

115<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 5333

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## AN ACT

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

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

1 **SECTION 1. SHORT TITLE.**

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

4 **TITLE I—OTC DRUG REVIEW**

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

6 **DRUGS THAT ARE MARKETED WITHOUT AN**

7 **APPROVED NEW DRUG APPLICATION.**

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

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

12 **DRUGS THAT ARE MARKETED WITHOUT AN**

13 **APPROVED NEW DRUG APPLICATION.**

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

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

22 CATEGORY I DRUGS SUBJECT TO A TENTATIVE

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

24 erally recognized as safe and effective within the

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

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

3 “(A) the drug is—

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

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

21 “(B) the drug is—

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

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

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

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

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

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

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

13           “(A) the drug is—

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

21           “(ii) in conformity with—

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

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

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

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

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

24 “(B) the drug is—

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

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

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

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

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

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

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

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

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

4               and

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

7       “(b) ADMINISTRATIVE ORDERS.—

8               “(1) IN GENERAL.—

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

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

17                      and

18                      “(ii) generally recognized as safe and  
19                      effective within the meaning of section  
20                      201(p)(1).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18          “(3) HEARINGS; JUDICIAL REVIEW.—

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

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

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

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

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

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

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

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

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

14           “(C) HEARING PROCEDURES.—

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

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

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

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

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

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

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

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

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

10 “(v) FINAL DECISION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15 “(B) SAFETY LABELING CHANGES.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 “(F) TIMING.—

10 “(i) FINAL ORDER AND HEARING.—

11 The Secretary shall—

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

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

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

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

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

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

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

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

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

24 “(I) file the request; and

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

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

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

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

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

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

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

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

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

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

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

1 the Secretary may cease proceedings under  
2 this subparagraph.

3 “(C) EXCLUSIVITY.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5           “(V) whether the administrative  
6           orders initiated by requestors under  
7           this section have been sufficient incen-  
8           tive to encourage innovation in the  
9           nonprescription drug market.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 “(c) PROCEDURE FOR MINOR CHANGES.—

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

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

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

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

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

20           “(2) ADDITIONAL INFORMATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

10 “(2) PUBLIC AVAILABILITY.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18 “(m) RULE OF CONSTRUCTION.—

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

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

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

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

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

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

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

22          “(3) PRESERVATION OF AUTHORITY.—

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

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

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

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

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

20          “(q) DEFINITIONS.—In this section:

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

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

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

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

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

12 **SEC. 102. MISBRANDING.**

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

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

20           “(ff) If it is a drug and it was manufactured, pre-  
21           pared, propagated, compounded, or processed in a facility  
22           for which fees have not been paid as required by section  
23           7440.”.

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

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

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

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

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

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

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

1           tion to the Secretary of Health and Human  
2           Services within 180 calendar days of the enact-  
3           ment of this Act, to transition into the review  
4           of such ingredient or combination of ingredients  
5           pursuant to the process set out in section 505G  
6           of the Federal Food, Drug, and Cosmetic Act,  
7           as added by section 101 of this Act.

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

12                 (i) the proposed sunscreen order in-  
13                 volved is deemed to be a request for an  
14                 order under subsection (b) of section 505G  
15                 of the Federal Food, Drug, and Cosmetic  
16                 Act, as added by section 101 of this Act;  
17                 and

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

21          (C) ELECTION NOT EXERCISED.—A spon-  
22          sor of a nonprescription sunscreen active ingre-  
23          dient or combination of nonprescription sun-  
24          screen active ingredients described in subpara-  
25          graph (A) that does not elect for such ingre-

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

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

19           (b) AMENDMENTS TO SUNSCREEN PROVISIONS.—

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

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

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

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

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

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

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

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

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

14 **“SEC. 586H. SUNSET.**

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

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

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

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

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

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

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

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

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

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

9           (b) COUGH AND COLD MONOGRAPH DESCRIBED.—

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

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

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

## 4 **TITLE II—USER FEES**

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

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

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

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

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

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

3   **“SEC. 744N. DEFINITIONS.**

4           “In this part:

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

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

10                           or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19                  “(i) is—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16             “(1) FACILITY FEE.—

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

24             “(B) EXCEPTIONS.—

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

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

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

19           “(D) DUE DATE.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8 “(3) REFUNDS.—

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

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

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

24 “(b) FEE REVENUE AMOUNTS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20                   “(1) INFLATION ADJUSTMENT.—

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

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

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

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

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

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

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

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

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

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

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

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

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

6                   “(2) OPERATING RESERVE ADJUSTMENT.—

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

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

19                         “(i) 3 weeks for fiscal year 2019;

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

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

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

23                         and

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

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

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

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

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

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

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

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

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

25           “(4) ANNUAL FEE SETTING.—

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

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

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

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

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

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

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

1 graph order request fees in the Federal  
2 Register.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15       “(d) REAUTHORIZATION.—

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

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

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

3           “(C) scientific and academic experts;

4           “(D) health care professionals;

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

7           “(F) the regulated industry.

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

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

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

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

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

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

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

Passed the House of Representatives July 16, 2018.

Attest:

*Clerk.*



115<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

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# H. R. 5333

## AN ACT

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