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115TH CONGRESS
2D SESSION

H. R. 5333

[Report No. 115–827]

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

IN THE HOUSE OF REPRESENTATIVES

MARCH 19, 2018

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

JULY 16, 2018

Additional sponsors: Ms. MATSUI, Mr. FLEISCHMANN, and Mr. SCHRADER

JULY 16, 2018

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on March 19, 2018]

A BILL

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

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

3 **SECTION 1. SHORT TITLE.**

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

6 **TITLE I—OTC DRUG REVIEW**

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

8 **DRUGS THAT ARE MARKETING WITHOUT AN**
 9 **APPROVED NEW DRUG APPLICATION.**

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

13 **“SEC. 505G. REGULATION OF CERTAIN NONPRESCRIPTION**
 14 **DRUGS THAT ARE MARKETING WITHOUT AN**
 15 **APPROVED NEW DRUG APPLICATION.**

16 **“(a) NONPRESCRIPTION DRUGS MARKETING WITHOUT**
 17 **AN APPROVED APPLICATION.—***Nonprescription drugs mar-*
 18 *keted without an approved new drug application under sec-*
 19 *tion 505, as of the date of the enactment of the Over-the-*
 20 *Counter Monograph Safety, Innovation, and Reform Act of*
 21 *2018, shall be treated in accordance with this subsection.*

22 **“(1) DRUGS SUBJECT TO A FINAL MONOGRAPH;**
 23 **CATEGORY I DRUGS SUBJECT TO A TENTATIVE FINAL**
 24 **MONOGRAPH.—***A drug is deemed to be generally rec-*
 25 *ognized as safe and effective within the meaning of*

1 *section 201(p)(1), not a new drug under section*
2 *201(p), and not subject to section 503(b)(1), 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), and*
11 *(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 of*
18 *this section, has been used to a material ex-*
19 *tent 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 such*
5 *tentative final monograph, any applicable*
6 *subsequent determination by the Secretary,*
7 *the general requirements for nonprescription*
8 *drugs, and requirements under subsections*
9 *(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 of*
16 *this section, has been used to a material ex-*
17 *tent and for a material time within the*
18 *meaning of section 201(p)(2).*

19 “(2) *TREATMENT OF SUNSCREEN DRUGS.—With*
20 *respect to sunscreen drugs subject to this section, the*
21 *applicable requirements shall be the requirements*
22 *specified in part 352 of title 21, Code of Federal Reg-*
23 *ulations, as published on May 21, 1999, beginning on*
24 *page 27687 of volume 64 of the Federal Register, ex-*
25 *cept that the applicable requirements governing effec-*

1 *tiveness and labeling shall be those specified in section*
 2 *201.327 of title 21, Code of Federal Regulations, sub-*
 3 *ject to the requirements of subsections (b), (c), and*
 4 *(k).*

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

13 *“(A) the drug is—*

14 *“(i) classified in category III for safety*
 15 *or effectiveness in the preamble of a pro-*
 16 *posed 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, Code*
 20 *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 for*
12 *nonprescription drugs and require-*
13 *ments under subsections (b) or (k); and*

14 “(iii) *in a dosage form that, imme-*
15 *diately prior to the date of the enactment of*
16 *this section, was not required to have satis-*
17 *fied the requirements of section 330.14 of*
18 *title 21, Code of Federal Regulations (as in*
19 *effect at that time), in order for such drug*
20 *to be lawfully marketed without an applica-*
21 *tion approved under section 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 of*
 15 *this section, has been used to a material ex-*
 16 *tent 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 deemed*
 25 *to be a new drug within the meaning of section*

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

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

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

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

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

3 “(b) *ADMINISTRATIVE ORDERS.*—

4 “(1) *IN GENERAL.*—

5 “(A) *DETERMINATION.*—The Secretary
6 may, on the initiative of the Secretary or at the
7 request of one or more requestors, issue adminis-
8 trative orders determining whether there are con-
9 ditions under which specific drugs, classes of
10 such drugs, or combinations of such drugs are
11 determined to be—

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

13 and

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

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

21 “(i) is determined by the Secretary to
22 meet the conditions specified in clauses (i)
23 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 is
13 not generally recognized as safe and effective
14 within the meaning of section 201(p)(1); or

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

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

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

24 “(i) make reasonable efforts to notify
25 informally, not later than 2 business days

1 *before the issuance of the proposed order, the*
2 *sponsors of drugs who have a listing in ef-*
3 *fect under section 510(j) for the drugs or*
4 *combination of drugs that will be subject to*
5 *the administrative order;*

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

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

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

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

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

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

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

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

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

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

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

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

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

18 “(ii) the Secretary shall provide for a
19 public comment period of no less than 180
20 calendar days with respect to such proposed
21 order, except when the Secretary determines,
22 for good cause, that a shorter period is in
23 the interests of public health; and

24 “(iii) any person who submits data in
25 such comment period shall include a certifi-

1 *cation that the person has submitted all evi-*
2 *dence created, obtained, or received by that*
3 *person that is both within the categories of*
4 *data identified in the proposed order and*
5 *relevant to a determination as to whether*
6 *the drug is generally recognized as safe and*
7 *effective within the meaning of section*
8 *201(p)(1).*

9 *“(3) HEARINGS; JUDICIAL REVIEW.—*

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

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

1 “(i) *IN GENERAL.*—*The Secretary shall*
2 *not be required to provide notice and an op-*
3 *portunity for a hearing pursuant to para-*
4 *graph (2)(A)(iv) if the final administrative*
5 *order involved relates to a drug—*

6 “(I) *that is described in subsection*
7 *(a)(3)(A); and*

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

15 “(ii) *HUMAN DATA STUDIES AND NON-*
16 *HUMAN DATA DEFINED.*—*In this subpara-*
17 *graph:*

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

23 “(II) *The term ‘non-human data’*
24 *means data from testing other than*
25 *with human subjects which provides*

1 *information concerning safety or effec-*
2 *tiveness.*

3 “(C) *HEARING PROCEDURES.*—

4 “(i) *DENIAL OF REQUEST FOR HEAR-*
5 *ING.*—*If the Secretary determines that in-*
6 *formation submitted in a request for a hear-*
7 *ing under subparagraph (A) with respect to*
8 *a final administrative order issued under*
9 *paragraph (2)(A)(iv), does not identify the*
10 *existence of a genuine and substantial ques-*
11 *tion of material fact, the Secretary may*
12 *deny such request. In making such a deter-*
13 *mination, the Secretary may consider only*
14 *information and data that are based on rel-*
15 *evant and reliable scientific principles and*
16 *methodologies.*

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

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

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

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

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

14 “(iv) *RIGHTS OF PARTIES TO HEAR-*
15 *ING.*—*The parties to a hearing requested*
16 *under subparagraph (A) shall have the right*
17 *to present testimony, including testimony of*
18 *expert witnesses, and to cross-examine wit-*
19 *nesses presented by other parties. Where ap-*
20 *propriate, the presiding officer may require*
21 *that cross-examination by parties rep-*
22 *resenting substantially the same interests be*
23 *consolidated to promote efficiency and avoid*
24 *duplication.*

25 “(v) *FINAL DECISION.*—

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

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

13 “(D) *JUDICIAL REVIEW OF FINAL ADMINIS-*
14 *TRATIVE ORDER.—*

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

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

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

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

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

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

20 “(4) *EXPEDITED PROCEDURE WITH RESPECT TO*
21 *ADMINISTRATIVE ORDERS INITIATED BY THE SEC-*
22 *RETARY.*—

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

1 “(i) *IN GENERAL.*—*In the case of a de-*
2 *termination by the Secretary that a drug,*
3 *class of drugs, or combination of drugs sub-*
4 *ject to this section poses an imminent haz-*
5 *ard to the public health, the Secretary, after*
6 *first making reasonable efforts to notify, not*
7 *later than 48 hours before issuance of such*
8 *order under this subparagraph, sponsors*
9 *who have a listing in effect under section*
10 *510(j) for such drug or combination of*
11 *drugs—*

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

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

21 “(III) *shall provide for a public*
22 *comment period of at least 45 calendar*
23 *days with respect to such interim final*
24 *order.*

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

5 “(B) *SAFETY LABELING CHANGES.*—

6 “(i) *IN GENERAL.*—*In the case of a de-*
7 *termination by the Secretary that a change*
8 *in the labeling of a drug, class of drugs, or*
9 *combination of drugs subject to this section*
10 *is reasonably expected to mitigate a signifi-*
11 *cant or unreasonable risk of a serious ad-*
12 *verse event associated with use of the drug,*
13 *the Secretary may—*

14 “(I) *make reasonable efforts to no-*
15 *tify informally, not later than 48 hours*
16 *before the issuance of the interim final*
17 *order, the sponsors of drugs who have*
18 *a listing in effect under section 510(j)*
19 *for such drug or combination of drugs;*

20 “(II) *after reasonable efforts of no-*
21 *tification, issue an interim final ad-*
22 *ministrative order in accordance with*
23 *paragraph (1) to require such change,*
24 *together with a detailed statement of*
25 *the reasons for such order;*

1 “(III) publish in the *Federal Reg-*
2 *ister a notice of availability of such*
3 *order; and*

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

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

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

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

20 “(i) *issue a final order in accordance*
21 *with paragraph (1);*

22 “(ii) *publish a notice of availability of*
23 *such final administrative order in the Fed-*
24 *eral Register; and*

1 “(iii) afford sponsors of such drugs
2 that will be subject to such an order the op-
3 portunity for formal dispute resolution up
4 to the level of the Director of the Center for
5 Drug Evaluation and Research, which must
6 initially be within 45 calendar days of the
7 issuance of the order, and for subsequent
8 levels of appeal, within 30 calendar days of
9 the prior decision.

10 “(E) HEARINGS.—A sponsor of a drug sub-
11 ject to a final order issued under subparagraph
12 (D) and that participated in each stage of for-
13 mal dispute resolution under clause (iii) of such
14 subparagraph may request a hearing on such
15 order. The provisions of subparagraphs (A), (B),
16 and (C) of paragraph (3), other than paragraph
17 (3)(C)(v)(II), shall apply with respect to a hear-
18 ing on such order in the same manner and to the
19 same extent as such provisions apply with re-
20 spect to a hearing on an administrative order
21 issued under paragraph (2)(A)(iv).

22 “(F) TIMING.—

23 “(i) FINAL ORDER AND HEARING.—The
24 Secretary shall—

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

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

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

17 “(G) *JUDICIAL REVIEW.—A final order*
18 *issued pursuant to subparagraph (F) shall be*
19 *subject to judicial review in accordance with*
20 *paragraph (3)(D).*

21 “(5) *ADMINISTRATIVE ORDER INITIATED AT THE*
22 *REQUEST OF A REQUESTOR.—*

23 “(A) *IN GENERAL.—In issuing an adminis-*
24 *trative order under paragraph (1) at the request*

1 *of a requestor with respect to certain drugs,*
2 *classes of drugs, or combinations of drugs—*

3 “(i) *the Secretary shall, after receiving*
4 *a request under this subparagraph, deter-*
5 *mine whether the request is sufficiently*
6 *complete and formatted to permit a sub-*
7 *stantive review;*

8 “(ii) *if the Secretary determines that*
9 *the request is sufficiently complete and for-*
10 *matted to permit a substantive review, the*
11 *Secretary shall—*

12 “(I) *file the request; and*

13 “(II) *initiate proceedings with re-*
14 *spect to issuing an administrative*
15 *order in accordance with paragraphs*
16 *(2) and (3); and*

17 “(iii) *except as provided in paragraph*
18 *(6), if the Secretary determines that a re-*
19 *quest does not meet the requirements for fil-*
20 *ing or is not sufficiently complete and for-*
21 *matted to permit a substantive review, the*
22 *requestor may demand that the request be*
23 *filed over protest, and the Secretary shall*
24 *initiate proceedings to review the request in*
25 *accordance with paragraph (2)(A).*

1 “(B) REQUEST TO INITIATE PRO-
2 CEEDINGS.—

3 “(i) *IN GENERAL.*—A requestor seeking
4 an administrative order under paragraph
5 (1) with respect to certain drugs, classes of
6 drugs, or combinations of drugs, shall sub-
7 mit to the Secretary a request to initiate
8 proceedings for such order in the form and
9 manner as specified by the Secretary. Such
10 requestor may submit a request under this
11 subparagraph for the issuance of an admin-
12 istrative order—

13 “(I) *determining whether a drug*
14 *is generally recognized as safe and ef-*
15 *fective within the meaning of section*
16 *201(p)(1), exempt from section*
17 *503(b)(1), and not required to be the*
18 *subject of an approved application*
19 *under section 505; or*

20 “(II) *determining whether a*
21 *change to a condition of use of a drug*
22 *is generally recognized as safe and ef-*
23 *fective within the meaning of section*
24 *201(p)(1), exempt from section*
25 *503(b)(1), and not required to be the*

1 *subject of an approved application*
2 *under section 505, if, absent such a*
3 *changed condition of use, such drug*
4 *is—*

5 *“(aa) generally recognized as*
6 *safe and effective within the*
7 *meaning of section 201(p)(1) in*
8 *accordance with subsection (a)(1),*
9 *(a)(2), or an order under this sub-*
10 *section; or*

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

21 *“(ii) EXCEPTION.—The Secretary is*
22 *not required to complete review of a request*
23 *for a change described in clause (i)(II) if*
24 *the Secretary determines that there is an*
25 *inadequate basis to find the drug is gen-*

1 *erally recognized as safe and effective with-*
2 *in the meaning of section 201(p)(1) under*
3 *paragraph (1) and issues a final order an-*
4 *nouncing that determination.*

5 “(iii) *WITHDRAWAL.*—*The requestor*
6 *may withdraw a request under this para-*
7 *graph, according to the procedures set forth*
8 *pursuant to subsection (d)(2)(B). Notwith-*
9 *standing any other provision of this section,*
10 *if such request is withdrawn, the Secretary*
11 *may cease proceedings under this subpara-*
12 *graph.*

13 “(C) *EXCLUSIVITY.*—

14 “(i) *IN GENERAL.*—*A final adminis-*
15 *trative order issued in response to a request*
16 *under this section shall have the effect of au-*
17 *thorizing solely the order requestor (or the*
18 *licensees, assignees, or successors in interest*
19 *of such requestor with respect to the subject*
20 *of such order), for a period of 18 months*
21 *following the effective date of such final*
22 *order, to market drugs—*

23 “(I) *incorporating changes de-*
24 *scribed in clause (ii);*

1 “(II) beginning on the date the re-
2 questor (or any such licensees, assign-
3 ees, or successors in interest) may law-
4 fully market such drugs pursuant to
5 the order; and

6 “(III) subject to the limitations
7 under clause (iv).

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

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

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

23 “(iii) *DRUGS DESCRIBED.*—The drugs
24 described in this clause are drugs—

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

3 “(II) subject to a final order
4 issued under this section;

5 “(III) subject to a final sunscreen
6 order (as defined in section 586(2)(A));
7 or

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

12 “(iv) LIMITATIONS ON EXCLUSIVITY.—

13 “(I) IN GENERAL.—Only one pe-
14 riod of exclusivity shall be granted,
15 under each order described in clause
16 (i), with respect to changes (to the drug
17 subject to such order) which are ei-
18 ther—

19 “(aa) changes described in
20 clause (ii)(I), relating to active
21 ingredients; or

22 “(bb) changes described in
23 clause (ii)(II), relating to condi-
24 tions of use.

1 “(II) No EXCLUSIVITY AL-
2 LOWED.—No exclusivity shall apply to
3 changes to a drug which are—

4 “(aa) the subject of a Tier 2
5 OTC monograph order request (as
6 defined in section 744N);

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

12 “(cc) changes related to
13 methods of testing safety or effi-
14 cacy.

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

22 “(I) have not been relied on by the
23 Secretary to support—

24 “(aa) a proposed or final de-
25 termination that a drug described

1 in subclauses (I), (II), or (III) of
2 clause (iii) is generally recognized
3 as safe and effective within the
4 meaning of section 201(p)(1); or

5 “(bb) approval of a drug that
6 was approved under section 505;
7 and

8 “(II) do not duplicate the results
9 of another study that was relied on by
10 the Secretary to support—

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

17 “(bb) approval of a drug that
18 was approved under section 505.

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

1 under subsection (e) with respect to the
2 change which is permitted under such order.

3 “(vii) *GAO STUDY*.—Not later than 4
4 years after the date of enactment of the
5 *Over-the-Counter Monograph, Safety, Inno-*
6 *vation, and Reform Act of 2018*, the *Comp-*
7 *troller General of the United States* shall
8 submit a study to the *Committee on Energy*
9 *and Commerce of the House of Representa-*
10 *tives and the Committee on Health, Edu-*
11 *cation, Labor, and Pensions of the Senate*
12 addressing the effectiveness and overall im-
13 pact of exclusivity under this section, in-
14 cluding its impact on consumer access.
15 Such study shall include—

16 “(I) the number of nonprescrip-
17 tion drug products that were granted
18 exclusivity and the indication for
19 which the nonprescription drug prod-
20 ucts were determined to be generally
21 recognized as safe and effective;

22 “(II) whether the exclusivity for
23 such drug products was granted for—

1 “(aa) a new active ingredient
2 (including any ester or salt of the
3 active ingredient); or

4 “(bb) changes in the condi-
5 tions of use of a drug, for which
6 new human data studies con-
7 ducted or sponsored by the re-
8 questor were essential;

9 “(III) whether, and to what ex-
10 tent, the exclusivity impacted the re-
11 questor’s or sponsor’s decision to de-
12 velop the drug product;

13 “(IV) an analysis of the imple-
14 mentation of the exclusivity provision
15 in this subparagraph, including—

16 “(aa) the resources used by
17 the Food and Drug Administra-
18 tion;

19 “(bb) the impact of such pro-
20 vision on innovation, as well as
21 research and development in the
22 nonprescription drug market;

23 “(cc) the impact of such pro-
24 vision on competition in the non-
25 prescription drug market;

1 “(dd) the impact of such pro-
 2 vision on consumer access to non-
 3 prescription drug products;

4 “(ee) the impact of such pro-
 5 vision on the prices of non-
 6 prescription drug products; and

7 “(ff) whether the administra-
 8 tive orders initiated by requestors
 9 under this section have been suffi-
 10 cient to encourage the development
 11 of nonprescription drug products
 12 that would likely not be otherwise
 13 developed, or developed in as
 14 timely a manner; and

15 “(V) whether the administrative
 16 orders initiated by requestors under
 17 this section have been sufficient incen-
 18 tive to encourage innovation in the
 19 nonprescription drug market.

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

24 “(A) IN GENERAL.—In response to a request
 25 under this section that a drug described in sub-

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

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

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

14 “(B) *DRUG DESCRIBED.*—A drug described
 15 in this subparagraph is a nonprescription drug
 16 which contains an active ingredient not pre-
 17 viously incorporated in a drug—

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

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

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

24 “(C) *INFORMATION DEMONSTRATING PRIMA*
 25 *FACIE SAFE NONPRESCRIPTION MARKETING AND*

1 *USE.—Information specified in this subpara-*
2 *graph, with respect to a request described in sub-*
3 *paragraph (A)(i), is—*

4 *“(i) information sufficient for a prima*
5 *facie demonstration that the drug subject to*
6 *such request has a verifiable history of being*
7 *marketed and safely used by consumers in*
8 *the United States as a nonprescription drug*
9 *under comparable conditions of use;*

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

19 *“(I) for such period of time as*
20 *needed to provide reasonable assur-*
21 *ances concerning the safe nonprescrip-*
22 *tion use of the drug; and*

23 *“(II) during such time was sub-*
24 *ject to sufficient monitoring by a regu-*
25 *latory body considered acceptable by*

1 *the Secretary for such monitoring pur-*
2 *poses, including for adverse events as-*
3 *sociated with nonprescription use of*
4 *the drug; or*

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

12 “(D) *MARKETING PURSUANT TO NEW DRUG*
13 *APPLICATION.—In the case of a request described*
14 *in subparagraph (A)(ii), the drug subject to such*
15 *request may be re-submitted for filing only if—*

16 “(i) *the drug is marketed as a non-*
17 *prescription drug, under conditions of use*
18 *comparable to the conditions specified in*
19 *the request, for such period of time as the*
20 *Secretary determines appropriate (not to*
21 *exceed five consecutive years) pursuant to*
22 *an application approved under section 505;*
23 *and*

24 “(ii) *during such time period, one mil-*
25 *lion retail packages of the drug, or an*

1 *equivalent quantity as determined by the*
2 *Secretary, were distributed for retail sale,*
3 *as determined in such manner as the Sec-*
4 *retary finds appropriate.*

5 “(E) *RULE OF APPLICATION.—Except in*
6 *the case of a request involving a drug described*
7 *in section 586(9), as in effect on January 1,*
8 *2017, if the Secretary refuses to file a request*
9 *under this paragraph, the requestor may not file*
10 *such request over protest under paragraph*
11 *(5)(A)(iii).*

12 “(7) *PACKAGING.—An administrative order*
13 *issued under paragraph (2), (4)(A), or (5) may in-*
14 *clude requirements for the packaging of a drug to en-*
15 *courage use in accordance with labeling. Such re-*
16 *quirements may include unit dose packaging, require-*
17 *ments for products intended for use by children, re-*
18 *quirements to reduce risk of harm from unsupervised*
19 *ingestion, and other appropriate requirements. This*
20 *paragraph does not authorize the Food and Drug Ad-*
21 *ministration to require standards or testing proce-*
22 *dures as described in part 1700 of title 16, Code of*
23 *Federal Regulations.*

1 “(8) *FINAL AND TENTATIVE FINAL MONOGRAPHS*
2 *FOR CATEGORY I DRUGS DEEMED FINAL ADMINISTRA-*
3 *TIVE ORDERS.*—

4 “(A) *IN GENERAL.*—A final monograph or
5 tentative final monograph described in subpara-
6 graph (B) shall be deemed to be a final adminis-
7 trative order under this subsection and may be
8 amended, revoked, or otherwise modified in ac-
9 cordance with the procedures of this subsection.

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

14 “(i) establishes conditions of use for a
15 drug described in paragraph (1) or (2) of
16 subsection (a); and

17 “(ii) represents the most recently pro-
18 mulgated version of such conditions, includ-
19 ing as modified, in whole or in part, by
20 any proposed or final rule.

21 “(C) *DEEMED ORDERS INCLUDE HARMO-*
22 *NIZING TECHNICAL AMENDMENTS.*—The deemed
23 establishment of a final administrative order
24 under subparagraph (A) shall be construed to in-
25 clude any technical amendments to such order as

1 *the Secretary determines necessary to ensure that*
2 *such order is appropriately harmonized, in*
3 *terms of terminology or cross-references, with the*
4 *applicable provisions of this Act (and regulations*
5 *thereunder) and any other orders issued under*
6 *this section.*

7 *“(c) PROCEDURE FOR MINOR CHANGES.—*

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

14 *“(A) the requestor maintains such informa-*
15 *tion as is necessary to demonstrate that the*
16 *change—*

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

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

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

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

3 “(2) *ADDITIONAL INFORMATION.*—

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

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

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

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

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

1 *additional information does not demonstrate*
2 *that the change does not affect the safety or effec-*
3 *tiveness of the drug or materially affect the ex-*
4 *tent of absorption or other exposure to the active*
5 *ingredient, the drug as modified is a new drug*
6 *within the meaning of section 201(p) and shall*
7 *be deemed to be misbranded under section*
8 *502(ee).*

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

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

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

1 *into account the special needs of populations, in-*
2 *cluding children.*

3 “(d) *CONFIDENTIALITY OF INFORMATION SUBMITTED*
4 *TO THE SECRETARY.*—

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

15 “(2) *PUBLIC AVAILABILITY.*—

16 “(A) *IN GENERAL.*—Except as provided in
17 *subparagraph (B), the Secretary shall—*

18 “(i) *make any information submitted*
19 *by a requestor in support of a request under*
20 *subsection (b)(5)(A) available to the public*
21 *not later than the date on which the pro-*
22 *posed order is issued; and*

23 “(ii) *make any information submitted*
24 *by any other person with respect to an*
25 *order requested (or initiated by the Sec-*

1 retary) under subsection (b), available to
2 the public upon such submission.

3 “(B) *LIMITATIONS ON PUBLIC AVAIL-*
4 *ABILITY.—Information described in subpara-*
5 *graph (A) shall not be made public if—*

6 “(i) *the information pertains to phar-*
7 *maceutical quality information, unless such*
8 *information is necessary to establish stand-*
9 *ards under which a drug is generally recog-*
10 *nized as safe and effective within the mean-*
11 *ing of section 201(p)(1);*

12 “(ii) *the information is submitted in a*
13 *requestor-initiated request, but the requestor*
14 *withdraws such request, in accordance with*
15 *withdrawal procedures established by the*
16 *Secretary, before the Secretary issues the*
17 *proposed order;*

18 “(iii) *the Secretary requests and ob-*
19 *tains the information under subsection (c)*
20 *and such information is not submitted in*
21 *relation to an order under subsection (b); or*

22 “(iv) *the information is of the type*
23 *contained in raw datasets.*

24 “(e) *UPDATES TO DRUG LISTING INFORMATION.—A*
25 *sponsor who makes a change to a drug subject to this section*

1 shall submit updated drug listing information for the drug
 2 in accordance with section 510(j) within 30 calendar days
 3 of the date when the drug is first commercially marketed,
 4 except that a sponsor who was the order requestor with re-
 5 spect to an order subject to subsection (b)(5)(C) (or a li-
 6 censee, assignee, or successor in interest of such requestor)
 7 shall submit updated drug listing information on or before
 8 the date when the drug is first commercially marketed.

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

23 “(g) PUBLIC AVAILABILITY OF ADMINISTRATIVE OR-
 24 DERS.—The Secretary shall establish, maintain, update (as
 25 determined necessary by the Secretary but no less frequently

1 *than annually), and make publicly available, with respect*
 2 *to orders issued under this section—*

3 “(1) *a repository of each final order and interim*
 4 *final order in effect, including the complete text of the*
 5 *order; and*

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

8 “(A) *a brief description of each such order;*
 9 *and*

10 “(B) *the Secretary’s expectations, if re-*
 11 *sources permit, for issuance of proposed orders*
 12 *over a three-year period.*

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

22 “(i) *PARTICIPATION OF MULTIPLE SPONSORS OR RE-*
 23 *QUESTORS.—The Secretary shall establish procedures to fa-*
 24 *cilitate efficient participation by multiple sponsors or re-*
 25 *questors in proceedings under this section, including provi-*

1 sion for joint meetings with multiple sponsors or requestors
 2 or with organizations nominated by sponsors or requestors
 3 to represent their interests in a proceeding.

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

6 “(k) *EFFECT ON EXISTING REGULATIONS GOVERNING*
 7 *NONPRESCRIPTION DRUGS*.—

8 “(1) *REGULATIONS OF GENERAL APPLICABILITY*
 9 *TO NONPRESCRIPTION DRUGS*.—Except as provided in
 10 this subsection, nothing in this section supersedes reg-
 11 ulations establishing general requirements for non-
 12 prescription drugs, including regulations of general
 13 applicability contained in parts 201, 250, and 330 of
 14 title 21, Code of Federal Regulations, or any successor
 15 regulations. The Secretary shall establish or modify
 16 such regulations by means of rulemaking in accord-
 17 ance with section 553 of title 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 effect
 22 on the day before the date of the enactment of
 23 this section, shall be deemed to be a final order
 24 under subsection (b).

1 “(B) *Regulations in effect on the day before*
2 *the date of the enactment of this section, estab-*
3 *lishing requirements for specific nonprescription*
4 *drugs marketed pursuant to this section (includ-*
5 *ing such requirements in parts 201 and 250 of*
6 *title 21, Code of Federal Regulations), shall be*
7 *deemed to be final orders under subsection (b),*
8 *only as they apply to drugs—*

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

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

13 “(3) *WITHDRAWAL OF REGULATIONS.—The Sec-*
14 *retary shall withdraw regulations establishing final*
15 *monographs and the procedures governing the over-*
16 *the-counter drug review under part 330 and other rel-*
17 *evant parts of title 21, Code of Federal Regulations*
18 *(as in effect on the day before the date of the enact-*
19 *ment of this section), or make technical changes to*
20 *such regulations to ensure conformity with appro-*
21 *priate terminology and cross references. Notwith-*
22 *standing subchapter II of chapter 5 of title 5, United*
23 *States Code, any such withdrawal or technical*
24 *changes shall be made without public notice and com-*
25 *ment and shall be effective upon publication through*

1 *notice in the Federal Register (or upon such date as*
2 *specified in such notice).*

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

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

8 “(2) *the format and content of data submissions*
9 *to the Secretary under this section;*

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

12 “(4) *consolidated proceedings and the procedures*
13 *for such proceedings where appropriate; and*

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

17 “(m) *RULE OF CONSTRUCTION.—*

18 “(1) *IN GENERAL.—This section shall not affect*
19 *the treatment or status of a nonprescription drug—*

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

23 “(B) *that is not subject to an order issued*
24 *under this section; and*

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

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

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

11 “(B) A drug described in this subparagraph
12 is a drug which, prior to the date of the enact-
13 ment of this section, the Secretary had deter-
14 mined in a proposed or final rule to be ineligible
15 for review under the OTC drug review (as such
16 phrase ‘OTC drug review’ was used in section
17 330.14 of title 21, Code of Federal Regulations,
18 as in effect on the day before the date of the en-
19 actment of this section).

20 “(3) *PRESERVATION OF AUTHORITY.—*

21 “(A) Nothing in paragraph (1) shall be con-
22 strued to preclude or limit the applicability of
23 any other provision of this Act.

24 “(B) Nothing in subsection (a) shall be con-
25 strued to prohibit the Secretary from issuing an

1 *order under this section finding a drug to be not*
 2 *generally recognized as safe and effective within*
 3 *the meaning of section 201(p)(1), as the Sec-*
 4 *retary determines appropriate.*

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

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

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

16 “(q) *DEFINITIONS.*—*In this section:*

17 “(1) *The term ‘nonprescription drug’ refers to a*
 18 *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 Administration.

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

6 **SEC. 102. MISBRANDING.**

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

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

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

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

20 (a) *IN GENERAL.*—Nothing in this Act (or the amend-
21 ments made by this Act) shall apply to any nonprescription
22 drug which was excluded by the Food and Drug Adminis-
23 tration from the Over-the-Counter Drug Review in accord-
24 ance with the statement set out at page 9466 of volume 37
25 of the Federal Register, published on May 11, 1972.

1 (b) *RULE OF CONSTRUCTION.*—*Nothing in this section*
 2 *shall be construed to preclude or limit the applicability of*
 3 *any other provision of the Federal Food, Drug, and Cos-*
 4 *metic Act (21 U.S.C. 301 et seq.).*

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

6 (a) *REVIEW OF NONPRESCRIPTION SUNSCREEN AC-*
 7 *TIVE INGREDIENTS.*—

8 (1) *APPLICABILITY OF SECTION 505G FOR PEND-*
 9 *ING SUBMISSIONS.*—

10 (A) *IN GENERAL.*—*A sponsor of a non-*
 11 *prescription sunscreen active ingredient or com-*
 12 *bination of nonprescription sunscreen active in-*
 13 *gredients that, as of the date of enactment of this*
 14 *Act, is subject to a proposed sunscreen order*
 15 *under section 586C of the Federal Food, Drug,*
 16 *and Cosmetic Act (21 U.S.C. 360fff–3) may elect,*
 17 *by means of giving written notification to the*
 18 *Secretary of Health and Human Services within*
 19 *180 calendar days of the enactment of this Act,*
 20 *to transition into the review of such ingredient*
 21 *or combination of ingredients pursuant to the*
 22 *process set out in section 505G of the Federal*
 23 *Food, Drug, and Cosmetic Act, as added by sec-*
 24 *tion 101 of this Act.*

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

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

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

13 (C) *ELECTION NOT EXERCISED*.—A sponsor
14 of a nonprescription sunscreen active ingredient
15 or combination of nonprescription sunscreen ac-
16 tive ingredients described in subparagraph (A)
17 that does not elect for such ingredient or com-
18 bination of ingredients to be reviewed under sec-
19 tion 505G of the Federal Food, Drug, and Cos-
20 metic Act, as added by section 101 of this Act,
21 shall continue to have such ingredient or com-
22 bination of ingredients reviewed in accordance
23 with section 586C of the Federal Food, Drug,
24 and Cosmetic Act (21 U.S.C. 360fff–3) and may
25 not subsequently elect to transition into the re-

view of such ingredient or combination of ingredients pursuant to the process set out in section 505G of such Act, as added by section 101 of this Act.

(2) *DEFINITIONS.*—In this subsection, the terms “sponsor”, “nonprescription”, “sunscreen active ingredient”, and “proposed sunscreen order” have the meanings given to those terms in section 586 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff).

(b) *AMENDMENTS TO SUNSCREEN PROVISIONS.*—

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

“(3) *RELATIONSHIP TO ORDERS UNDER SECTION 505G.*—A final sunscreen order shall be deemed to be a final order under section 505G.”.

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

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

“(A) *IN GENERAL.*—A sponsor may request”; and

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

2 “(B) *CONFIDENTIAL MEETINGS.*—A sponsor
3 may request one or more confidential meetings
4 with respect to a proposed sunscreen order, in-
5 cluding a letter deemed to be a proposed sun-
6 screen order under paragraph (3), to discuss
7 matters involving confidential commercial infor-
8 mation or trade secrets. The Secretary shall con-
9 vene a confidential meeting with such sponsor in
10 a reasonable time period. If a sponsor requests
11 more than one confidential meeting for the same
12 proposed sunscreen order, the Secretary may
13 refuse to grant an additional confidential meet-
14 ing request if the Secretary determines that such
15 additional confidential meeting is not reasonably
16 necessary for the sponsor to advance its proposed
17 sunscreen order, or if the request for a confiden-
18 tial meeting fails to include sufficient informa-
19 tion upon which to base a substantive discussion.
20 The Secretary shall publish a post-meeting sum-
21 mary of each confidential meeting under this
22 subparagraph that does not disclose confidential
23 commercial information or trade secrets.”.

24 (3) *SUNSET PROVISION.*—Subchapter I of chap-
25 ter V of the Federal Food, Drug, and Cosmetic Act

1 (21 U.S.C. 360fff et seq.) is amended by adding at the
2 end the following:

3 **“SEC. 586H. SUNSET.**

4 *“This subchapter shall cease to be effective at the end*
5 *of fiscal year 2022.”.*

6 (4) *TREATMENT OF FINAL SUNSCREEN ORDER.—*

7 *The Federal Food, Drug, and Cosmetic Act is amend-*
8 *ed by striking section 586E of such Act (21 U.S.C.*
9 *360fff-5).*

10 (c) *TREATMENT OF NON-SUNSCREEN TIME AND EX-*
11 *TENT APPLICATIONS.—*

12 (1) *IN GENERAL.—Any application described in*
13 *section 586F of the Federal Food, Drug, and Cosmetic*
14 *Act (21 U.S.C. 360fff-6) that was submitted to the*
15 *Secretary of Health and Human Services pursuant to*
16 *section 330.14 of title 21, Code of Federal Regula-*
17 *tions, as such provisions were in effect immediately*
18 *prior to the date of enactment date of this Act, shall*
19 *be extinguished as of such date of enactment, subject*
20 *to paragraph (2).*

21 (2) *ORDER REQUEST.—Nothing in paragraph*
22 *(1) precludes the submission of an order request under*
23 *section 505G(b) of the Federal Food, Drug, and Cos-*
24 *metic Act, as added by section 101 of this Act, with*

1 *respect to a drug that was the subject of an applica-*
 2 *tion extinguished under paragraph (1).*

3 **SEC. 105. ANNUAL UPDATE TO CONGRESS ON APPROPRIATE**
 4 **PEDIATRIC INDICATION FOR CERTAIN OTC**
 5 **COUGH AND COLD DRUGS.**

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

14 (1) *in evaluating the cough and cold monograph*
 15 *described in subsection (b) with respect to children*
 16 *under age 6; and*

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

22 (b) *COUGH AND COLD MONOGRAPH DESCRIBED.*—The
 23 cough and cold monograph described in this subsection con-
 24 sists of the conditions under which nonprescription drugs
 25 containing antitussive, expectorant, nasal decongestant, or

1 *antihistamine active ingredients (or combinations thereof)*
 2 *are generally recognized as safe and effective, as specified*
 3 *in part 341 of title 21, Code of Federal Regulations (as*
 4 *in effect immediately prior to the date of enactment of this*
 5 *Act), and included in an order deemed to be established*
 6 *under section 505G(b) of the Federal Food, Drug, and Cos-*
 7 *metic Act, as added by section 101 of this Act.*

8 (c) *DURATION OF AUTHORITY.*—*The requirement*
 9 *under subsection (a) shall terminate as of the date of a letter*
 10 *submitted by the Secretary of Health and Human Services*
 11 *pursuant to such subsection in which the Secretary indi-*
 12 *cates that the Food and Drug Administration has completed*
 13 *its evaluation and revised, in a final order, as applicable,*
 14 *the cough and cold monograph as described in subsection*
 15 *(a)(2).*

16 ***TITLE II—USER FEES***

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

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

20 (b) *FINDING.*—*The Congress finds that the fees author-*
 21 *ized by the amendments made in this title will be dedicated*
 22 *to OTC monograph drug activities, as set forth in the goals*
 23 *identified for purposes of part 10 of subchapter C of chapter*
 24 *VII of the Federal Food, Drug, and Cosmetic Act, in the*
 25 *letters from the Secretary of Health and Human Services*

1 *to the Chairman of the Committee on Health, Education,*
 2 *Labor, and Pensions of the Senate and the Chairman of*
 3 *the Committee on Energy and Commerce of the House of*
 4 *Representatives, as set forth in the Congressional Record.*

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

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

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

11 **“SEC. 744N. DEFINITIONS.**

12 *“In this part:*

13 *“(1) The term ‘affiliate’ means a business entity*
 14 *that has a relationship with a second business entity*
 15 *if, directly or indirectly—*

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

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

20 *“(2) The term ‘contract manufacturing organiza-*
 21 *tion facility’ means an OTC monograph drug facility*
 22 *where neither the owner of such manufacturing facil-*
 23 *ity nor any affiliate of such owner or facility sells the*
 24 *OTC monograph drug produced at such facility di-*

1 rectly to wholesalers, retailers, or consumers in the
2 United States.

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

7 “(A) officers and employees of the Food and
8 Drug Administration, contractors of the Food
9 and Drug Administration, advisory committees,
10 and costs related to such officers, employees, and
11 committees and costs related to contracts with
12 such contractors;

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

16 “(C) leasing, maintenance, renovation, and
17 repair of facilities and acquisition, maintenance,
18 and repair of fixtures, furniture, scientific equip-
19 ment, and other necessary materials and sup-
20 plies; and

21 “(D) collecting fees under section 744O and
22 accounting for resources allocated for OTC mono-
23 graph drug activities.

24 “(4) The term ‘FDA establishment identifier’ is
25 the unique number automatically generated by Food

1 *and Drug Administration’s Field Accomplishments*
2 *and Compliance Tracking System (FACTS) (or any*
3 *successor system).*

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

8 “(6) *The term ‘OTC monograph drug activities’*
9 *means activities of the Secretary associated with OTC*
10 *monograph drugs and inspection of facilities associ-*
11 *ated with such products, including the following ac-*
12 *tivities:*

13 “(A) *The activities necessary for review and*
14 *evaluation of OTC monographs and OTC mono-*
15 *graph order requests, including—*

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

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

1 “(iii) all OTC monograph drug devel-
2 opment and review activities, including
3 intraagency collaboration;

4 “(iv) regulation and policy develop-
5 ment activities related to OTC monograph
6 drugs;

7 “(v) development of product standards
8 for products subject to review and evalua-
9 tion;

10 “(vi) meetings referred to in section
11 505G(i);

12 “(vii) review of labeling prior to
13 issuance of orders related to OTC mono-
14 graph drugs or conditions of use; and

15 “(viii) regulatory science activities re-
16 lated to OTC monograph drugs.

17 “(B) Inspections related to OTC monograph
18 drugs.

19 “(C) Monitoring of clinical and other re-
20 search conducted in connection with OTC mono-
21 graph drugs.

22 “(D) Safety activities with respect to OTC
23 monograph drugs, including—

1 “(i) collecting, developing, and review-
2 ing safety information on OTC monograph
3 drugs, including adverse event reports;

4 “(ii) developing and using improved
5 adverse event data-collection systems, in-
6 cluding information technology systems;
7 and

8 “(iii) developing and using improved
9 analytical tools to assess potential safety
10 risks, including access to external databases.

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

13 “(7) The term ‘OTC monograph order request’
14 means a request for an order submitted under section
15 505G(b)(5).

16 “(8) The term ‘Tier 1 OTC monograph order re-
17 quest’ means any OTC monograph order request not
18 determined to be a Tier 2 OTC monograph order re-
19 quest.

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

23 “(i) the reordering of existing information
24 in the drug facts label of an OTC monograph
25 drug;

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

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

10 “(iv) the standardization of the concentra-
11 tion or dose of a specific finalized ingredient
12 within a particular finalized monograph;

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

16 “(vi) addition of an interchangeable term in
17 accordance with section 330.1 of title 21, Code of
18 Federal Regulations (or any successor regula-
19 tions).

20 “(B) The Secretary may, based on program im-
21 plementation experience or other factors found appro-
22 priate by the Secretary, characterize any OTC mono-
23 graph order request as a Tier 2 OTC monograph
24 order request (including recharacterizing a request
25 from Tier 1 to Tier 2) and publish such determina-

1 *tion in a proposed order issued pursuant to section*
2 *505G.*

3 *“(10)(A) The term ‘OTC monograph drug facil-*
4 *ity’ means a foreign or domestic business or other en-*
5 *tity that—*

6 *“(i) is—*

7 *“(I) under one management, either di-*
8 *rect or indirect; and*

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

13 *“(ii) includes a finished dosage form manu-*
14 *facturer facility in a contractual relationship*
15 *with the sponsor of one or more OTC monograph*
16 *drugs to manufacture or process such drugs; and*

17 *“(iii) does not include a business or other*
18 *entity whose only manufacturing or processing*
19 *activities are one or more of the following: pro-*
20 *duction of clinical research supplies, or testing.*

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

1 “(i) closely related to the same business en-
2 terprise;

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

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

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

14 “(11) The term ‘OTC monograph drug meeting’
15 means any meeting regarding the content of a pro-
16 posed OTC monograph order request.

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

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

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

23 “(a) *TYPES OF FEES.*—Beginning with fiscal year
24 2019, the Secretary shall assess and collect fees in accord-
25 ance with this section as follows:

1 “(1) *FACILITY FEE.*—

2 “(A) *IN GENERAL.*—*Each person that owns*
3 *a facility identified as an OTC monograph drug*
4 *facility on December 31 of the fiscal year or at*
5 *any time during the preceding 12-month period*
6 *shall be assessed an annual fee for each such fa-*
7 *cility as determined under subsection (c).*

8 “(B) *EXCEPTIONS.*—

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

18 “(ii) *The amount of the fee for a con-*
19 *tract manufacturing organization facility*
20 *shall be equal to $\frac{2}{3}$ the amount of the fee for*
21 *an OTC monograph drug facility that is*
22 *not a contract manufacturing organization*
23 *facility.*

1 “(C) *AMOUNT.*—*The amount of fees estab-*
 2 *lished under subparagraph (A) shall be estab-*
 3 *lished under subsection (c).*

4 “(D) *DUE DATE.*—

5 “(i) *FOR FIRST PROGRAM YEAR.*—*For*
 6 *fiscal year 2019, the facility fees required*
 7 *under subparagraph (A) shall be due 45 cal-*
 8 *endar days after publication of the Federal*
 9 *Register notice provided for under sub-*
 10 *section (c)(4)(A).*

11 “(ii) *SUBSEQUENT FISCAL YEARS.*—
 12 *For each fiscal year after fiscal year 2019,*
 13 *the facility fees required under subpara-*
 14 *graph (A) shall be due on the later of—*

15 “(I) *the first business day of June*
 16 *of such year; or*

17 “(II) *the first business day after*
 18 *the enactment of an appropriations*
 19 *Act providing for the collection and ob-*
 20 *ligation of fees under this section for*
 21 *such year.*

22 “(2) *OTC MONOGRAPH ORDER REQUEST FEE.*—

23 “(A) *IN GENERAL.*—*Each person that sub-*
 24 *mits an OTC monograph order request shall be*

1 *subject to a fee for an OTC monograph order re-*
2 *quest. The amount of such fee shall be—*

3 “(i) *for a Tier 1 OTC monograph*
4 *order request, \$500,000, adjusted for infla-*
5 *tion for the fiscal year (as determined under*
6 *subsection (c)(1)(B)); and*

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

11 “(B) *DUE DATE.—The OTC monograph*
12 *order request fees required under subparagraph*
13 *(A) shall be due on the date of submission of the*
14 *OTC monograph order request.*

15 “(C) *EXCEPTION FOR CERTAIN SAFETY*
16 *CHANGES.—A person who is named as the re-*
17 *questor in an OTC monograph order shall not be*
18 *subject to a fee under subparagraph (A) if the*
19 *Secretary finds that the OTC monograph order*
20 *request seeks to change the drug facts labeling of*
21 *an OTC monograph drug in a way that would*
22 *add to or strengthen—*

23 “(i) *a contraindication, warning, or*
24 *precaution;*

1 “(ii) a statement about risk associated
2 with misuse or abuse; or

3 “(iii) an instruction about dosage and
4 administration that is intended to increase
5 the safe use of the OTC monograph drug.

6 “(D) REFUND OF FEE IF ORDER REQUEST
7 IS RECATEGORIZED AS A TIER 2 OTC MONO-
8 GRAPH ORDER REQUEST.—If the Secretary deter-
9 mines that an OTC monograph request initially
10 characterized as Tier 1 shall be re-characterized
11 as a Tier 2 OTC monograph order request, and
12 the requestor has paid a Tier 1 fee in accordance
13 with subparagraph (A)(i), the Secretary shall re-
14 fund the requestor the difference between the Tier
15 1 and Tier 2 fees determined under subpara-
16 graphs (A)(i) and (A)(ii), respectively.

17 “(E) REFUND OF FEE IF ORDER REQUEST
18 REFUSED FOR FILING OR WITHDRAWN BEFORE
19 FILING.—The Secretary shall refund 75 percent
20 of the fee paid under subparagraph (B) for any
21 order request which is refused for filing or was
22 withdrawn before being accepted or refused for
23 filing.

24 “(F) FEES FOR ORDER REQUESTS PRE-
25 VIOUSLY REFUSED FOR FILING OR WITHDRAWN

1 *BEFORE FILING.—An OTC monograph order re-*
2 *quest that was submitted but was refused for fil-*
3 *ing, or was withdrawn before being accepted or*
4 *refused for filing, shall be subject to the full fee*
5 *under subparagraph (A) upon being resubmitted*
6 *or filed over protest.*

7 “(G) *REFUND OF FEE IF ORDER REQUEST*
8 *WITHDRAWN.—If an order request is withdrawn*
9 *after the order request was filed, the Secretary*
10 *may refund the fee or a portion of the fee if no*
11 *substantial work was performed on the order re-*
12 *quest after the application was filed. The Sec-*
13 *retary shall have the sole discretion to refund a*
14 *fee or a portion of the fee under this subpara-*
15 *graph. A determination by the Secretary con-*
16 *cerning a refund under this subparagraph shall*
17 *not be reviewable.*

18 “(3) *REFUNDS.—*

19 “(A) *IN GENERAL.—Other than refunds*
20 *provided in subparagraphs (D) through (G) of*
21 *paragraph (2), the Secretary shall not refund*
22 *any fee paid under paragraph (1) except as pro-*
23 *vided in subparagraph (B).*

24 “(B) *DISPUTES CONCERNING FEES.—To*
25 *qualify for the return of a fee claimed to have*

1 *been paid in error under paragraph (1) or (2),*
 2 *a person shall submit to the Secretary a written*
 3 *request justifying such return within 180 cal-*
 4 *endar days after such fee was paid.*

5 *“(4) NOTICE.—Within the timeframe specified in*
 6 *subsection (c), the Secretary shall publish in the Fed-*
 7 *eral Register the amount of the fees under paragraph*
 8 *(1) for such fiscal year.*

9 *“(b) FEE REVENUE AMOUNTS.—*

10 *“(1) FISCAL YEAR 2019.—For fiscal year 2019,*
 11 *fees under subsection (a)(1) shall be established to*
 12 *generate a total facility fee revenue amount equal to*
 13 *the sum of—*

14 *“(A) the annual base revenue for fiscal year*
 15 *2019 (as determined under paragraph (3);*

16 *“(B) 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)); and*

20 *“(C) additional direct cost adjustments (as*
 21 *determined under subsection (c)(3)).*

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

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

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

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

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

12 “(E) additional dollar amounts for each fis-
13 cal year as follows:

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

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

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

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

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

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

22 “(B) for fiscal years 2020 through 2023, the
23 dollar amount of the total revenue amount estab-
24 lished under this subsection for the previous fis-

1 *cal year, not including any adjustments made*
 2 *under subsection (c)(2) or (c)(3).*

3 “(c) *ADJUSTMENTS; ANNUAL FEE SETTING.—*

4 “(1) *INFLATION ADJUSTMENT.—*

5 “(A) *IN GENERAL.—For purposes of sub-*
 6 *section (b)(2)(B), the dollar amount of the infla-*
 7 *tion adjustment to the annual base revenue for*
 8 *fiscal year 2020 and each subsequent fiscal year*
 9 *shall be equal to the product of—*

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

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

14 “(B) *OTC MONOGRAPH ORDER REQUEST*
 15 *FEES.—For purposes of subsection (a)(2), the*
 16 *dollar amount of the inflation adjustment to the*
 17 *fee for OTC monograph order requests for fiscal*
 18 *year 2020 and each subsequent fiscal year shall*
 19 *be equal to the product of—*

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

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

24 “(C) *INFLATION ADJUSTMENT PERCENT-*
 25 *AGE.—The inflation adjustment percentage*

1 *under this subparagraph for a fiscal year is*
2 *equal to—*

3 “(i) *for each of fiscal years 2020 and*
4 *2021, the average annual percent change*
5 *that occurred in the Consumer Price Index*
6 *for urban consumers (Washington-Balti-*
7 *more, DC–MD–VA–WV; Not Seasonally Ad-*
8 *justed; All items; Annual Index) for the first*
9 *3 years of the preceding 4 years of available*
10 *data; and*

11 “(ii) *for each of fiscal years 2022 and*
12 *2023, the sum of—*

13 “(I) *the average annual percent*
14 *change in the cost, per full-time equiv-*
15 *alent position of the Food and Drug*
16 *Administration, of all personnel com-*
17 *penetration and benefits paid with re-*
18 *spect to such positions for the first 3*
19 *years of the preceding 4 fiscal years,*
20 *multiplied by the proportion of per-*
21 *sonnel compensation and benefits costs*
22 *to total costs of OTC monograph drug*
23 *activities for the first 3 years of the*
24 *preceding 4 fiscal years; and*

1 “(II) the average annual percent
 2 change that occurred in the Consumer
 3 Price Index for urban consumers
 4 (Washington-Baltimore, DC–MD–VA–
 5 WV; Not Seasonally Adjusted; All
 6 items; Annual Index) for the first 3
 7 years of the preceding 4 years of avail-
 8 able data multiplied by the proportion
 9 of all costs other than personnel com-
 10 pensation and benefits costs to total
 11 costs of OTC monograph drug activi-
 12 ties for the first 3 years of the pre-
 13 ceding 4 fiscal years.

14 “(2) OPERATING RESERVE ADJUSTMENT.—

15 “(A) IN GENERAL.—For fiscal year 2019
 16 and subsequent fiscal years, for purposes of sub-
 17 sections (b)(1)(B) and (b)(2)(C), the Secretary
 18 may, in addition to adjustments under para-
 19 graph (1), further increase the fee revenue and
 20 fees if such an adjustment is necessary to provide
 21 operating reserves of carryover user fees for OTC
 22 monograph drug activities for not more than the
 23 number of weeks specified in subparagraph (B).

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

- 1 “(i) 3 weeks for fiscal year 2019;
 2 “(ii) 7 weeks for fiscal year 2020;
 3 “(iii) 10 weeks for fiscal year 2021;
 4 “(iv) 10 weeks for fiscal year 2022;
 5 and
 6 “(v) 10 weeks for fiscal year 2023.

7 “(C) *DECREASE*.—If the Secretary has car-
 8 ryover balances for such process in excess of 10
 9 weeks of the operating reserves referred to in sub-
 10 paragraph (A), the Secretary shall decrease the
 11 fee revenue and fees referred to in such subpara-
 12 graph to provide for not more than 10 weeks of
 13 such operating reserves.

14 “(D) *RATIONALE FOR ADJUSTMENT*.—If an
 15 adjustment under this paragraph is made, the
 16 rationale for the amount of the increase or de-
 17 crease (as applicable) in fee revenue and fees
 18 shall be contained in the annual Federal Reg-
 19 ister notice under paragraph (4) establishing fee
 20 revenue and fees for the fiscal year involved.

21 “(3) *ADDITIONAL DIRECT COST ADJUSTMENT*.—
 22 The Secretary shall, in addition to adjustments under
 23 paragraphs (1) and (2), further increase the fee rev-
 24 enue and fees for purposes of subsection (b)(2)(D) by
 25 an amount equal to—

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

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

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

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

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

6 “(4) ANNUAL FEE SETTING.—

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

9 “(i) establish OTC monograph drug fa-
10 cility fees for fiscal year 2019 under sub-
11 section (a), based on the revenue amount for
12 such year under subsection (b) and the ad-
13 justments provided under this subsection;
14 and

15 “(ii) publish fee revenue, facility fees,
16 and OTC monograph order requests in the
17 Federal Register.

18 “(B) SUBSEQUENT FISCAL YEARS.—The
19 Secretary shall, not later than January 31 of
20 each fiscal year that begins after September 30,
21 2019, establish for each such fiscal year, based on
22 the revenue amounts under subsection (b) and
23 the adjustments provided under this subsection—

24 “(i) OTC monograph drug facility fees
25 under subsection (a)(1);

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

3 “(iii) publish such fee revenue
4 amounts, facility fees, and OTC monograph
5 order request fees in the Federal Register.

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

11 “(1) be submitted as part of the requirements for
12 drug establishment registration set forth in section
13 510; and

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

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

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

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

23 “(i) The Secretary shall place the facil-
24 ity on a publicly available arrears list.

1 “(ii) *All OTC monograph drugs manu-*
2 *factured in such a facility or containing an*
3 *ingredient manufactured in such a facility*
4 *shall be deemed misbranded under section*
5 *502(a).*

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

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

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

19 “(f) *CREDITING AND AVAILABILITY OF FEES.—*

20 “(1) *IN GENERAL.—Fees authorized under sub-*
21 *section (a) shall be collected and available for obliga-*
22 *tion only to the extent and in the amount provided*
23 *in advance in appropriations Acts. Such fees are au-*
24 *thorized to remain available until expended. Such*
25 *sums as may be necessary may be transferred from*

1 *the Food and Drug Administration salaries and ex-*
 2 *penses appropriation account without fiscal year lim-*
 3 *itation to such appropriation account for salaries and*
 4 *expenses with such fiscal year limitation. The sums*
 5 *transferred shall be available solely for OTC mono-*
 6 *graph drug activities.*

7 “(2) *COLLECTIONS AND APPROPRIATION ACTS.—*

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

15 “(B) *USE OF FEES AND LIMITATION.—The*
 16 *fees authorized by this section shall be available*
 17 *to defray increases in the costs of the resources*
 18 *allocated for OTC monograph drug activities*
 19 *(including increases in such costs for an addi-*
 20 *tional number of full-time equivalent positions*
 21 *in the Department of Health and Human Serv-*
 22 *ices to be engaged in such activities), only if the*
 23 *Secretary allocates for such purpose an amount*
 24 *for such fiscal year (excluding amounts from fees*
 25 *collected under this section) no less than*

1 \$12,000,000, multiplied by the adjustment factor
 2 applicable to the fiscal year involved under sub-
 3 section (c)(1).

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

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

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

23 “(g) COLLECTION OF UNPAID FEES.—In any case
 24 where the Secretary does not receive payment of a fee as-
 25 sessed under subsection (a) within 30 calendar days after

1 *it is due, such fee shall be treated as a claim of the United*
 2 *States Government subject to subchapter II of chapter 37*
 3 *of title 31, United States Code.*

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

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

13 “(a) *PERFORMANCE REPORT.*—*Beginning with fiscal*
 14 *year 2019, and not later than 120 calendar days after the*
 15 *end of each fiscal year thereafter for which fees are collected*
 16 *under this part, the Secretary shall prepare and submit to*
 17 *the Committee on Energy and Commerce of the House of*
 18 *Representatives and the Committee on Health, Education,*
 19 *Labor, and Pensions of the Senate a report concerning the*
 20 *progress of the Food and Drug Administration in achieving*
 21 *the goals identified in the letters described in section 201(b)*
 22 *of the Over-the-Counter Monograph Safety, Innovation, and*
 23 *Reform Act of 2018 during such fiscal year and the future*
 24 *plans of the Food and Drug Administration for meeting*
 25 *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, the
4 Secretary shall prepare and submit to the Committee on
5 Energy and Commerce of the House of Representatives and
6 the Committee on Health, Education, Labor, and Pensions
7 of the Senate a report on the implementation of the author-
8 ity for such fees during such fiscal year and the use, by
9 the Food and Drug Administration, of the fees collected for
10 such fiscal year.

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

15 “(d) *REAUTHORIZATION.*—

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

23 “(A) the Committee on Energy and Com-
24 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 RECOMMENDATIONS.—
9 After negotiations with the regulated industry, the
10 Secretary shall—

11 “(A) present the recommendations developed
12 under paragraph (1) to the congressional com-
13 mittees 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 recommendations;
21 and

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

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

Union Calendar No. 640

115TH CONGRESS
2D Session

H. R. 5333

[Report No. 115-827]

A BILL

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

JULY 16, 2018

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed