subject to subsection
25 (a)(3), but only if such requestor

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

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

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

1 the Secretary may cease proceedings under
2 this subparagraph.

3 “(C) EXCLUSIVITY.—

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

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

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

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

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

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

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

13 “(iii) DRUGS DESCRIBED.—The drugs
14 described in this clause are drugs—

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

17 “(II) subject to a final order
18 issued under this section;

19 “(III) subject to a final sun-
20 screen order (as defined in section
21 586(2)(A)); or

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

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

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

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

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

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

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

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

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

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

11 “(I) have not been relied on by
12 the Secretary to support—

13 “(aa) a proposed or final de-
14 termination that a drug described
15 in subclauses (I), (II), or (III) of
16 clause (iii) is generally recognized
17 as safe and effective within the
18 meaning of section 201(p)(1); or

19 “(bb) approval of a drug
20 that was approved under section
21 505; and

22 “(II) do not duplicate the results
23 of another study that was relied on by
24 the Secretary to support—

1 “(aa) a proposed or final de-
2 termination that a drug described
3 in subclauses (I), (II), or (III) of
4 clause (iii) is generally recognized
5 as safe and effective within the
6 meaning of section 201(p)(1); or

7 “(bb) approval of a drug
8 that was approved under section
9 505.

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

19 “(vii) GAO STUDY.—Not later than 4
20 years after the date of enactment of the
21 Over-the-Counter Monograph, Safety, In-
22 novation, and Reform Act of 2018, the
23 Comptroller General of the United States
24 shall submit a study to the Committee on
25 Energy and Commerce of the House of

1 Representatives and the Committee on
2 Health, Education, Labor, and Pensions of
3 the Senate addressing the effectiveness and
4 overall impact of exclusivity under this sec-
5 tion, including its impact on consumer ac-
6 cess. Such study shall include—

7 “(I) the number of nonprescrip-
8 tion drug products that were granted
9 exclusivity and the indication for
10 which the nonprescription drug prod-
11 ucts were determined to be generally
12 recognized as safe and effective;

13 “(II) whether the exclusivity for
14 such drug products was granted for—

15 “(aa) a new active ingre-
16 dient (including any ester or salt
17 of the active ingredient); or

18 “(bb) changes in the condi-
19 tions of use of a drug, for which
20 new human data studies con-
21 ducted or sponsored by the re-
22 questor were essential;

23 “(III) whether, and to what ex-
24 tent, the exclusivity impacted the re-

1 questor’s or sponsor’s decision to de-
2 velop the drug product;

3 “(IV) an analysis of the imple-
4 mentation of the exclusivity provision
5 in this subparagraph, including—

6 “(aa) the resources used by
7 the Food and Drug Administra-
8 tion;

9 “(bb) the impact of such
10 provision on innovation, as well
11 as research and development in
12 the nonprescription drug market;

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

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

19 “(ee) the impact of such
20 provision on the prices of non-
21 prescription drug products; and

22 “(ff) whether the adminis-
23 trative orders initiated by reques-
24 tors under this section have been
25 sufficient to encourage the devel-

opment of nonprescription drug products that would likely not be otherwise developed, or developed in as timely a manner; and

“(V) whether the administrative orders initiated by requestors under this section have been sufficient incentive to encourage innovation in the nonprescription drug market.

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

“(A) IN GENERAL.—In response to a request under this section that a drug described in subparagraph (B) be generally recognized as safe and effective, the Secretary—

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

“(ii) if the request fails to include information specified under subparagraph (C), shall refuse to file such request and

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

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

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

10 “(ii) subject to a final order under
11 this section; or

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

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

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

1 “(ii) if the drug has not been pre-
2 viously marketed in the United States as a
3 nonprescription drug, information suffi-
4 cient for a prima facie demonstration that
5 the drug was marketed and safely used
6 under comparable conditions of marketing
7 and use in a country listed in section
8 802(b)(1)(A) or designated by the Sec-
9 retary in accordance with section
10 802(b)(1)(B)—

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

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

22 “(iii) if the Secretary determines that
23 information described in clauses (i) or (ii)
24 is not needed to provide a prima facie dem-
25 onstration that the drug can be safely mar-

1 keted and used as a nonprescription drug,
2 such other information the Secretary deter-
3 mines is sufficient for such purposes.

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

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

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

23 “(E) RULE OF APPLICATION.—Except in
24 the case of a request involving a drug described
25 in section 586(9), as in effect on January 1,

1 2017, if the Secretary refuses to file a request
2 under this paragraph, the requestor may not
3 file such request over protest under paragraph
4 (5)(A)(iii).

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

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

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

1 accordance with the procedures of this sub-
2 section.

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

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

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

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

25 “(c) PROCEDURE FOR MINOR CHANGES.—

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

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

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

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

16 “(B) the change is in conformity with the
17 requirements of an applicable administrative
18 order issued by the Secretary under paragraph
19 (3).

20 “(2) ADDITIONAL INFORMATION.—

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

1 such a request, or such longer period as the
2 Secretary may provide.

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

10 “(i) may so inform the sponsor of the
11 drug in writing; and

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

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

1 tion 201(p) and shall be deemed to be mis-
2 branded under section 502(ee).

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

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

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

22 “(d) CONFIDENTIALITY OF INFORMATION SUB-
23 MITTED TO THE SECRETARY.—

24 “(1) IN GENERAL.—Subject to paragraph (2),
25 any information, including reports of testing con-

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

10 “(2) PUBLIC AVAILABILITY.—

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

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

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

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

1 “(i) the information pertains to phar-
2 maceutical quality information, unless such
3 information is necessary to establish stand-
4 ards under which a drug is generally rec-
5 ognized as safe and effective within the
6 meaning of section 201(p)(1);

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

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

18 “(iv) the information is of the type
19 contained in raw datasets.

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

1 requestor with respect to an order subject to subsection
2 (b)(5)(C) (or a licensee, assignee, or successor in interest
3 of such requestor) shall submit updated drug listing infor-
4 mation on or before the date when the drug is first com-
5 mercially marketed.

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

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

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

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

6 “(A) a brief description of each such order;
7 and

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

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

20 “(i) PARTICIPATION OF MULTIPLE SPONSORS OR RE-
21 QUESTORS.—The Secretary shall establish procedures to
22 facilitate efficient participation by multiple sponsors or re-
23 questors in proceedings under this section, including provi-
24 sion for joint meetings with multiple sponsors or reques-

1 tors or with organizations nominated by sponsors or re-
2 questors to represent their interests in a proceeding.

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

5 “(k) EFFECT ON EXISTING REGULATIONS GOV-
6 ERNING NONPRESCRIPTION DRUGS.—

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

18 “(2) REGULATIONS ESTABLISHING REQUIRE-
19 MENTS FOR SPECIFIC NONPRESCRIPTION DRUGS.—

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

1 “(B) Regulations in effect on the day be-
2 fore the date of the enactment of this section,
3 establishing requirements for specific non-
4 prescription drugs marketed pursuant to this
5 section (including such requirements in parts
6 201 and 250 of title 21, Code of Federal Regu-
7 lations), shall be deemed to be final orders
8 under subsection (b), only as they apply to
9 drugs—

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

12 “(ii) otherwise subject to an order
13 under this section.

14 “(3) WITHDRAWAL OF REGULATIONS.—The
15 Secretary shall withdraw regulations establishing
16 final monographs and the procedures governing the
17 over-the-counter drug review under part 330 and
18 other relevant parts of title 21, Code of Federal
19 Regulations (as in effect on the day before the date
20 of the enactment of this section), or make technical
21 changes to such regulations to ensure conformity
22 with appropriate terminology and cross references.
23 Notwithstanding subchapter II of chapter 5 of title
24 5, United States Code, any such withdrawal or tech-
25 nical changes shall be made without public notice

1 and comment and shall be effective upon publication
2 through notice in the Federal Register (or upon such
3 date as specified in such notice).

4 “(l) GUIDANCE.—The Secretary shall issue guidance
5 that specifies—

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

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

11 “(3) the format of electronic submissions to the
12 Secretary under this section;

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

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

18 “(m) RULE OF CONSTRUCTION.—

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

22 “(A) that is marketed without an applica-
23 tion approved under section 505 as of the date
24 of the enactment of this section;

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

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

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

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

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

22 “(3) PRESERVATION OF AUTHORITY.—

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

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

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

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

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

20 “(q) DEFINITIONS.—In this section:

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

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

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

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

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

12 **SEC. 102. MISBRANDING.**

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

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

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

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

3 (a) IN GENERAL.—Nothing in this Act (or the
4 amendments made by this Act) shall apply to any non-
5 prescription drug which was excluded by the Food and
6 Drug Administration from the Over-the-Counter Drug Re-
7 view in accordance with the statement set out at page
8 9466 of volume 37 of the Federal Register, published on
9 May 11, 1972.

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

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

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

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

19 (A) IN GENERAL.—A sponsor of a non-
20 prescription sunscreen active ingredient or com-
21 bination of nonprescription sunscreen active in-
22 gredients that, as of the date of enactment of
23 this Act, is subject to a proposed sunscreen
24 order under section 586C of the Federal Food,
25 Drug, and Cosmetic Act (21 U.S.C. 360fff–3)
26 may elect, by means of giving written notifica-

tion to the Secretary of Health and Human Services within 180 calendar days of the enactment of this Act, to transition into the review of such ingredient or combination of ingredients pursuant to the process set out in section 505G of the Federal Food, Drug, and Cosmetic Act, as added by section 101 of this Act.

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

(i) the proposed sunscreen order involved is deemed to be a request for an order under subsection (b) of section 505G of the Federal Food, Drug, and Cosmetic Act, as added by section 101 of this Act; and

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

(C) ELECTION NOT EXERCISED.—A sponsor of a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients described in subparagraph (A) that does not elect for such ingre-

1 dient or combination of ingredients to be re-
2 viewed under section 505G of the Federal Food,
3 Drug, and Cosmetic Act, as added by section
4 101 of this Act, shall continue to have such in-
5 gredient or combination of ingredients reviewed
6 in accordance with section 586C of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C.
8 360fff–3) and may not subsequently elect to
9 transition into the review of such ingredient or
10 combination of ingredients pursuant to the
11 process set out in section 505G of such Act, as
12 added by section 101 of this Act.

13 (2) DEFINITIONS.—In this subsection, the
14 terms “sponsor”, “nonprescription”, “sunscreen ac-
15 tive ingredient”, and “proposed sunscreen order”
16 have the meanings given to those terms in section
17 586 of the Federal Food, Drug, and Cosmetic Act
18 (21 U.S.C. 360fff).

19 (b) AMENDMENTS TO SUNSCREEN PROVISIONS.—

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

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

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

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

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

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

12 “(B) CONFIDENTIAL MEETINGS.—A spon-
13 sor may request one or more confidential meet-
14 ings with respect to a proposed sunscreen order,
15 including a letter deemed to be a proposed sun-
16 screen order under paragraph (3), to discuss
17 matters involving confidential commercial infor-
18 mation or trade secrets. The Secretary shall
19 convene a confidential meeting with such spon-
20 sor in a reasonable time period. If a sponsor re-
21 quests more than one confidential meeting for
22 the same proposed sunscreen order, the Sec-
23 retary may refuse to grant an additional con-
24 fidential meeting request if the Secretary deter-
25 mines that such additional confidential meeting

1 is not reasonably necessary for the sponsor to
 2 advance its proposed sunscreen order, or if the
 3 request for a confidential meeting fails to in-
 4 clude sufficient information upon which to base
 5 a substantive discussion. The Secretary shall
 6 publish a post-meeting summary of each con-
 7 fidential meeting under this subparagraph that
 8 does not disclose confidential commercial infor-
 9 mation or trade secrets.”.

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

14 **“SEC. 586H. SUNSET.**

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

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

21 (c) TREATMENT OF NON-SUNSCREEN TIME AND EX-
 22 TENT APPLICATIONS.—

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

1 to the Secretary of Health and Human Services pur-
2 suant to section 330.14 of title 21, Code of Federal
3 Regulations, as such provisions were in effect imme-
4 diately prior to the date of enactment date of this
5 Act, shall be extinguished as of such date of enact-
6 ment, subject to paragraph (2).

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

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

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

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

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

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

21 (c) DURATION OF AUTHORITY.—The requirement
22 under subsection (a) shall terminate as of the date of a
23 letter submitted by the Secretary of Health and Human
24 Services pursuant to such subsection in which the Sec-
25 retary indicates that the Food and Drug Administration

1 has completed its evaluation and revised, in a final order,
2 as applicable, the cough and cold monograph as described
3 in subsection (a)(2).

4 **TITLE II—USER FEES**

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

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

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

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

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

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

3 **“SEC. 744N. DEFINITIONS.**

4 “In this part:

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

8 “(A) one business entity controls, or has
9 the power to control, the other business entity;
10 or

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

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

20 “(3) The term ‘costs of resources allocated for
21 OTC monograph drug activities’ means the expenses
22 in connection with OTC monograph drug activities
23 for—

24 “(A) officers and employees of the Food
25 and Drug Administration, contractors of the
26 Food and Drug Administration, advisory com-

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

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

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

12 “(D) collecting fees under section 744O
13 and accounting for resources allocated for OTC
14 monograph drug activities.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19 “(i) is—

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

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

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

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

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

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

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

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

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

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

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

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

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

11 **“SEC. 744O. AUTHORITY TO ASSESS AND USE OTC MONO-**
12 **GRAPH FEES.**

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

16 “(1) FACILITY FEE.—

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

24 “(B) EXCEPTIONS.—

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

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

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

19 “(D) DUE DATE.—

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

1 “(ii) SUBSEQUENT FISCAL YEARS.—

2 For each fiscal year after fiscal year 2019,
3 the facility fees required under subpara-
4 graph (A) shall be due on the later of—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8 “(3) REFUNDS.—

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

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

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

24 “(b) FEE REVENUE AMOUNTS.—

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

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

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

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

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

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

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

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

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

3 “(E) additional dollar amounts for each
4 fiscal year as follows:

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

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

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

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

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

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

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

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

20 “(1) INFLATION ADJUSTMENT.—

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

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

3 “(ii) the inflation adjustment percent-
4 age under subparagraph (C).

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

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

14 “(ii) the inflation adjustment percent-
15 age under subparagraph (C).

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

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

1 first 3 years of the preceding 4 years of
2 available data; and

3 “(ii) for each of fiscal years 2022 and
4 2023, the sum of—

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

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

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

6 “(2) OPERATING RESERVE ADJUSTMENT.—

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

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

19 “(i) 3 weeks for fiscal year 2019;

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

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

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

23 and

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

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

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

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

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

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

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

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

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

25 “(4) ANNUAL FEE SETTING.—

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

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

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

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

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

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

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

1 graph order request fees in the Federal
2 Register.

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

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

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

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

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

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

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

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

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

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

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

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

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

17 “(1) IN GENERAL.—Fees authorized under sub-
18 section (a) shall be collected and available for obliga-
19 tion only to the extent and in the amount provided
20 in advance in appropriations Acts. Such fees are au-
21 thorized to remain available until expended. Such
22 sums as may be necessary may be transferred from
23 the Food and Drug Administration salaries and ex-
24 penses appropriation account without fiscal year lim-
25 itation to such appropriation account for salaries

1 and expenses with such fiscal year limitation. The
2 sums transferred shall be available solely for OTC
3 monograph drug activities.

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

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

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

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

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

10 “(D) PROVISION FOR EARLY PAYMENTS IN
11 SUBSEQUENT YEARS.—Payment of fees author-
12 ized under this section for a fiscal year (after
13 fiscal year 2019), prior to the due date for such
14 fees, may be accepted by the Secretary in ac-
15 cordance with authority provided in advance in
16 a prior year appropriations Act.

17 “(3) AUTHORIZATION OF APPROPRIATIONS.—
18 For each of the fiscal years 2019 through 2023,
19 there is authorized to be appropriated for fees under
20 this section an amount equal to the total amount of
21 fees assessed for such fiscal year under this section.

22 “(g) COLLECTION OF UNPAID FEES.—In any case
23 where the Secretary does not receive payment of a fee as-
24 sessed under subsection (a) within 30 calendar days after
25 it is due, such fee shall be treated as a claim of the United

1 States Government subject to subchapter II of chapter 37
2 of title 31, United States Code.

3 “(h) CONSTRUCTION.—This section may not be con-
4 strued to require that the number of full-time equivalent
5 positions in the Department of Health and Human Serv-
6 ices, for officers, employers, and advisory committees not
7 engaged in OTC monograph drug activities, be reduced
8 to offset the number of officers, employees, and advisory
9 committees so engaged.

10 **“SEC. 744P. REAUTHORIZATION; REPORTING REQUIRE-**
11 **MENTS.**

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

1 “(b) FISCAL REPORT.—Not later than 120 calendar
2 days after the end of fiscal year 2019 and each subsequent
3 fiscal year for which fees are collected under this part,
4 the Secretary shall prepare and submit to the Committee
5 on Energy and Commerce of the House of Representatives
6 and the Committee on Health, Education, Labor, and
7 Pensions of the Senate a report on the implementation
8 of the authority for such fees during such fiscal year and
9 the use, by the Food and Drug Administration, of the fees
10 collected for such fiscal year.

11 “(c) PUBLIC AVAILABILITY.—The Secretary shall
12 make the reports required under subsections (a) and (b)
13 available to the public on the Internet website of the Food
14 and Drug Administration.

15 “(d) REAUTHORIZATION.—

16 “(1) CONSULTATION.—In developing rec-
17 ommendations to present to the Congress with re-
18 spect to the goals described in subsection (a), and
19 plans for meeting the goals, for OTC monograph
20 drug activities for the first 5 fiscal years after fiscal
21 year 2023, and for the reauthorization of this part
22 for such fiscal years, the Secretary shall consult
23 with—

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

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

3 “(C) scientific and academic experts;

4 “(D) health care professionals;

5 “(E) representatives of patient and con-
6 sumer advocacy groups; and

7 “(F) the regulated industry.

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

11 “(A) present the recommendations devel-
12 oped under paragraph (1) to the congressional
13 committees specified in such paragraph;

14 “(B) publish such recommendations in the
15 Federal Register;

16 “(C) provide for a period of 30 calendar
17 days for the public to provide written comments
18 on such recommendations;

19 “(D) hold a meeting at which the public
20 may present its views on such recommenda-
21 tions; and

22 “(E) after consideration of such public
23 views and comments, revise such recommenda-
24 tions as necessary.

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

Passed the House of Representatives July 16, 2018.

Attest:

Clerk.

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.