

115TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

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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IN THE HOUSE OF REPRESENTATIVES

M. \_\_\_\_\_ introduced the following bill; which was referred to the Committee on \_\_\_\_\_

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**A BILL**

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

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Over-the-Counter  
5 Monograph Safety, Innovation, and Reform Act of 2017”.

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 CURRENTLY MAR-  
12 KETED WITHOUT AN APPROVED NEW DRUG APPLICA-  
13 TION.—Drugs marketed without an approved new drug  
14 application under section 505, as of the date of the enact-  
15 ment of the Over-the-Counter Monograph Safety, Innova-  
16 tion, and Reform Act of 2017, shall be treated in accord-  
17 ance with this 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 (6)), and the gen-  
6           eral requirements for nonprescription  
7           drugs, including any modifications of those  
8           requirements under subsections (b), (c),  
9           and (k); and

10           “(ii) except as permitted by an admin-  
11           istrative order issued under subsection (b)  
12           or, in the case of a minor change in the  
13           drug, in conformity with an order issued  
14           under subsection (c), in a dosage form that  
15           has been used to a material extent and for  
16           a material time within the meaning of sec-  
17           tion 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, and the general requirements for  
6 nonprescription drugs, including any modi-  
7 fications of those requirements under sub-  
8 sections (b), (c), and (k); and

9 “(iii) except as permitted by an ad-  
10 ministrative order issued under subsection  
11 (b) or, in the case of a minor change in the  
12 drug, in conformity with an order issued  
13 under subsection (c), in a dosage form that  
14 has been used to a material extent and for  
15 a material time within the meaning of sec-  
16 tion 201(p)(2).

17 “(2) DRUGS SUBJECT TO A FINAL ADMINISTRA-  
18 TIVE ORDER.—A drug is deemed to be generally rec-  
19 ognized as safe and effective within the meaning of  
20 section 201(p)(1), not a new drug under section  
21 201(p), and not subject to section 503(b)(1), if the  
22 drug is in conformity with—

23 “(A) the requirements of a final adminis-  
24 trative order issued under subsection (b) deter-  
25 mining that such drug is generally recognized

1 as safe and effective within the meaning of sec-  
2 tion 201(p)(1); and

3 “(B) the general requirements for non-  
4 prescription drugs, including any modifications  
5 of those requirements under subsections (b),  
6 (c), and (k).

7 “(3) CATEGORY III DRUGS SUBJECT TO A TEN-  
8 TATIVE FINAL MONOGRAPH; CATEGORY I DRUGS  
9 SUBJECT TO PROPOSED MONOGRAPH OR ADVANCE  
10 NOTICE OF PROPOSED RULEMAKING.—A drug that  
11 is not described in paragraphs (1), (2), or (4) is not  
12 required to be the subject of an application approved  
13 under section 505, and is not subject to section  
14 503(b)(1), if—

15 “(A) the drug is—

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

23 “(ii) in conformity with—

24 “(I) the conditions of use, includ-  
25 ing indication and dosage strength, if

1 any, described for such category III  
2 drug in such preamble or in an appli-  
3 cable subsequent proposed rule;

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

12 “(III) the general requirements  
13 for nonprescription drugs, including  
14 any modifications of those require-  
15 ments under subsections (b) or (k);  
16 and

17 “(iii) in a dosage form that, imme-  
18 diately prior to the date of the enactment  
19 of this section, has been used to a material  
20 extent and for a material time within the  
21 meaning of section 201(p)(2); 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, and  
10 the general requirements for nonprescrip-  
11 tion drugs, including any modifications of  
12 those requirements under subsections (b)  
13 or (k); and

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

19 “(4) CATEGORY II DRUGS DEEMED NEW  
20 DRUGS.—A drug that is classified in category II for  
21 safety or effectiveness in a preamble of a proposed  
22 rule establishing a tentative final monograph that is  
23 the most recently applicable proposal issued under  
24 part 330 of title 21, Code of Federal Regulations,  
25 shall be deemed to be a new drug within the mean-

1       ing of section 201(p), misbranded under section  
2       502(ee), and subject to the requirement for an ap-  
3       proved new drug application under section 505 be-  
4       ginning on the day that is 180 calendar days after  
5       the date of the enactment of this section, unless, be-  
6       fore such day, the Secretary determines that it is in  
7       the interest of public health to extend the period  
8       during which the drug may be marketed without  
9       such an approved 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) TREATMENT OF SUNSCREEN DRUGS.—  
21       With respect to sunscreen drugs subject to this sec-  
22       tion, the applicable requirements shall be those set  
23       out at part 352 of title 21, Code of Federal Regula-  
24       tions, as published at volume 64 page 27687 of the  
25       Federal Register, except that the applicable require-



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

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

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

11           and

12           “(B) is not described in paragraphs (1),  
13           (2), (3), (4), (5), or (6).

14       “(b) ADMINISTRATIVE ORDERS.—

15           “(1) IN GENERAL.—

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

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

1 “(ii) generally recognized as safe and  
2 effective within the meaning of section  
3 201(p)(1); and

4 “(iii) not required to be approved  
5 under section 505.

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

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

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

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

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

23 “(i) make reasonable efforts to notify  
24 informally, not later than 2 business days  
25 before the issuance of the proposed order,

1 sponsors of drugs that will be subject to  
2 the administrative order;

3 “(ii) after any such reasonable efforts  
4 of notification—

5 “(I) issue a proposed administra-  
6 tive order by publishing it on the  
7 website of the Food and Drug Admin-  
8 istration and include in such order the  
9 reasons for the issuance of such order;  
10 and

11 “(II) publish a notice of avail-  
12 ability of such proposed order in the  
13 Federal Register;

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

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

23 “(I) issue the final administrative  
24 order, together with a detailed state-  
25 ment of reasons, which order shall not

1 take effect until the time for request-  
2 ing judicial review under paragraph  
3 (3)(D)(ii) has expired;

4 “(II) publish a notice of such  
5 final administrative order in the Fed-  
6 eral Register;

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

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

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

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

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

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

19                           “(ii) the Secretary shall provide for a  
20                           public comment period of no less than 180  
21                           calendar days with respect to such pro-  
22                           posed order, except when the Secretary de-  
23                           termines, for good cause, that a shorter pe-  
24                           riod is in the interests of public health;  
25                           and

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

11          “(3) HEARINGS; JUDICIAL REVIEW.—

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

1           “(B) NO HEARING REQUIRED WITH RE-  
2           SPECT TO ORDERS RELATING TO CERTAIN  
3           DRUGS.—

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

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

11                   “(II) with respect to which no  
12                   human or non-human data relevant to  
13                   the safety or effectiveness of such  
14                   drug have been submitted to the ad-  
15                   ministrative record since the issuance  
16                   of the most recent tentative final  
17                   monograph relating to such drug.

18           “(ii) HUMAN AND NON-HUMAN DATA  
19           DEFINED.—In this subparagraph:

20                   “(I) The term ‘human data’  
21                   means data from any testing with  
22                   human subjects, including clinical  
23                   trials of safety or effectiveness (in-  
24                   cluding actual use studies), pharmaco-  
25                   kinetics, bioavailability, label com-

1                   prehension studies (including self-se-  
2                   lection studies), or human factors.

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

8                   “(C) HEARING PROCEDURES.—

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

22                  “(ii) SINGLE HEARING FOR MULTIPLE  
23                  RELATED REQUESTS.—If more than one  
24                  request for a hearing is submitted with re-  
25                  spect to the same administrative order



1 under subparagraph (A), the Secretary  
2 may direct that a single hearing be con-  
3 ducted in which all persons whose hearing  
4 requests were granted may participate.

5 “(iii) PRESIDING OFFICER.—The pre-  
6 siding officer of a hearing requested under  
7 subparagraph (A) shall—

8 “(I) be appointed by the Sec-  
9 retary;

10 “(II) not be an employee of the  
11 Center for Drug Evaluation and Re-  
12 search; and

13 “(III) not have been previously  
14 involved in the development of the ad-  
15 ministrative order involved or pro-  
16 ceedings relating to that administra-  
17 tive order.

18 “(iv) RIGHTS OF PARTIES TO HEAR-  
19 ING.—The parties to a hearing requested  
20 under subparagraph (A) shall have the  
21 right to present testimony, including testi-  
22 mony of expert witnesses, and to cross-ex-  
23 amine witnesses presented by other parties.  
24 Where appropriate, the presiding officer  
25 may require that cross-examination by par-

1 ties representing substantially the same in-  
2 terests be consolidated to promote effi-  
3 ciency and avoid duplication.

4 “(v) FINAL DECISION.—

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

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

17 “(D) JUDICIAL REVIEW OF FINAL ADMIN-  
18 ISTRATIVE ORDER.—

19 “(i) IN GENERAL.—The procedures  
20 described in section 505(h) shall apply  
21 with respect to judicial review of final ad-  
22 ministrative orders issued under this sub-  
23 section in the same manner and to the  
24 same extent as such section applies to an  
25 order described in such section except that

1 the judicial review shall be taken by filing  
2 in an appropriate district court of the  
3 United States in lieu of the appellate  
4 courts specified in such section.

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

13 “(I) the date on which notice of  
14 such order is published;

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

18 “(III) the date on which a final  
19 decision is made following a hearing  
20 under subparagraph (C)(v); or

21 “(IV) if no hearing is requested,  
22 the date on which the time for re-  
23 questing a hearing expires.

1           “(4) EXPEDITED PROCEDURE WITH RESPECT  
2           TO ADMINISTRATIVE ORDERS INITIATED BY THE  
3           SECRETARY.—

4                   “(A) IMMINENT HAZARD TO THE PUBLIC  
5           HEALTH.—

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

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

23   “(II) shall publish in the Federal  
24   Register a notice of availability of any  
25   such order; and

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

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

9                   “(B) SAFETY LABELING CHANGES.—

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

18                   “(I) make reasonable efforts to  
19                   notify informally, not later than 48  
20                   hours before the issuance of the in-  
21                   terim final order, the sponsors of  
22                   drugs who have a listing in effect  
23                   under section 510(j) for such drug or  
24                   combination of drugs;

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

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

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

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

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

23                   “(D) FINAL ORDER.—After the completion  
24                   of the proceedings in subparagraph (A) or (B),  
25                   the Secretary shall—

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

3 “(ii) publish a notice of availability of  
4 such final administrative order in the Fed-  
5 eral Register; and

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

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

1           ministrative order issued under paragraph  
2           (2)(A)(iv).

3           “(F) TIMING.—Not later than 12 months  
4           after the date on which an interim final order  
5           is issued under subparagraph (A) or (B), the  
6           Secretary shall issue a final order in accordance  
7           with paragraph (1) and complete any required  
8           hearing.

9           “(G) JUDICIAL REVIEW.—A final order  
10          issued pursuant to subparagraph (F) shall be  
11          subject to judicial review in accordance with  
12          paragraph (3)(D).

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

15          “(A) IN GENERAL.—In issuing an adminis-  
16          trative order under paragraph (1) at the re-  
17          quest of a requestor with respect to certain  
18          drugs, classes of drugs, or combinations of  
19          drugs—

20                 “(i) the Secretary shall, after receiv-  
21                 ing a request under this subparagraph, de-  
22                 termine whether the request is sufficiently  
23                 complete and formatted to permit a sub-  
24                 stantive review;



1                   “(ii) if the Secretary determines that  
2                   the request is sufficiently complete and for-  
3                   matted to permit a substantive review, the  
4                   Secretary shall—

5                               “(I) file the request; and

6                               “(II) initiate proceedings with re-  
7                               spect to issuing an administrative  
8                               order in accordance with paragraphs  
9                               (2) and (3); and

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

19                   “(B)   REQUEST   TO   INITIATE   PRO-  
20                   CEEDINGS.—

21                               “(i) IN GENERAL.—A requestor seek-  
22                               ing an administrative order under para-  
23                               graph (1) with respect to certain drugs,  
24                               classes of drugs, or combinations of drugs,  
25                               shall submit to the Secretary a request to

1 initiate proceedings for such order in the  
2 form and manner as specified by the Sec-  
3 retary. Such requestor may submit a re-  
4 quest under this subparagraph for the  
5 issuance of an administrative order—

6 “(I) determining whether a drug  
7 is generally recognized as safe and ef-  
8 fective within the meaning of section  
9 201(p)(1), exempt from section  
10 503(b)(1), and not required to be the  
11 subject of an approved application  
12 under section 505; or

13 “(II) determining whether a  
14 change to a condition of use of a drug  
15 is generally recognized as safe and ef-  
16 fective within the meaning of section  
17 201(p)(1), exempt from section  
18 503(b)(1), and not required to be the  
19 subject of an approved application  
20 under section 505, if such drug is—

21 “(aa) generally recognized  
22 as safe and effective within the  
23 meaning of section 201(p)(1)  
24 under subsection (a)(1) or (a)(2);  
25 or

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

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

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

1 this section, if such request is withdrawn,  
2 the Secretary may cease proceedings under  
3 this subparagraph.

4 “(C) EXCLUSIVITY.—

5 “(i) IN GENERAL.—A final adminis-  
6 trative order issued in response to a re-  
7 quest under this section shall have the ef-  
8 fect of providing the order requestor (or  
9 the licensees, assignees, or successors in  
10 interest of such requestor) the exclusive  
11 right, for a period of **24 months**, to  
12 market drugs under this section—

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

15 “(II) beginning on the date the  
16 requestor may lawfully market such  
17 drugs pursuant to the order; and

18 “(III) subject to the limitations  
19 under clause (iv).

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

24 “(I) provides for a drug to con-  
25 tain an active ingredient not pre-

1                   viously incorporated in a marketed  
2                   drug listed in clause (iii); or

3                   “**(II)** provides for a change in the  
4                   conditions of use of a drug, for which  
5                   original human data studies con-  
6                   ducted or sponsored by the requestor  
7                   (or for which the requestor has an ex-  
8                   clusive right of reference) were essen-  
9                   tial to the issuance of such order.

10                  “(iii) **MARKETED DRUGS.**—The mar-  
11                  keted drugs listed in this clause are  
12                  drugs—

13                         “(I) marketed in accordance with  
14                         a final monograph issued under part  
15                         330 of title 21, Code of Federal Regu-  
16                         lations (including conditions of use  
17                         thereunder), as in effect as of the date  
18                         of the enactment of this section;

19                         “(II) marketed as category I or  
20                         III in accordance with a tentative  
21                         final monograph issued under part  
22                         330 of title 21, Code of Federal Regu-  
23                         lations (including conditions of use  
24                         and any applicable subsequent deter-

1 terminations thereunder), as in effect on  
2 such date of enactment;

3 “(III) marketed as category I in  
4 accordance with an advance notice of  
5 proposed rulemaking issued under  
6 part 330 of title 21, Code of Federal  
7 Regulations (including conditions of  
8 use and any applicable subsequent de-  
9 terminations thereunder), as in effect  
10 on such date of enactment;

11 “(IV) marketed in accordance  
12 with a final order issued under this  
13 section;

14 “(V) marketed in accordance  
15 with a final sunscreen order (as de-  
16 fined in section 586(2)(A)) that has  
17 been included in part 352 of title 21,  
18 Code of Federal Regulations (or any  
19 successor regulations) pursuant to  
20 section 586C(e)(3); or

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

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

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

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

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

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

18                  “(aa) ‘Tier Two’ changes, as  
19                  defined by the Secretary;

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

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

4                   “(v) HUMAN DATA DEFINED.—In this  
5                   subparagraph, the term ‘human data’ has  
6                   the meaning given such term in paragraph  
7                   (3)(B)(ii)(I).

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

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

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

21                  “(ii) if the request fails to include in-  
22                  formation specified under subparagraph  
23                  (C), shall refuse to file such request and  
24                  require that nonprescription marketing of



1           the drug be pursuant to a new drug appli-  
2           cation as described in subparagraph (D).

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

7                   “(i) in a drug marketed in accordance  
8                   with a final monograph issued under part  
9                   330 of title 21, Code of Federal Regula-  
10                  tions (including conditions of use there-  
11                  under), as in effect on the day before the  
12                  date of the enactment of this section;

13                   “(ii) in a drug marketed as category  
14                   I in accordance with a tentative final  
15                   monograph issued under part 330 of title  
16                   21, Code of Federal Regulations (including  
17                   conditions of use and any applicable subse-  
18                   quent determinations thereunder), as in ef-  
19                   fect on such day; or

20                   “(iii) in a drug marketed in accord-  
21                   ance with a final order issued under this  
22                   section.

23           “(C) INFORMATION DEMONSTRATING  
24           PRIMA FACIE SAFE NONPRESCRIPTION MAR-  
25           KETING AND USE.—Information specified in

1           this subparagraph, with respect to a request de-  
2           scribed in subparagraph (A)(i), is—

3                   “(i) information sufficient for a prima  
4                   facie demonstration that the drug subject  
5                   to such request has a verifiable history of  
6                   being marketed and safely used by con-  
7                   sumers in the United States as a non-  
8                   prescription drug under comparable condi-  
9                   tions of use;

10                   “(ii) if the drug has not been pre-  
11                   viously marketed in the United States as a  
12                   nonprescription drug, information suffi-  
13                   cient for a prima facie demonstration that  
14                   the drug was marketed and safely used  
15                   under comparable conditions of marketing  
16                   and use in a country listed in section  
17                   802(b)(1)(A) or designated by the Sec-  
18                   retary in accordance with section  
19                   802(b)(1)(B)—

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

24                           “(II) during such time was sub-  
25                           ject to sufficient monitoring by a reg-

1                   ulatory body considered acceptable by  
2                   the Secretary for such monitoring  
3                   purposes, including for adverse events  
4                   associated with nonprescription use of  
5                   the drug; or

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

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

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

1           “(ii) during such time period, one mil-  
2           lion retail packages of the drug, or an  
3           equivalent quantity as determined by the  
4           Secretary, were distributed for retail sale,  
5           as determined in such manner as the Sec-  
6           retary finds appropriate.

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

14          “(7) PACKAGING.—[An administrative order  
15          issued under paragraph (2), (4), or (5) may include  
16          requirements for the packaging of a drug to encour-  
17          age use in accordance with labeling. Such require-  
18          ments may include unit dose packaging, require-  
19          ments for products intended for use by children, and  
20          other appropriate requirements to prevent abuse or  
21          misuse, including protection against unsupervised in-  
22          gestion.]

23          “(8) FINAL AND TENTATIVE FINAL MONO-  
24          GRAPHS FOR CATEGORY I DRUGS DEEMED FINAL  
25          ADMINISTRATIVE ORDERS.—

1           “(A) IN GENERAL.—Subject to subpara-  
2           graph (B), a final monograph or tentative final  
3           monograph establishing conditions of use for a  
4           drug described in subsection (a)(1), shall be  
5           deemed to be a final administrative order under  
6           this subsection and may be amended, revoked,  
7           or otherwise modified in accordance with the  
8           procedures of this subsection.

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

20          “(c) PROCEDURE FOR MINOR CHANGES.—

21                 “(1) IN GENERAL.—Minor changes in the dos-  
22                 age form of a drug that is described in paragraph  
23                 (1) or (2) of subsection (a) may be made by a re-  
24                 questor without the issuance of an administrative  
25                 order under subsection (b) if—

1           “(A) the requestor maintains such infor-  
2 mation as is necessary to demonstrate that the  
3 change—

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

6           “(ii) will not materially affect the ex-  
7 tent of absorption or other exposure to the  
8 active ingredient in comparison to a suit-  
9 able reference product; and

10          “(B) the requestor submits updated drug  
11 listing information for the drug in accordance  
12 with the requirements of section 510(j) within  
13 30 calendar days of the date of first introduc-  
14 tion of the drug with the change into interstate  
15 commerce; and

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

20          “(2) ADDITIONAL INFORMATION.—

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

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

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

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

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

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

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

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

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

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

23           “(d) CONFIDENTIALITY OF INFORMATION SUB-  
24          MITTED BY REQUESTORS.—



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

12          “(2) PUBLIC AVAILABILITY.—Notwithstanding  
13          paragraph (1), the Secretary shall make available to  
14          the public any information (other than raw data  
15          sets) submitted by a requestor in support of a re-  
16          quest under subsection (b)(5)(A) as of the date on  
17          which the proposed order is made public unless—

18                 “(A) the information pertains to pharma-  
19                 ceutical quality information which is necessary  
20                 to establish standards under which a drug is  
21                 generally recognized as safe and effective within  
22                 the meaning of section 201(p)(1);

23                 “(B) the information is submitted in a re-  
24                 questor-initiated request, but the requestor  
25                 withdraws such request, in accordance with

1 withdrawal procedures established by the Sec-  
2 retary, before the Secretary issues the proposed  
3 order; or

4 “(C) the Secretary obtains the information  
5 under subsection (c).

6 “(e) UPDATES TO DRUG LISTING INFORMATION.—

7 A sponsor who makes a change, other than a change to  
8 a dosage form, that keeps a drug in conformity with the  
9 requirements under subsection (a)(1), (a)(2), or (a)(3)—

10 “(1) shall not be subject to the requirements  
11 under subsection (b) or (c) for such change; and

12 “(2) shall submit updated drug listing informa-  
13 tion for the drug in accordance with the require-  
14 ments of section 510(j) within 30 calendar days of  
15 the date the drug is first introduced or delivered for  
16 introduction into interstate commerce with the  
17 change.

18 “(f) APPROVALS UNDER SECTION 505.—The provi-  
19 sions of this section shall not be construed to preclude a  
20 person from seeking or maintaining the approval of a drug  
21 under sections 505(b)(1), 505(b)(2), and 505(j). A deter-  
22 mination under this section that a drug is not subject to  
23 section 503(b)(1), is generally recognized as safe and ef-  
24 fective within the meaning of section 201(p)(1), and is not  
25 a new drug under section 201(p) shall constitute a finding

1 that the drug is safe and effective that may be relied upon  
2 for purposes of an application under section 505(b)(2), so  
3 that the applicant shall be required to submit for purposes  
4 of such application only information needed to support any  
5 modification of the drug that is not covered by such deter-  
6 mination under this section.

7 “(g) PUBLIC AVAILABILITY OF ADMINISTRATIVE OR-  
8 DERS.—The Secretary shall establish, maintain, update  
9 (as determined necessary by the Secretary but no less fre-  
10 quently than annually), and make publicly available, with  
11 respect to administrative orders issued under this sec-  
12 tion—

13 “(1) a repository of each final administrative  
14 order and interim final order in effect, including the  
15 complete text of the administrative order; and

16 “(2) a listing of all administrative orders pro-  
17 posed and under development under subsection  
18 (b)(2), including—

19 “(A) a brief description of each such ad-  
20 ministrative order; and

21 “(B) the Secretary’s expectations, if re-  
22 sources permit, for issuance of proposed admin-  
23 istrative orders over a three-year period.

24 “(h) DEVELOPMENT ADVICE TO SPONSORS OR RE-  
25 QUESTORS.—The Secretary shall establish procedures

1 under which sponsors or requestors may meet with appro-  
2 priate officials of the Food and Drug Administration to  
3 obtain advice on the studies and other information nec-  
4 essary to support submissions under this section and other  
5 matters relevant to the regulation of nonprescription  
6 drugs and the development of new nonprescription drugs  
7 under this section.

8       “(i) PARTICIPATION OF MULTIPLE SPONSORS OR RE-  
9 QUESTORS.—The Secretary shall establish procedures to  
10 facilitate efficient participation by multiple sponsors or re-  
11 questors in proceedings under this section, including provi-  
12 sion for joint meetings with multiple sponsors or reques-  
13 tors or with organizations nominated by sponsors or re-  
14 questors to represent their interests in a proceeding.

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

17       “(k) EFFECT ON EXISTING REGULATIONS GOV-  
18 ERNING NONPRESCRIPTION DRUGS.—

19               “(1) REGULATIONS OF GENERAL APPLICA-  
20 BILITY TO NONPRESCRIPTION DRUGS.—Except as  
21 provided in this subsection, nothing in this section  
22 supersedes regulations establishing general require-  
23 ments for nonprescription drugs, including regula-  
24 tions of general applicability contained in parts 201,  
25 250, and 330 of title 21, Code of Federal Regula-

1 tions, or any successor regulations. The Secretary  
2 shall establish or modify such regulations by means  
3 of rulemaking in accordance with section 553 of title  
4 5, United States Code.

5 “(2) REGULATIONS ESTABLISHING REQUIRE-  
6 MENTS FOR SPECIFIC NONPRESCRIPTION DRUGS.—

7 “(A) The provisions of section 310.545 of  
8 title 21, Code of Federal Regulations, as in ef-  
9 fect on the date of the enactment of this sec-  
10 tion, shall be deemed to be a final administra-  
11 tive order under subsection (b).

12 “(B) Regulations in effect on the date im-  
13 mediately before the date of the enactment of  
14 this section, establishing requirements for spe-  
15 cific nonprescription drugs marketed pursuant  
16 to this section (including such requirements in  
17 parts 201 and 250 of title 21, Code of Federal  
18 Regulations), shall be deemed to be final ad-  
19 ministrative orders under subsection (b), only  
20 as they apply to drugs subject to paragraphs  
21 (1), (2), (3), and (6) of subsection (a).

22 “(3) WITHDRAWAL OF REGULATIONS.—The  
23 Secretary shall withdraw regulations establishing  
24 final monographs and the procedures governing the  
25 over-the-counter drug review under part 330 and

1 other relevant parts of title 21, Code of Federal  
2 Regulations (as in effect on the day preceding the  
3 date of the enactment of this section) or make tech-  
4 nical changes to such regulations to ensure con-  
5 formity with appropriate terminology and cross ref-  
6 erences. Notwithstanding subchapter II of chapter 5  
7 of title 5, United States Code, any such withdrawal  
8 or technical changes shall be made without public  
9 notice and comment and shall be effective upon pub-  
10 lication through notice in the Federal Register (or  
11 upon such date as specified in such notice).

12 “(1) GUIDANCE.—The Secretary shall issue guidance  
13 that specifies—

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

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

19 “(3) the format of electronic submissions to the  
20 Secretary under this section;

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

23 “(5) for minor changes in drugs, recommenda-  
24 tions on how to comply with the requirements in ad-  
25 ministrative orders issued under subsection (c)(3).

1 “(m) RULE OF CONSTRUCTION.—

2 “(1) IN GENERAL.—This section shall not af-  
3 fect the treatment or status of a nonprescription  
4 drug—

5 “(A) that is marketed without an applica-  
6 tion approved under section 505 as of the date  
7 of the enactment of this section;

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

10 “(C) to which paragraphs (1), (2), (3), (4),  
11 (5), or (6) of subsection (a) do not apply.

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

15 “(A) Notwithstanding subsection (a), a  
16 drug described in subparagraph (B) may only  
17 be lawfully marketed, without an application  
18 approved under section 505, pursuant to an  
19 order issued under this section.

20 “(B) A drug described in this subpara-  
21 graph is a drug which, prior to the date of the  
22 enactment of this section, the Secretary had de-  
23 termined in a proposed or final rule to be ineli-  
24 gible for review under the OTC drug review (as  
25 such phrase ‘OTC drug review’ was used in sec-

1           tion 330.14 of title 21, Code of Federal Regula-  
2           tions, as in effect on the day before the date of  
3           the enactment of this section).

4           “(3) PRESERVATION OF AUTHORITY.—

5                 “(A) Nothing in this subsection shall be  
6           construed to preclude or limit the applicability  
7           of any other provision of this Act.

8                 “(B) Nothing in this subsection shall be  
9           construed to prohibit the Secretary from issuing  
10          an order under this section finding a drug to be  
11          not generally recognized as safe and effective  
12          within the meaning of section 201(p)(1), as the  
13          Secretary determines appropriate.

14          “(n) INAPPLICABILITY OF PAPERWORK REDUCTION  
15          ACT.—Chapter 35 of title 44, United States Code, shall  
16          not apply to collections of information made under this  
17          section.

18          “(o) INAPPLICABILITY OF NOTICE AND COMMENT  
19          RULEMAKING REQUIREMENTS.—The requirements of  
20          subsection (b) shall apply with respect to administrative  
21          orders issued under this section instead of the require-  
22          ments of subchapter II of chapter 5 of title 5, United  
23          States Code.

24          “(p) DEFINITIONS.—In this section:



1           “(1) The term ‘nonprescription drug’ refers to  
2           a drug, an active ingredient, or a combination of ac-  
3           tive ingredients, not subject to the requirements of  
4           section 503(b)(1).

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

8                   “(A) is listed pursuant to section 510(j);  
9                   and

10                   “(B) is or will be subject to an administra-  
11                   tive order of the Food and Drug Administra-  
12                   tion.

13           “(3) the term ‘requestor’ refers to any person  
14           or group of persons marketing, manufacturing, proc-  
15           essing, or developing a drug.”.

16 **SEC. 102. MISBRANDING.**

17           Section 502 of the Federal Food, Drug, and Cosmetic  
18 Act (21 U.S.C. 352) is amended by inserting after para-  
19 graph (dd) the following:

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

24           “(ff) If it is a drug and it was manufactured, pre-  
25 pared, propagated, compounded, or processed in a facility

1 for which fees have not been paid as required by section  
2 7440.”.

3 **SEC. 103. DRUGS EXCLUDED FROM THE OVER-THE-**  
4 **COUNTER DRUG REVIEW.**

5 (a) IN GENERAL.—Nothing in this Act (or the  
6 amendments made by this Act) shall apply to any non-  
7 prescription drug which was excluded by the Food and  
8 Drug Administration from the Over-the-Counter Drug Re-  
9 view in accordance with the statement set out at page  
10 9466 of volume 37 of the Federal Register, published on  
11 May 11, 1972.

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

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

17 (a) REVIEW OF NONPRESCRIPTION SUNSCREEN AC-  
18 TIVE INGREDIENTS.—

19 (1) APPLICABILITY OF SECTION 505G FOR  
20 PENDING SUBMISSIONS.—

21 (A) IN GENERAL.—A sponsor of a non-  
22 prescription sunscreen active ingredient or com-  
23 bination of nonprescription sunscreen active in-  
24 gredients that, as of the date of enactment of  
25 this Act, is subject to a proposed sunscreen

1 order may elect, by means of giving notification  
2 to the Secretary of Health and Human Serv-  
3 ices, to transition into the review of such ingre-  
4 dient or combination of ingredients pursuant to  
5 the process set out in section 505G of such Act,  
6 as added by section 101 of this Act.

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

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

16 (ii) such administrative order is  
17 deemed to have been accepted for filing  
18 under subsection (b)(6)(A)(i) of such sec-  
19 tion 505G.

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

1 viewed under section 505G of the Federal Food,  
2 Drug, and Cosmetic Act, as added by section  
3 101 of this Act, shall continue to have such in-  
4 gredient or combination of ingredients reviewed  
5 in accordance with section 586C of such Act  
6 (21 U.S.C. 360fff-3).

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

13 (b) AMENDMENTS TO SUNSCREEN PROVISIONS.—

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

18 “(3) RELATIONSHIP TO ORDERS UNDER SEC-  
19 TION 505G.—A final sunscreen order shall be deemed  
20 to be a final administrative order under section  
21 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  
7 sponsor may request one or more confidential  
8 meetings with respect to a proposed sunscreen  
9 order, including a letter deemed to be a pro-  
10 posed sunscreen order under paragraph (3), to  
11 discuss matters involving confidential commer-  
12 cial information or trade secrets. The Secretary  
13 shall convene a confidential meeting with such  
14 sponsor not later than 90 calendar days after  
15 the date of such request for a meeting. If a  
16 sponsor requests more than one confidential  
17 meeting for the same proposed sunscreen order,  
18 the Secretary may refuse to grant an additional  
19 confidential meeting request if the Secretary de-  
20 termines that such additional confidential meet-  
21 ing is not reasonably necessary for the sponsor  
22 to advance such proposed sunscreen order. The  
23 Secretary shall publish a post-meeting summary  
24 of each confidential meeting under this sub-

1 paragraph that does not disclose confidential  
2 commercial information or trade secrets.】”.]

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

7 【“SEC. 586H. SUNSET.

8 “【This subchapter shall cease to be effective at the  
9 end of fiscal year 2022.】”.]

## 10 **TITLE II—USER FEES**

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

12 (a) SHORT TITLE.—This title may be cited as the  
13 “Over-the-Counter Monograph User Fee Act of 2017”.

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

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

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

5 **“PART 10—FEES RELATING TO OVER-THE-**  
6 **COUNTER DRUGS.**

7 **“SEC. 744N. DEFINITIONS.**

8 “In this part:

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

12 “(A) one business entity controls, or has  
13 the power to control, the other business entity;  
14 or

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

17 “(2) The term ‘contract manufacturing organi-  
18 zation facility’ means an OTC monograph drug facil-  
19 ity where neither the owner of such manufacturing  
20 facility nor any affiliate of such owner or facility  
21 sells the OTC monograph drug products produced at  
22 such facility directly to wholesalers, retailers, or con-  
23 sumers in the United States.

24 “(3) The term ‘costs of resources allocated for  
25 OTC monograph drug activities’ means the expenses

1 in connection with OTC monograph drug activities  
2 for—

3 “(A) officers and employees of the Food  
4 and Drug Administration, contractors of the  
5 Food and Drug Administration, advisory com-  
6 mittees, and costs related to such officers, em-  
7 ployees, and committees and costs related to  
8 contracts with such contractors;

9 “(B) management of information, and the  
10 acquisition, maintenance, and repair of com-  
11 puter resources;

12 “(C) leasing, maintenance, renovation, and  
13 repair of facilities and acquisition, maintenance,  
14 and repair of fixtures, furniture, scientific  
15 equipment, and other necessary materials and  
16 supplies; and

17 “(D) collecting fees under section 744O  
18 and accounting for resources allocated for OTC  
19 monograph drug activities.

20 “(4) The term ‘firm establishment identifier’ is  
21 the unique number automatically generated by Food  
22 and Drug Administration’s Field Accomplishments  
23 and Compliance Tracking System (FACTS) (or any  
24 successor system).



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

5           “(6) The term ‘OTC monograph drug activities’  
6 means activities of the Secretary associated with  
7 OTC monograph drugs and inspection of facilities  
8 associated with such products, including the fol-  
9 lowing activities:

10           “(A) The activities necessary for review  
11 and evaluation of OTC monographs and OTC  
12 monograph order requests, including—

13           “(i) orders proposing or finalizing ap-  
14 plicable conditions of use for OTC mono-  
15 graph drugs;

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

21           “(iii) all OTC monograph drug devel-  
22 opment and review activities, including  
23 intraagency collaboration;

1                   “(iv) regulation and policy develop-  
2                   ment activities related to OTC monograph  
3                   drugs;

4                   “(v) development of product standards  
5                   for products subject to review and evalua-  
6                   tion;

7                   “(vi) meetings referred to in section  
8                   505G(i);

9                   “(vii) review of labeling prior to  
10                  issuance of orders related to OTC mono-  
11                  graph drugs or conditions of use; and

12                  “(viii) regulatory science activities re-  
13                  lated to OTC monograph drugs;

14                  “(B) Inspections related to OTC mono-  
15                  graph drugs.

16                  “(C) Monitoring of clinical and other re-  
17                  search conducted in connection with OTC  
18                  monograph drugs.

19                  “(D) Safety activities with respect to OTC  
20                  monograph drugs, including—

21                         “(i) collecting, developing, and review-  
22                         ing safety information on OTC monograph  
23                         drugs, including adverse event reports;

24                         “(ii) developing and using improved  
25                         adverse event data-collection systems, in-

1 cluding information technology systems;  
2 and

3 “(iii) developing and using improved  
4 analytical tools to assess potential safety  
5 risks, including access to external data-  
6 bases.

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

9 “(7) The term ‘OTC monograph order request’  
10 means a request for an administrative order sub-  
11 mitted under section 505G(b)(6).

12 “(8) The term ‘Tier 1 OTC monograph order  
13 request’ means any OTC monograph order request  
14 not determined to be a Tier 2 OTC monograph  
15 order request.

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

19 “(i) the reordering of existing infor-  
20 mation in the drug facts label of an OTC  
21 monograph drug product;

22 “(ii) the addition of information to  
23 the other information section of the drug  
24 facts label of an OTC monograph drug  
25 product, as limited by section 201.66(e)(7)

1 of title 21, Code of Federal Regulations (or  
2 any successor regulations);

3 “(iii) modification to the directions for  
4 use section of the drug facts label of an  
5 OTC monograph drug product, if such  
6 changes conform to changes made pursu-  
7 ant to section 505G(c)(3)(A);

8 “(iv) the standardization of the con-  
9 centration or dose of a specific finalized in-  
10 gredient within a particular finalized  
11 monograph;

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

15 “(vi) addition of an interchangeable  
16 term in accordance with section 330.1 of  
17 title 21, Code of Federal Regulations.

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

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

4                   “(i) that is—

5                           “(I) under one management, ei-  
6                           ther direct or indirect; and

7                           “(II) at one geographic location  
8                           or address engaged in manufacturing  
9                           or processing the finished dosage form  
10                          of an OTC monograph drug;

11                          “(ii) includes a finished dosage form  
12                          manufacturer facility in a contractual rela-  
13                          tionship with the sponsor of one or more  
14                          OTC monograph drugs to manufacture or  
15                          process such drugs; and

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

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

1           “(i) closely related to the same business  
2           enterprise;

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

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

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

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

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

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

1 **“SEC. 7440. AUTHORITY TO ASSESS AND USE OTC MONO-**  
2 **GRAPH FEES.**

3 “(a) TYPES OF FEES.—Beginning with fiscal year  
4 2018, the Secretary shall assess and collect fees in accord-  
5 ance with this section as follows:

6 “(1) FACILITY FEE.—

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

14 “(B) EXCEPTIONS.—

15 “(i) A fee shall not be assessed under  
16 subparagraph (A) if the identified OTC  
17 monograph drug facility has ceased all ac-  
18 tivities related to OTC monograph drug  
19 products prior to the date specified in sub-  
20 paragraph (D)(ii) and has updated its reg-  
21 istration to reflect such change under the  
22 requirements for drug establishment reg-  
23 istration set forth in section 510.

24 “(ii) The amount of the fee for a con-  
25 tract manufacturing organization facility  
26 shall be equal to  $\frac{2}{3}$  the amount of the fee

1           for an OTC monograph drug facility that  
2           is not a contract manufacturing organiza-  
3           tion facility.

4           “(C) AMOUNT.—The amount of fees estab-  
5           lished under subparagraph (A) shall be estab-  
6           lished under subsection (c).

7           “(D) DUE DATE.—For each fiscal year,  
8           the facility fees required under subparagraph  
9           (A) shall be due on the later of—

10           “(i) the first business day of April of  
11           such year; and

12           “(ii) the first business day after the  
13           enactment of an appropriations Act pro-  
14           viding for the collection and obligation of  
15           fees under this section for such year.

16           “(2) OTC MONOGRAPH ORDER REQUEST  
17           FEE.—

18           “(A) IN GENERAL.—Each person that sub-  
19           mits an OTC monograph order request shall be  
20           subject to a fee for an OTC monograph order  
21           request. The amount of such fee shall be—

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



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

5                   “(B) DUE DATE.—The OTC monograph  
6                   order request fees required under subparagraph  
7                   (A) shall be due on the date of submission of  
8                   the OTC monograph order request.

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

17                         “(i) a contraindication, warning, or  
18                         precaution;

19                         “(ii) a statement about risk associated  
20                         with misuse or abuse; or

21                         “(iii) an instruction about dosage and  
22                         administration that is intended to increase  
23                         the safe use of the OTC monograph drug  
24                         product.

1           “(D) REFUND OF FEE IF ORDER REQUEST  
2 IS RECATEGORIZED AS A TIER 2 OTC MONO-  
3 GRAPH ORDER REQUEST.—If the Secretary de-  
4 termines that an OTC monograph request ini-  
5 tially characterized as Tier 1 shall be re-charac-  
6 terized as a Tier 2 OTC monograph order re-  
7 quest, and the requestor has paid a Tier 1 fee  
8 in accordance with subparagraph (A)(i), the  
9 Secretary shall refund the requestor the dif-  
10 ference between the Tier 1 and Tier 2 fees de-  
11 termined under subparagraphs (A)(i) and  
12 (A)(ii), respectively.

13           “(E) REFUND OF FEE IF ORDER REQUEST  
14 REFUSED FOR FILING OR WITHDRAWN BEFORE  
15 FILING.—The Secretary shall refund 75 percent  
16 of the fee paid under subparagraph (B) for any  
17 order request which is refused for filing.

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

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

12          “(3) REFUNDS.—

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

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

24                 “(4) NOTICE.—Within the timeframe specified  
25                 in subsection (c), the Secretary shall publish in the

1 Federal Register the amount of the fees under para-  
2 graph (1) for such fiscal year.

3 “(b) FREE REVENUE AMOUNTS.—

4 “(1) FISCAL YEAR 2018.—For fiscal year 2018,  
5 fees under subsection (a)(1) shall be established to  
6 generate a total facility fee revenue amount equal to  
7 the sum of—

8 “(A) the annual base revenue for fiscal  
9 year 2018 (as determined under paragraph (3));

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

14 “(C) additional direct cost adjustments (as  
15 determined under subsection (c)(3)).

16 “(2) SUBSEQUENT FISCAL YEARS.—For each of  
17 the fiscal years 2019 through 2022, fees under sub-  
18 section (a)(1) shall be established to generate a total  
19 facility fee revenue amount equal to the sum of—

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

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

1           “(C) 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));

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

7           “(E) additional dollar amounts for each  
8           fiscal year as follows:

9                   “(i) \$7,000,000 for fiscal year 2019;

10                   “(ii) \$6,000,000 for fiscal year 2020.

11                   “(iii) \$7,000,000 for fiscal year 2021.

12                   “(iv) \$3,000,000 for fiscal year 2022.

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

17                   “(A) for fiscal year 2018, \$8,000,000; and

18                   “(B) for fiscal years 2019 through 2022,

19           the dollar amount of the total revenue amount

20           established under this subsection for the pre-

21           vious fiscal year, not including any adjustments

22           made under subsection (c)(2) or (c)(3).

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

24           “(1) INFLATION ADJUSTMENT.—

1           “(A) IN GENERAL.—For purposes of sub-  
2 section (b)(2)(B), the dollar amount of the in-  
3 flation adjustment to the annual base revenue  
4 for fiscal year 2019 and each subsequent fiscal  
5 year shall be equal to the product of—

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

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

10          “(B) OTC MONOGRAPH ORDER REQUEST  
11 FEES.—For purposes of subsection (a)(2), the  
12 dollar amount of the inflation adjustment to the  
13 fee for OTC monograph order requests for fis-  
14 cal year 2019 and each subsequent fiscal year  
15 shall be equal to the product of—

16          “(i) the applicable fee under sub-  
17 section (a)(2) for the preceding fiscal year;  
18 and

19          “(ii) the inflation adjustment percent-  
20 age under subparagraph (C).

21          “(C) INFLATION ADJUSTMENT PERCENT-  
22 AGE.—The inflation adjustment percentage  
23 under this subparagraph for a fiscal year is  
24 equal to—

1 “(i) for each of fiscal years 2019 and  
2 2020, the average annual percent change  
3 that occurred in the Consumer Price Index  
4 for urban consumers (Washington-Balti-  
5 more, DC–MD–VA–WV; Not Seasonally  
6 Adjusted; All items; Annual Index) for the  
7 first 3 years of the preceding 4 years of  
8 available data; and

9 “(ii) for each of fiscal years 2021 and  
10 2022, the sum of—

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

24 “(II) the average annual percent  
25 change that occurred in the Consumer

1 Price Index for urban consumers  
2 (Washington-Baltimore, DC–MD–VA–  
3 WV; Not Seasonally Adjusted; All  
4 items; Annual Index) for the first 3  
5 years of the preceding 4 years of  
6 available data multiplied by the pro-  
7 portion of all costs other than per-  
8 sonnel compensation and benefits  
9 costs to total costs of OTC mono-  
10 graph drug activities for the first 3  
11 years of the preceding 4 fiscal years.

12 “(2) OPERATING RESERVE ADJUSTMENT.—

13 “(A) IN GENERAL.—For fiscal year 2018  
14 and subsequent fiscal years, for purposes of  
15 subsections (b)(1)(B) and (b)(2)(C), the Sec-  
16 retary may, in addition to adjustments under  
17 paragraph (1), further increase the fee revenue  
18 and fees if such an adjustment is necessary to  
19 provide operating reserves of carryover user  
20 fees for OTC monograph drug activities for not  
21 more than the number of weeks specified in  
22 subparagraph (B).

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

25 “(i) 3 weeks for fiscal year 2018;



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

6 “(C) DECREASE.—If the Secretary has  
7 carryover balances for such process in excess of  
8 10 weeks of the operating reserves referred to  
9 in subparagraph (A), the Secretary shall de-  
10 crease the fee revenue and fees referred to in  
11 such subparagraph to provide for not more than  
12 10 weeks of such operating reserves.

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

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

25 “(A) \$14,000,000 for fiscal year 2018;

1 “(B) \$7,000,000 for fiscal year 2019;

2 “(C) \$4,000,000 for fiscal year 2020;

3 “(D) \$3,000,000 for fiscal year 2021; and

4 “(E) \$3,000,000 for fiscal year 2022.

5 “(4) ANNUAL FEE SETTING.—

6 “(A) FISCAL YEAR 2018.—The Secretary  
7 shall, not later than January 31, 2018—

8 “(i) establish OTC monograph drug  
9 facility fees for fiscal year 2018 under sub-  
10 section (a), based on the revenue amount  
11 for such year under subsection (b) and the  
12 adjustments provided under this sub-  
13 section; and

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

17 “(B) SUBSEQUENT FISCAL YEARS.—The  
18 Secretary shall, not later than January 31 of  
19 each fiscal year that begins after September 30,  
20 2018, establish for each such fiscal year, based  
21 on the revenue amounts under subsection (b)  
22 and the adjustments provided under this sub-  
23 section—

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

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

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

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

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

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

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

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

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

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

3                   “(ii) All OTC monograph drug prod-  
4                   ucts manufactured in such a facility or  
5                   containing an ingredient manufactured in  
6                   such a facility shall be deemed misbranded  
7                   under section 502(a).

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

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

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

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

22                  “(1) IN GENERAL.—Subject to paragraph  
23                  (2)(D), fees authorized under subsection (a) shall be  
24                  collected and available for obligation only to the ex-  
25                  tent and in the amount provided in advance in ap-

1        appropriations Acts. Such fees are authorized to re-  
2        main available until expended. Such sums as may be  
3        necessary may be transferred from the Food and  
4        Drug Administration salaries and expenses appro-  
5        priation account without fiscal year limitation to  
6        such appropriation account for salaries and expenses  
7        with such fiscal year limitation. The sums trans-  
8        ferred shall be available solely for OTC monograph  
9        drug activities.

10        “(2)    COLLECTIONS    AND    APPROPRIATION  
11        ACTS.—

12                “(A) IN GENERAL.—Subject to subpara-  
13                graphs (C) and (D), the fees authorized by this  
14                section shall be collected and available in each  
15                fiscal year in an amount not to exceed the  
16                amount specified in appropriation Acts, or oth-  
17                erwise made available for obligation, for such  
18                fiscal year.

19                “(B) USE OF FEES AND LIMITATION.—  
20                The fees authorized by this section shall be  
21                available to defray increases in the costs of the  
22                resources allocated for OTC monograph drug  
23                activities (including increases in such costs for  
24                an additional number of full-time equivalent po-  
25                sitions in the Department of Health and

1 Human Services to be engaged in such activi-  
2 ties), only if the Secretary allocates for such  
3 purpose an amount for such fiscal year (exclud-  
4 ing amounts from fees collected under this sec-  
5 tion) no less than \$12,000,000, multiplied by  
6 the adjustment factor applicable to the fiscal  
7 year involved under subsection (c)(1).

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

15 “(D) FEE COLLECTION DURING FIRST  
16 PROGRAM YEAR.—Until the date of the enact-  
17 ment of an Act making appropriations and pro-  
18 viding for the collection and obligation of fees  
19 under this section through September 30, 2018,  
20 for the salaries and expenses account of the  
21 Food and Drug Administration, fees authorized  
22 by this section for fiscal year 2018 may be col-  
23 lected and shall be credited to such account and  
24 remain available until expended.

1           “(E) PROVISION FOR EARLY PAYMENTS IN  
2           SUBSEQUENT YEARS.—Payment of fees author-  
3           ized under this section for a fiscal year (after  
4           fiscal year 2018), prior to the due date for such  
5           fees, may be accepted by the Secretary in ac-  
6           cordance with authority provided in advance in  
7           a prior year appropriations Act.

8           “(3) AUTHORIZATION OF APPROPRIATIONS.—  
9           For each of the fiscal years 2018 through 2022,  
10          there is authorized to be appropriated for fees under  
11          this section an amount equal to the total amount of  
12          fees assessed for such fiscal year under this section.

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

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

1 **“SEC. 744P. REAUTHORIZATION; REPORTING REQUIRE-**  
2 **MENTS.**

3       “(a) PERFORMANCE REPORT.—Beginning with fiscal  
4 year 2018, and not later than 120 calendar days after the  
5 end of each fiscal year thereafter for which fees are col-  
6 lected under this part, the Secretary shall prepare and  
7 submit to the Committee on Energy and Commerce of the  
8 House of Representatives and the Committee on Health,  
9 Education, Labor, and Pensions of the Senate a report  
10 concerning the progress of the Food and Drug Adminis-  
11 tration in achieving the goals identified in the letters de-  
12 scribed in section 201(b) of the Over-the-Counter Mono-  
13 graph Safety, Innovation, and Reform Act of 2017 during  
14 such fiscal year and the future plans of the Food and  
15 Drug Administration for meeting such goals.

16       “(b) FISCAL REPORT.—Not later than 120 calendar  
17 days after the end of fiscal year 2018 and each subsequent  
18 fiscal year for which fees are collected under this part,  
19 the Secretary shall prepare and submit to the Committee  
20 on Energy and Commerce of the House of Representatives  
21 and the Committee on Health, Education, Labor, and  
22 Pensions of the Senate a report on the implementation  
23 of the authority for such fees during such fiscal year and  
24 the use, by the Food and Drug Administration, of the fees  
25 collected for such fiscal year.



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

5       “(d) REAUTHORIZATION.—

6           “(1) CONSULTATION.—In developing rec-  
7 ommendations to present to the Congress with re-  
8 spect to the goals described in subsection (a), and  
9 plans for meeting the goals, for OTC monograph  
10 drug activities for the first 5 fiscal years after fiscal  
11 year 2022, and for the reauthorization of this part  
12 for such fiscal years, the Secretary shall consult  
13 with—

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

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

18           “(C) scientific and academic experts;

19           “(D) health care professionals;

20           “(E) representatives of patient and con-  
21 sumer advocacy groups; and

22           “(F) the regulated industry.

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

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

4           “(B) publish such recommendations in the  
5           Federal Register;

6           “(C) provide for a period of 30 calendar  
7           days for the public to provide written comments  
8           on such recommendations;

9           “(D) hold a meeting at which the public  
10          may present its views on such recommenda-  
11          tions; and

12          “(E) after consideration of such public  
13          views and comments, revise such recommenda-  
14          tions as necessary.

15          “(3) TRANSMITTAL OF RECOMMENDATIONS.—  
16          Not later than January 15, 2022, the Secretary  
17          shall transmit to the Congress the revised rec-  
18          ommendations under paragraph (2), a summary of  
19          the views and comments received under such para-  
20          graph, and any changes made to the recommenda-  
21          tions in response to such views and comments.”.