

## Calendar No. 518

115<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION**H. R. 5333**

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IN THE SENATE OF THE UNITED STATES

JULY 17, 2018

Received; read twice and placed on the calendar

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**AN ACT**

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

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

3 **SECTION 1. SHORT TITLE.**

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

1       **TITLE I—OTC DRUG REVIEW**

2       **SEC. 101. REGULATION OF CERTAIN NONPRESCRIPTION**  
3                   **DRUGS THAT ARE MARKETED WITHOUT AN**  
4                   **APPROVED NEW DRUG APPLICATION.**

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

8       **“SEC. 505G. REGULATION OF CERTAIN NONPRESCRIPTION**  
9                   **DRUGS THAT ARE MARKETED WITHOUT AN**  
10                  **APPROVED NEW DRUG APPLICATION.**

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

18                   “(1) DRUGS SUBJECT TO A FINAL MONOGRAPH;  
19           CATEGORY I DRUGS SUBJECT TO A TENTATIVE  
20           FINAL MONOGRAPH.—A drug is deemed to be gen-  
21           erally recognized as safe and effective within the  
22           meaning of section 201(p)(1), not a new drug under  
23           section 201(p), and not subject to section 503(b)(1),  
24           if—

25                           “(A) the drug is—

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

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

18 “(B) the drug is—

19 “(i) classified in category I for safety  
20 and effectiveness under a tentative final  
21 monograph that is the most recently appli-  
22 cable proposal or determination issued  
23 under part 330 of title 21, Code of Federal  
24 Regulations;

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

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

17           “(2) TREATMENT OF SUNSCREEN DRUGS.—

18 With respect to sunscreen drugs subject to this sec-  
19 tion, the applicable requirements shall be the re-  
20 quirements specified in part 352 of title 21, Code of  
21 Federal Regulations, as published on May 21, 1999,  
22 beginning on page 27687 of volume 64 of the Fed-  
23 eral Register, except that the applicable require-  
24 ments governing effectiveness and labeling shall be  
25 those specified in section 201.327 of title 21, Code

1 of Federal Regulations, subject to the requirements  
2 of subsections (b), (c), and (k).

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

11 “(A) the drug is—

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

19 “(ii) in conformity with—

20 “(I) the conditions of use, includ-  
21 ing indication and dosage strength, if  
22 any, described for such category III  
23 drug in such preamble or in an appli-  
24 cable subsequent proposed rule;

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

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

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

22                  “(B) the drug is—

23                         “(i) classified in category I for safety  
24                         and effectiveness under a proposed mono-  
25                         graph or advance notice of proposed rule-

1 making that is the most recently applicable  
2 proposal or determination for such drug  
3 issued under part 330 of title 21, Code of  
4 Federal Regulations;

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

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

18 “(4) CATEGORY II DRUGS DEEMED NEW  
19 DRUGS.—A drug that is classified in category II for  
20 safety or effectiveness under a tentative final mono-  
21 graph or that is subject to a determination to be not  
22 safe or effective in a proposed rule that is the most  
23 recently applicable proposal issued under part 330 of  
24 title 21, Code of Federal Regulations, shall be  
25 deemed to be a new drug within the meaning of sec-

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

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

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



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

2           and

3           “(B) is not described in paragraphs (1),

4           (2), (3), (4), or (5), or subsection (b)(1)(B).

5           “(b) ADMINISTRATIVE ORDERS.—

6           “(1) IN GENERAL.—

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

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

15                 and

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

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

23                 “(i) is determined by the Secretary to  
24                 meet the conditions specified in clauses (i)  
25                 and (ii) of subparagraph (A);

1 “(ii) is marketed in conformity with  
2 an administrative order under this sub-  
3 section;

4 “(iii) meets the general requirements  
5 for nonprescription drugs; and

6 “(iv) meets the requirements under  
7 subsections (c) and (k).

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

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

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

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

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

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

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

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

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

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

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

1           appropriate to issue a final administrative  
2           order—

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

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

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

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

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

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

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

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

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

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

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

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

15          “(3) HEARINGS; JUDICIAL REVIEW.—

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

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

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

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

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

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

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

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

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

11                 “(C) HEARING PROCEDURES.—

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



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

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

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

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

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

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

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

8 “(v) FINAL DECISION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12                  “(B) SAFETY LABELING CHANGES.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6 “(F) TIMING.—

7 “(i) FINAL ORDER AND HEARING.—

8 The Secretary shall—

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

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

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



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

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

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

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

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

21                           “(I) file the request; and

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

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

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

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

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

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

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

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

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

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

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

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

23 “(C) EXCLUSIVITY.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6 “(I) have not been relied on by  
7 the Secretary to support—

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

14 “(bb) approval of a drug  
15 that was approved under section  
16 505; and

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

23           “(c) PROCEDURE FOR MINOR CHANGES.—

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

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

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

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

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

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

18 “(2) ADDITIONAL INFORMATION.—

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

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

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

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

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

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

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

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

20           “(d) CONFIDENTIALITY OF INFORMATION SUB-  
21 MITTED TO THE SECRETARY.—

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

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

8 “(2) PUBLIC AVAILABILITY.—

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

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

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

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

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

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

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

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

15 or

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13           “(m) RULE OF CONSTRUCTION.—

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

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

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

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

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

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

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

18           “(3) PRESERVATION OF AUTHORITY.—

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

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

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

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

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

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

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

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

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

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

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

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

7 **SEC. 102. MISBRANDING.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

14 (b) AMENDMENTS TO SUNSCREEN PROVISIONS.—

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

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

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

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

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

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

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

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

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

8   **“SEC. 586H. SUNSET.**

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

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

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

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

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

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

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

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

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

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

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

## 21 **TITLE II—USER FEES**

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

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

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

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

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

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

18 **“SEC. 744N. DEFINITIONS.**

19 “In this part:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12                   “(i) is—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10           “(1) FACILITY FEE.—

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

18           “(B) EXCEPTIONS.—

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

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

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

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

12 “(D) DUE DATE.—

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

3           “(3) REFUNDS.—

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

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

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

19          “(b) FEE REVENUE AMOUNTS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 “(1) INFLATION ADJUSTMENT.—

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

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

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

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

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

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

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

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

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

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

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

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

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

25                   “(2) OPERATING RESERVE ADJUSTMENT.—

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

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

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

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

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

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

17                 and

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

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



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

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

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

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

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

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

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

18          “(4) ANNUAL FEE SETTING.—

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

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

1 adjustments provided under this sub-  
2 section; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6 “(B) USE OF FEES AND LIMITATION.—

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

20 “(C) COMPLIANCE.—The Secretary shall

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

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

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

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

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

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

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

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

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

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

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

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

7 “(d) REAUTHORIZATION.—

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

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

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

20 “(C) scientific and academic experts;

21 “(D) health care professionals;

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

24 “(F) the regulated industry.



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

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

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

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

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

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

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

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

Passed the House of Representatives July 16, 2018.

Attest:

KAREN L. HAAS,

*Clerk.*



Calendar No. 518

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.

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JULY 17, 2018

Received; read twice and placed on the calendar