

116TH CONGRESS  
1ST SESSION

# S. 2740

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 SENATE OF THE UNITED STATES

OCTOBER 30, 2019

Mr. ISAKSON (for himself and Mr. CASEY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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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; TABLE OF CONTENTS.**

4       (a) SHORT TITLE.—This Act may be cited as the  
5       “Over-the-Counter Monograph Safety, Innovation, and  
6       Reform Act of 2019”.

7       (b) TABLE OF CONTENTS.—The table of contents for  
8       this Act is as follows:

Sec. 1. Short title; table of contents.

## TITLE I—OTC DRUG REVIEW

Sec. 101. Regulation of certain nonprescription drugs that are marketed without an approved drug application.

Sec. 102. Misbranding.

Sec. 103. Drugs excluded from the over-the-counter drug review.

Sec. 104. Treatment of Sunscreen Innovation Act.

Sec. 105. Annual update to Congress on appropriate pediatric indication for certain OTC cough and cold drugs.

Sec. 106. Technical corrections.

## TITLE II—USER FEES

Sec. 201. Short title; finding.

Sec. 202. Fees relating to over-the-counter drugs.

# 1      **TITLE I—OTC DRUG REVIEW**

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

5            (a) IN GENERAL.—Chapter V of the Federal Food,  
6 Drug, and Cosmetic Act is amended by inserting after section 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 DRUG APPLICATION.**

11            “(a) NONPRESCRIPTION DRUGS MARKETED WITHOUT  
12 OUT AN APPROVED APPLICATION.—Nonprescription  
13 drugs marketed without an approved drug application  
14 under section 505, as of the date of the enactment of this  
15 section, shall be treated in accordance with this subsection.  
16

17            “(1) DRUGS SUBJECT TO A FINAL MONOGRAPH;  
18            CATEGORY I DRUGS SUBJECT TO A TENTATIVE

1 FINAL MONOGRAPH.—A drug is deemed to be gen-  
2 erally recognized as safe and effective under section  
3 201(p)(1), not a new drug under section 201(p), and  
4 not subject to section 503(b)(1), if—

5 “(A) the drug is—

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

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

23 “(B) the drug is—

24 “(i) classified in category I for safety  
25 and effectiveness under a tentative final

monograph that is the most recently applicable proposal or determination issued under part 330 of title 21, Code of Federal Regulations;

“(ii) in conformity with the proposed requirements for nonprescription use of such tentative final monograph, any applicable subsequent determination by the Secretary, the general requirements for nonprescription drugs, and conditions or requirements under subsections (b), (c), and (k); and

“(iii) except as permitted by an order issued under subsection (b) or, in the case of a minor change in the drug, in conformity with an order issued under subsection (c), in a dosage form that, immediately prior to the date of the enactment of this section, has been used to a material extent and for a material time under section 201(p)(2).

“(2) TREATMENT OF SUNSCREEN DRUGS.—

With respect to sunscreen drugs subject to this section, the applicable requirements in terms of conformity with a final monograph, for purposes of

1 paragraph (1)(A)(i), shall be the requirements speci-  
2 fied in part 352 of title 21, Code of Federal Regula-  
3 tions, as published on May 21, 1999, beginning on  
4 page 27687 of volume 64 of the Federal Register,  
5 except that the applicable requirements governing ef-  
6 fectiveness and labeling shall be those specified in  
7 section 201.327 of title 21, Code of Federal Regula-  
8 tions.

9 “(3) CATEGORY III DRUGS SUBJECT TO A TEN-  
10 TATIVE FINAL MONOGRAPH; CATEGORY I DRUGS  
11 SUBJECT TO PROPOSED MONOGRAPH OR ADVANCE  
12 NOTICE OF PROPOSED RULEMAKING.—A drug that  
13 is not described in paragraph (1), (2), or (4) is not  
14 required to be the subject of an application approved  
15 under section 505, and is not subject to section  
16 503(b)(1), if—

17 “(A) the drug is—

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

25 “(ii) in conformity with—

1 “(I) the conditions of use, includ-  
2 ing indication and dosage strength, if  
3 any, described for such category III  
4 drug in such preamble or in an appli-  
5 cable subsequent proposed rule;

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

14 “(III) the general requirements  
15 for nonprescription drugs and condi-  
16 tions or requirements under sub-  
17 section (b) or (k); and

18 “(iii) in a dosage form that, imme-  
19 diately prior to the date of the enactment  
20 of this section, had been used to a material  
21 extent and for a material time under sec-  
22 tion 201(p)(2); or

23 “(B) the drug is—

24 “(i) classified in category I for safety  
25 and effectiveness under a proposed mono-

graph or advance notice of proposed rulemaking that is the most recently applicable proposal or determination for such drug issued under part 330 of title 21, Code of Federal Regulations;

“(ii) in conformity with the requirements for nonprescription use of such proposed monograph or advance notice of proposed rulemaking, any applicable subsequent determination by the Secretary, the general requirements for nonprescription drugs, and conditions or requirements under subsection (b) or (k); and

“(iii) in a dosage form that, immediately prior to the date of the enactment of this section, has been used to a material extent and for a material time under section 201(p)(2).

“(4) CATEGORY II DRUGS DEEMED NEW DRUGS.—A drug that is classified in category II for safety or effectiveness under a tentative final monograph or that is subject to a determination to be not generally recognized as safe and effective in a proposed rule that is the most recently applicable proposal issued under part 330 of title 21, Code of Fed-

1       eral Regulations, shall be deemed to be a new drug  
 2       under section 201(p), misbranded under section  
 3       502(ee), and subject to the requirement for an ap-  
 4       proved new drug application under section 505 be-  
 5       ginning on the day that is 180 calendar days after  
 6       the date of the enactment of this section, unless, be-  
 7       fore such day, the Secretary determines that it is in  
 8       the interest of public health to extend the period  
 9       during which the drug may be marketed without  
 10      such an approved new drug application.

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

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

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

25                   and



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

3           “(b) ADMINISTRATIVE ORDERS.—

4           “(1) IN GENERAL.—

5           “(A) DETERMINATION.—The Secretary  
 6           may, on the initiative of the Secretary or at the  
 7           request of one or more requestors, issue an ad-  
 8           ministrative order determining whether there  
 9           are conditions under which a specific drug, a  
 10          class of drugs, or a combination of drugs, is de-  
 11          termined to be—

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

13                   and

14                   “(ii) generally recognized as safe and  
 15                   effective under section 201(p)(1).

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

20                   “(i) is determined by the Secretary to  
 21                   meet the conditions specified in clauses (i)  
 22                   and (ii) of subparagraph (A);

23                   “(ii) is marketed in conformity with  
 24                   an administrative order under this sub-  
 25                   section;

1 “(iii) meets the general requirements  
2 for nonprescription drugs; and

3 “(iv) meets the requirements under  
4 subsections (c) and (k).

5 “(C) STANDARD.—The Secretary shall find  
6 that a drug is not generally recognized as safe  
7 and effective under section 201(p)(1) if—

8 “(i) the evidence shows that the drug  
9 is not generally recognized as safe and ef-  
10 fective under section 201(p)(1); or

11 “(ii) the evidence is inadequate to  
12 show that the drug is generally recognized  
13 as safe and effective under section  
14 201(p)(1).

15 “(2) ADMINISTRATIVE ORDERS INITIATED BY  
16 THE SECRETARY.—

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

20 “(i) make reasonable efforts to notify  
21 informally, not later than 2 business days  
22 before the issuance of the proposed order,  
23 the sponsors of drugs who have a listing in  
24 effect under section 510(j) for the drugs or

1 combination of drugs that will be subject  
2 to 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 under  
6           section 201(p)(1), the Secretary shall follow the  
7           procedures in subparagraph (A), except that—

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

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

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

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

23                   “(iii) any person who submits data in  
24           such comment period shall include a cer-  
25           tification that the person has submitted all

1 evidence created, obtained, or received by  
2 that person that is both within the cat-  
3 egories of data identified in the proposed  
4 order and relevant to a determination as to  
5 whether the drug is generally recognized as  
6 safe and effective under section 201(p)(1).

7 “(3) HEARINGS; JUDICIAL REVIEW.—

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

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

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

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

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

16 “(ii) HUMAN DATA STUDIES AND  
 17 NON-HUMAN DATA DEFINED.—In this sub-  
 18 paragraph:

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

24 “(II) The term ‘non-human data’  
 25 means data from testing other than

1 with human subjects which provides  
2 information concerning safety or ef-  
3 fectiveness.

4 “(C) HEARING PROCEDURES.—

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

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



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

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

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

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

14           “(iv) RIGHTS OF PARTIES TO HEAR-  
15           ING.—The parties to a hearing requested  
16           under subparagraph (A) shall have the  
17           right to present testimony, including testi-  
18           mony of expert witnesses, and to cross-ex-  
19           amine witnesses presented by other parties.  
20           Where appropriate, the presiding officer  
21           may require that cross-examination by par-  
22           ties representing substantially the same in-  
23           terests be consolidated to promote effi-  
24           ciency and avoid duplication.

25           “(v) FINAL DECISION.—

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

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

13                  “(D) JUDICIAL REVIEW OF FINAL ADMIN-  
14                  ISTRATIVE ORDER.—

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

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

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

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

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

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

20 “(4) EXPEDITED PROCEDURE WITH RESPECT  
 21 TO ADMINISTRATIVE ORDERS INITIATED BY THE  
 22 SECRETARY.—

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

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

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

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

21                 “(III) shall provide for a public  
22                 comment period of at least 45 cal-  
23                 endar days with respect to such in-  
24                 terim final order.

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

5           “(B) SAFETY LABELING CHANGES.—

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

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

21               “(II) after reasonable efforts of  
22               notification, issue an interim final ad-  
23               ministrative order in accordance with  
24               paragraph (1) to require such change,

1 together with a detailed statement of  
2 the reasons for such order;

3 “(III) publish in the Federal  
4 Register a notice of availability of  
5 such order; and

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

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

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

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

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

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

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

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

1 “(F) TIMING.—

2 “(i) FINAL ORDER AND HEARING.—

3 The Secretary shall—

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

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

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

21 “(G) JUDICIAL REVIEW.—A final order  
22 issued pursuant to subparagraph (F) shall be  
23 subject to judicial review in accordance with  
24 paragraph (3)(D).



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

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

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

13          “(ii) if the Secretary determines that  
14      the request is sufficiently complete and for-  
15      matted to permit a substantive review, the  
16      Secretary shall—

17           “(I) file the request; and

18           “(II) initiate proceedings with re-  
19      spect to issuing an administrative  
20      order in accordance with paragraphs  
21      (2) and (3); and

22          “(iii) except as provided in paragraph  
23      (6), if the Secretary determines that a re-  
24      quest does not meet the requirements for  
25      filing or is not sufficiently complete and

1 formatted to permit a substantive review,  
2 the requestor may demand that the request  
3 be filed over protest, and the Secretary  
4 shall initiate proceedings to review the re-  
5 quest in accordance with paragraph (2)(A).

6 “(B) REQUEST TO INITIATE PRO-  
7 CEEDINGS.—

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

18 “(I) determining whether a drug  
19 is generally recognized as safe and ef-  
20 fective under section 201(p)(1), ex-  
21 empt from section 503(b)(1), and not  
22 required to be the subject of an ap-  
23 proved application under section 505;  
24 or

1 “(II) determining whether a  
2 change to a condition of use of a drug  
3 is generally recognized as safe and ef-  
4 fective under section 201(p)(1), ex-  
5 empt from section 503(b)(1), and not  
6 required to be the subject of an ap-  
7 proved application under section 505,  
8 if, absent such a changed condition of  
9 use, such drug is—

10 “(aa) generally recognized  
11 as safe and effective under sec-  
12 tion 201(p)(1) in accordance with  
13 subsection (a)(1), (a)(2), or an  
14 order under this subsection; or

15 “(bb) subject to subsection  
16 (a)(3), but only if such requestor  
17 initiates such request in conjunc-  
18 tion with a request for the Sec-  
19 retary to determine whether such  
20 drug is generally recognized as  
21 safe and effective under section  
22 201(p)(1), which is filed by the  
23 Secretary under subparagraph  
24 (A)(ii).

1           “(ii) EXCEPTION.—The Secretary is  
2 not required to complete review of a re-  
3 quest for a change described in clause  
4 (i)(II) if the Secretary determines that  
5 there is an inadequate basis to find the  
6 drug is generally recognized as safe and ef-  
7 fective under section 201(p)(1) under para-  
8 graph (1) and issues a final order an-  
9 nouncing that determination.

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

18           “(C) EXCLUSIVITY.—

19           “(i) IN GENERAL.—A final adminis-  
20 trative order issued in response to a re-  
21 quest under this section shall have the ef-  
22 fect of authorizing solely the order re-  
23 questor (or the licensees, assignees, or suc-  
24 cessors in interest of such requestor with  
25 respect to the subject of such order), for a

1 period of 18 months following the effective  
2 date of such final order and beginning on  
3 the date the requestor may lawfully market  
4 such drugs pursuant to the order, to mar-  
5 ket drugs—

6 “(I) incorporating changes de-  
7 scribed in clause (ii); and

8 “(II) subject to the limitations  
9 under clause (iv).

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

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

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

1 “(iii) DRUGS DESCRIBED.—The drugs  
2 described in this clause are drugs—

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

5 “(II) subject to a final order  
6 issued under this section;

7 “(III) subject to a final sun-  
8 screen order (as defined in section  
9 586(2)(A)); or

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

14 “(iv) LIMITATIONS ON EXCLU-  
15 SIVITY.—

16 “(I) IN GENERAL.—Only one 18-  
17 month period under this subpara-  
18 graph shall be granted, under each  
19 order described in clause (i), with re-  
20 spect to changes (to the drug subject  
21 to such order) which are either—

22 “(aa) changes described in  
23 clause (ii)(I), relating to active  
24 ingredients; or

1 “(bb) changes described in  
2 clause (ii)(II), relating to condi-  
3 tions of use.

4 “(II) NO EXCLUSIVITY AL-  
5 LOWED.—No exclusivity shall apply to  
6 changes to a drug which are—

7 “(aa) the subject of a Tier 2  
8 OTC monograph order request  
9 (as defined in section 744L);

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

15 “(cc) changes related to  
16 methods of testing safety or effi-  
17 cacy.

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

1 “(I) have not been relied on by  
2 the Secretary to support—

3 “(aa) a proposed or final de-  
4 termination that a drug described  
5 in subclause (I), (II), or (III) of  
6 clause (iii) is generally recognized  
7 as safe and effective under sec-  
8 tion 201(p)(1); or

9 “(bb) approval of a drug  
10 that was approved under section  
11 505; and

12 “(II) do not duplicate the results  
13 of another study that was relied on by  
14 the Secretary to support—

15 “(aa) a proposed or final de-  
16 termination that a drug described  
17 in subclause (I), (II), or (III) of  
18 clause (iii) is generally recognized  
19 as safe and effective under sec-  
20 tion 201(p)(1); or

21 “(bb) approval of a drug  
22 that was approved under section  
23 505.

24 “(vi) NOTIFICATION OF DRUG NOT  
25 AVAILABLE FOR SALE.—A requestor that



1 is granted exclusivity with respect to a  
2 drug under this subparagraph shall notify  
3 the Secretary in writing within 1 year of  
4 the issuance of the final administrative  
5 order if the drug that is the subject of  
6 such order will not be available for sale  
7 within 1 year of the date of issuance of  
8 such order. The requestor shall include  
9 with such notice the—

10 “(I) identity of the drug by es-  
11 tablished name and by proprietary  
12 name, if any;

13 “(II) strength of the drug;

14 “(III) date on which the drug  
15 will be available for sale, if known;  
16 and

17 “(IV) reason for not marketing  
18 the drug after issuance of the order.

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

23 “(A) IN GENERAL.—In response to a re-  
24 quest under this section that a drug described

in subparagraph (B) be generally recognized as safe and effective, the Secretary—

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

“(ii) if the request fails to include information specified under subparagraph (C), shall refuse to file such request and require that nonprescription marketing of the drug be pursuant to a new drug application as described in subparagraph (D).

“(B) DRUG DESCRIBED.—A drug described in this subparagraph is a nonprescription drug which contains an active ingredient not previously incorporated in a drug—

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

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

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

“(C) INFORMATION DEMONSTRATING PRIMA FACIE SAFE NONPRESCRIPTION MAR-

1 KETING AND USE.—Information specified in  
2 this subparagraph, with respect to a request de-  
3 scribed in subparagraph (A)(i), is—

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

11 “(ii) if the drug has not been pre-  
12 viously marketed in the United States as a  
13 nonprescription drug, information suffi-  
14 cient for a prima facie demonstration that  
15 the drug was marketed and safely used  
16 under comparable conditions of marketing  
17 and use in a country listed in section  
18 802(b)(1)(A) or designated by the Sec-  
19 retary in accordance with section  
20 802(b)(1)(B)—

21 “(I) for such period as needed to  
22 provide reasonable assurances con-  
23 cerning the safe nonprescription use  
24 of the drug; and

1                   “(II) during such time was sub-  
2                   ject to sufficient monitoring by a reg-  
3                   ulatory body considered acceptable by  
4                   the Secretary for such monitoring  
5                   purposes, including for adverse events  
6                   associated with nonprescription use of  
7                   the drug; or

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

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

20                  “(i) the drug is marketed as a non-  
21                  prescription drug, under conditions of use  
22                  comparable to the conditions specified in  
23                  the request, for such period as the Sec-  
24                  retary determines appropriate (not to ex-  
25                  ceed 5 consecutive years) pursuant to an

1 application approved under section 505;  
2 and

3 “(ii) during such period, 1,000,000  
4 retail packages of the drug, or an equiva-  
5 lent quantity as determined by the Sec-  
6 retary, were distributed for retail sale, as  
7 determined in such manner as the Sec-  
8 retary finds appropriate.

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

16 “(7) PACKAGING.—An administrative order  
17 issued under paragraph (2), (4)(A), or (5) may in-  
18 clude requirements for the packaging of a drug to  
19 encourage use in accordance with labeling. Such re-  
20 quirements may include unit dose packaging, re-  
21 quirements for products intended for use by pedi-  
22 atric populations, requirements to reduce risk of  
23 harm from unsupervised ingestion, and other appro-  
24 priate requirements. This paragraph does not au-  
25 thorize the Food and Drug Administration to re-

1       quire standards or testing procedures as described in  
2       part 1700 of title 16, Code of Federal Regulations.

3               “(8) FINAL AND TENTATIVE FINAL MONO-  
4       GRAPHS FOR CATEGORY I DRUGS DEEMED FINAL  
5       ADMINISTRATIVE ORDERS.—

6               “(A) IN GENERAL.—A final monograph or  
7       tentative final monograph described in subpara-  
8       graph (B) shall be deemed to be a final admin-  
9       istrative order under this subsection and may  
10      be amended, revoked, or otherwise modified in  
11      accordance with the procedures of this sub-  
12      section.

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

17              “(i) establishes conditions of use for a  
18      drug described in paragraph (1) or (2) of  
19      subsection (a); and

20              “(ii) represents the most recently pro-  
21      mulgated version of such conditions, in-  
22      cluding as modified, in whole or in part, by  
23      any proposed or final rule.

24              “(C) DEEMED ORDERS INCLUDE HARMO-  
25      NIZING        TECHNICAL        AMENDMENTS.—The

1       deemed establishment of a final administrative  
 2       order under subparagraph (A) shall be con-  
 3       strued to include any technical amendments to  
 4       such order as the Secretary determines nec-  
 5       essary to ensure that such order is appro-  
 6       priately harmonized, in terms of terminology or  
 7       cross-references, with the applicable provisions  
 8       of this Act (and regulations thereunder) and  
 9       any other orders issued under this section.

10       “(c) PROCEDURE FOR MINOR CHANGES.—

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

17       “(A) the requestor maintains such infor-  
 18       mation as is necessary to demonstrate that the  
 19       change—

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

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

1 “(B) the change is in conformity with the  
2 requirements of an applicable administrative  
3 order issued by the Secretary under paragraph  
4 (3).

5 “(2) ADDITIONAL INFORMATION.—

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

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

19 “(i) may so inform the sponsor of the  
20 drug in writing; and

21 “(ii) if the Secretary so informs the  
22 sponsor, shall provide the sponsor of the  
23 drug with a reasonable opportunity to pro-  
24 vide additional information.



1           “(C) FAILURE TO SUBMIT SUFFICIENT IN-  
2           FORMATION.—If the sponsor fails to provide  
3           such additional information within a time pre-  
4           scribed by the Secretary, or if the Secretary de-  
5           termines that such additional information does  
6           not demonstrate that the change does not—

7                   “(i) affect the safety or effectiveness  
8                   of the drug; or

9                   “(ii) materially affect the extent of  
10                  absorption or other exposure to the active  
11                  ingredient in comparison to a suitable ref-  
12                  erence product,

13           the drug as modified is a new drug under sec-  
14           tion 201(p) and shall be deemed to be mis-  
15           branded under section 502(ee).

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

18                   “(A) IN GENERAL.—The Secretary shall  
19                   issue one or more administrative orders speci-  
20                   fying requirements for determining whether a  
21                   minor change made by a sponsor pursuant to  
22                   this subsection will affect the safety or effective-  
23                   ness of a drug or materially affect the extent of  
24                   absorption or other exposure to an active ingre-  
25                   dient in the drug in comparison to a suitable

1 reference product, together with guidance for  
2 applying those orders to specific dosage forms.

3 “(B) STANDARD PRACTICES.—The orders  
4 and guidance issued by the Secretary under  
5 subparagraph (A) shall take into account rel-  
6 evant public standards and standard practices  
7 for evaluating the quality of drugs, and may  
8 take into account the special needs of popu-  
9 lations, including children.

10 “(d) CONFIDENTIALITY OF INFORMATION SUB-  
11 MITTED TO THE SECRETARY.—

12 “(1) IN GENERAL.—Subject to paragraph (2),  
13 any information, including reports of testing con-  
14 ducted on the drug or drugs involved, that is sub-  
15 mitted by a requestor in connection with proceedings  
16 on an order under this section (including any minor  
17 change under subsection (c)) and is a trade secret  
18 or confidential information subject to section  
19 552(b)(4) of title 5, United States Code, or section  
20 1905 of title 18, United States Code, shall not be  
21 disclosed to the public unless the requestor consents  
22 to that disclosure.

23 “(2) PUBLIC AVAILABILITY.—

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

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

6 “(ii) make any information submitted  
7 by any other person with respect to an  
8 order requested (or initiated by the Sec-  
9 retary) under subsection (b), available to  
10 the public upon such submission.

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

14 “(i) the information pertains to phar-  
15 maceutical quality information, unless such  
16 information is necessary to establish stand-  
17 ards under which a drug is generally rec-  
18 ognized as safe and effective under section  
19 201(p)(1);

20 “(ii) the information is submitted in a  
21 requestor-initiated request, but the re-  
22 questor withdraws such request, in accord-  
23 ance with withdrawal procedures estab-  
24 lished by the Secretary, before the Sec-  
25 retary issues the proposed order;

1                   “(iii) the Secretary requests and ob-  
2                   tains the information under subsection (c)  
3                   and such information is not submitted in  
4                   relation to an order under subsection (b);  
5                   or

6                   “(iv) the information is of the type  
7                   contained in raw datasets.

8           “(e) UPDATES TO DRUG LISTING INFORMATION.—  
9   A sponsor who makes a change to a drug subject to this  
10 section shall submit updated drug listing information for  
11 the drug in accordance with section 510(j) within 30 cal-  
12 endar days of the date when the drug is first commercially  
13 marketed, except that a sponsor who was the order re-  
14 questor with respect to an order subject to subsection  
15 (b)(5)(C) (or a licensee, assignee, or successor in interest  
16 of such requestor) shall submit updated drug listing infor-  
17 mation on or before the date when the drug is first com-  
18 mercially marketed.

19           “(f) APPROVALS UNDER SECTION 505.—The provi-  
20 sions of this section shall not be construed to preclude a  
21 person from seeking or maintaining the approval of an ap-  
22 plication for a drug under sections 505(b)(1), 505(b)(2),  
23 and 505(j). A determination under this section that a drug  
24 is not subject to section 503(b)(1), is generally recognized  
25 as safe and effective under section 201(p)(1), and is not

1 a new drug under section 201(p) shall constitute a finding  
 2 that the drug is safe and effective that may be relied upon  
 3 for purposes of an application under section 505(b)(2), so  
 4 that the applicant shall be required to submit for purposes  
 5 of such application only information needed to support any  
 6 modification of the drug that is not covered by such deter-  
 7 mination under this section.

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

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

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

18 “(A) a brief description of each such order;

19 and

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

23 “(h) DEVELOPMENT ADVICE TO SPONSORS OR RE-  
 24 QUESTORS.—The Secretary shall establish procedures  
 25 under which sponsors or requestors may meet with appro-

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

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

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

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

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

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

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

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

11 “(B) Regulations in effect on the day be-  
 12 fore the date of the enactment of this section,  
 13 establishing requirements for specific non-  
 14 prescription drugs marketed pursuant to this  
 15 section (including such requirements in parts  
 16 201 and 250 of title 21, Code of Federal Regu-  
 17 lations), shall be deemed to be final orders  
 18 under subsection (b), only as they apply to  
 19 drugs—

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

22 “(ii) otherwise subject to an order  
 23 under this section.

24 “(3) WITHDRAWAL OF REGULATIONS.—The  
 25 Secretary shall withdraw regulations establishing

1 final monographs and the procedures governing the  
2 over-the-counter drug review under part 330 and  
3 other relevant parts of title 21, Code of Federal  
4 Regulations (as in effect on the day before the date  
5 of the enactment of this section), or make technical  
6 changes to such regulations to ensure conformity  
7 with appropriate terminology and cross references.  
8 Notwithstanding subchapter II of chapter 5 of title  
9 5, United States Code, any such withdrawal or tech-  
10 nical changes shall be made without public notice  
11 and comment and shall be effective upon publication  
12 through notice in the Federal Register (or upon such  
13 date as specified in such notice).

14 “(1) GUIDANCE.—The Secretary shall issue guidance  
15 that specifies—

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

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

21 “(3) the format of electronic submissions to the  
22 Secretary under this section;

23 “(4) consolidated proceedings for appeal and  
24 the procedures for such proceedings where appro-  
25 priate; and



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

4 “(m) RULE OF CONSTRUCTION.—

5 “(1) IN GENERAL.—This section shall not af-  
 6 fect the treatment or status of a nonprescription  
 7 drug—

8 “(A) that is marketed without an applica-  
 9 tion approved under section 505 as of the date  
 10 of the enactment of this section;

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

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

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

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

23 “(B) A drug described in this subpara-  
 24 graph is a drug which, prior to the date of the  
 25 enactment of this section, the Secretary deter-

1           mined in a proposed or final rule to be ineligible  
2           for review under the OTC drug review (as such  
3           phrase ‘OTC drug review’ was used in section  
4           330.14 of title 21, Code of Federal Regulations,  
5           as in effect on the day before the date of the  
6           enactment of this section).

7           “(3) PRESERVATION OF AUTHORITY.—

8                 “(A) Nothing in paragraph (1) shall be  
9           construed to preclude or limit the applicability  
10          of any provision of this Act other than this sec-  
11          tion.

12                “(B) Nothing in subsection (a) shall be  
13          construed to prohibit the Secretary from issuing  
14          an order under this section finding a drug to be  
15          not generally recognized as safe and effective  
16          under section 201(p)(1), as the Secretary deter-  
17          mines appropriate.

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

21          “(o) INAPPLICABILITY OF PAPERWORK REDUCTION  
22          ACT.—Chapter 35 of title 44, United States Code, shall  
23          not apply to collections of information made under this  
24          section.

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

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

8               “(1) The term ‘nonprescription drug’ refers to  
 9 a drug not subject to the requirements of section  
 10 503(b)(1).

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

14                      “(A) is listed pursuant to section 510(j);  
 15 and

16                      “(B) is or will be subject to an administra-  
 17 tive order under this section of the Food and  
 18 Drug Administration.

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

22       (b) GAO STUDY.—Not later than 4 years after the  
 23 date of enactment of this Act, the Comptroller General  
 24 of the United States shall submit a study to the Com-  
 25 mittee on Energy and Commerce of the House of Rep-

1 representatives and the Committee on Health, Education,  
2 Labor, and Pensions of the Senate addressing the effec-  
3 tiveness and overall impact of exclusivity under section  
4 505G of the Federal Food, Drug, and Cosmetic Act, as  
5 added by subsection (a), and section 586C of such Act  
6 (21 U.S.C. 360fff-3), including the impact of such exclu-  
7 sivity on consumer access. Such study shall include—

8           (1) an analysis of the impact of exclusivity  
9       under such section 505G for nonprescription drug  
10      products, including—

11           (A) the number of nonprescription drug  
12       products that were granted exclusivity and the  
13       indication for which the nonprescription drug  
14       products were determined to be generally recog-  
15       nized as safe and effective;

16           (B) whether the exclusivity for such drug  
17       products was granted for—

18           (i) a new active ingredient (including  
19       any ester or salt of the active ingredient);  
20       or

21           (ii) changes in the conditions of use of  
22       a drug, for which new human data studies  
23       conducted or sponsored by the requestor  
24       were essential;

1 (C) whether, and to what extent, the exclu-  
2 sivity impacted the requestor's or sponsor's de-  
3 cision to develop the drug product;

4 (D) an analysis of the implementation of  
5 the exclusivity provision in such section 505G,  
6 including—

7 (i) the resources used by the Food  
8 and Drug Administration;

9 (ii) the impact of such provision on  
10 innovation, as well as research and devel-  
11 opment in the nonprescription drug mar-  
12 ket;

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

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

19 (v) the impact of such provision on  
20 the prices of nonprescription drug prod-  
21 ucts; and

22 (vi) whether the administrative orders  
23 initiated by requestors under such section  
24 505G have been sufficient to encourage the  
25 development of nonprescription drug prod-

1           ucts that would likely not be otherwise de-  
2           veloped, or developed in as timely a man-  
3           ner; and

4           (E) whether the administrative orders ini-  
5           tiated by requestors under such section 505G  
6           have been sufficient incentive to encourage in-  
7           novation in the nonprescription drug market;  
8           and

9           (2) an analysis of the impact of exclusivity  
10          under such section 586C for sunscreen ingredients,  
11          including—

12           (A) the number of sunscreen ingredients  
13           that were granted exclusivity and the specific  
14           ingredient that was determined to be generally  
15           recognized as safe and effective;

16           (B) whether, and to what extent, the exclu-  
17           sivity impacted the requestor's or sponsor's de-  
18           cision to develop the sunscreen ingredient;

19           (C) whether, and to what extent, the sun-  
20           screen ingredient granted exclusivity had pre-  
21           viously been available outside of the United  
22           States;

23           (D) an analysis of the implementation of  
24           the exclusivity provision in such section 586C,  
25           including—

- 1 (i) the resources used by the Food  
2 and Drug Administration;
- 3 (ii) the impact of such provision on  
4 innovation, as well as research and devel-  
5 opment in the sunscreen market;
- 6 (iii) the impact of such provision on  
7 competition in the sunscreen market;
- 8 (iv) the impact of such provision on  
9 consumer access to sunscreen products;
- 10 (v) the impact of such provision on  
11 the prices of sunscreen products; and
- 12 (vi) whether the administrative orders  
13 initiated by requestors under such section  
14 505G have been utilized by sunscreen in-  
15 gredient sponsors and whether such proc-  
16 ess has been sufficient to encourage the  
17 development of sunscreen ingredients that  
18 would likely not be otherwise developed, or  
19 developed in as timely a manner; and
- 20 (E) whether the administrative orders ini-  
21 tiated by requestors under such section 586C  
22 have been sufficient incentive to encourage in-  
23 novation in the sunscreen market.

1 (c) CONFORMING AMENDMENT.—Section 751(d)(1)  
 2 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
 3 379r(d)(1)) is amended—

4 (1) in the matter preceding subparagraph (A)—

5 (A) by striking “final regulation promul-  
 6 gated” and inserting “final order under section  
 7 505G”; and

8 (B) by striking “and not misbranded”; and

9 (2) in subparagraph (A), by striking “regula-  
 10 tion in effect” and inserting “regulation or order in  
 11 effect”.

12 **SEC. 102. MISBRANDING.**

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

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

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



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

3 (a) IN GENERAL.—Nothing in this Act (or the  
 4 amendments made by this Act) shall apply to any non-  
 5 prescription drug (as defined in section 505G(q) of the  
 6 Federal Food, Drug, and Cosmetic Act, as added by sec-  
 7 tion 101 of this Act) which was excluded by the Food and  
 8 Drug Administration from the Over-the-Counter Drug Re-  
 9 view in accordance with the paragraph numbered 25 on  
 10 page 9466 of volume 37 of the Federal Register, published  
 11 on 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  
 26 order under section 586C of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 360fff–3)  
2 may elect, by means of giving written notifica-  
3 tion to the Secretary of Health and Human  
4 Services within 180 calendar days of the enact-  
5 ment of this Act, to transition into the review  
6 of such ingredient or combination of ingredients  
7 pursuant to the process set out in section 505G  
8 of the Federal Food, Drug, and Cosmetic Act,  
9 as added by section 101 of this Act.

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

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

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

23 (C) ELECTION NOT EXERCISED.—If a noti-  
24 fication under subparagraph (A) is not received  
25 by the Secretary of Health and Human Services

1 within 180 calendar days of the date of enact-  
 2 ment of this Act, the review of the proposed  
 3 sunscreen order described in subparagraph  
 4 (A)—

5 (i) shall continue under section 586C  
 6 of the Federal Food, Drug, and Cosmetic  
 7 Act (21 U.S.C. 360fff-3); and

8 (ii) shall not be eligible for review  
 9 under section 505G, added by section 101  
 10 of this Act.

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

17 (b) AMENDMENTS TO SUNSCREEN PROVISIONS.—

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

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

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

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

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

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

9           “(B) CONFIDENTIAL MEETINGS.—A spon-  
10       sor may request one or more confidential meet-  
11       ings with respect to a proposed sunscreen order,  
12       including a letter deemed to be a proposed sun-  
13       screen order under paragraph (3), to discuss  
14       matters relating to data requirements to sup-  
15       port a general recognition of safety and effec-  
16       tiveness involving confidential information and  
17       public information related to such proposed  
18       sunscreen order, as appropriate. The Secretary  
19       shall convene a confidential meeting with such  
20       sponsor in a reasonable time period. If a spon-  
21       sor requests more than one confidential meeting  
22       for the same proposed sunscreen order, the Sec-  
23       retary may refuse to grant an additional con-  
24       fidential meeting request if the Secretary deter-  
25       mines that such additional confidential meeting

1 is not reasonably necessary for the sponsor to  
 2 advance its proposed sunscreen order, or if the  
 3 request for a confidential meeting fails to in-  
 4 clude sufficient information upon which to base  
 5 a substantive discussion. The Secretary shall  
 6 publish a post-meeting summary of each con-  
 7 fidential meeting under this subparagraph that  
 8 does not disclose confidential commercial infor-  
 9 mation or trade secrets. This subparagraph  
 10 does not authorize the disclosure of confidential  
 11 commercial information or trade secrets subject  
 12 to 552(b)(4) of title 5, United States Code, or  
 13 section 1905 of title 18, United States Code.”.

14 (3) EXCLUSIVITY.—Section 586C of the Fed-  
 15 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
 16 360fff–3) is amended by adding at the end the fol-  
 17 lowing:

18 “(f) EXCLUSIVITY.—

19 “(1) IN GENERAL.—A final sunscreen order  
 20 shall have the effect of authorizing solely the order  
 21 requestor (or the licensees, assignees, or successors  
 22 in interest of such requestor with respect to the sub-  
 23 ject of such request and listed under paragraph (5))  
 24 for a period of 18 months, to market a sunscreen in-  
 25 gredient under this section incorporating changes

1 described in paragraph (2) subject to the limitations  
2 under paragraph (4), beginning on the date the re-  
3 questor (or any licensees, assignees, or successors in  
4 interest of such requestor with respect to the subject  
5 of such request and listed under paragraph (5)) may  
6 lawfully market such sunscreen ingredient pursuant  
7 to the order.

8 “(2) CHANGES DESCRIBED.—A change de-  
9 scribed in this paragraph is a change subject to an  
10 order specified in paragraph (1) that permits a sun-  
11 screen to contain an active sunscreen ingredient not  
12 previously incorporated in a marketed sunscreen list-  
13 ed in paragraph (3).

14 “(3) MARKETED SUNSCREEN.—The marketed  
15 sunscreen ingredients described in this paragraph  
16 are sunscreen ingredients—

17 “(A) marketed in accordance with a final  
18 monograph for sunscreen drug products set  
19 forth at part 352 of title 21, Code of Federal  
20 Regulations (as published at 64 Fed. Reg.  
21 27687); or

22 “(B) marketed in accordance with a final  
23 order issued under this section.

1           “(4) LIMITATIONS ON EXCLUSIVITY.—Only one  
2       18-month period may be granted per ingredient  
3       under paragraph (1).

4           “(5) LISTING OF LICENSEES, ASSIGNEES, OR  
5       SUCCESSORS IN INTEREST.—Requestors shall submit  
6       to the Secretary at the time when a drug subject to  
7       such request is introduced or delivered for introduc-  
8       tion into interstate commerce, a list of licensees, as-  
9       signees, or successors in interest under paragraph  
10      (1).”.

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

15      **“SEC. 586H. SUNSET.**

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

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

22          (c) TREATMENT OF AUTHORITY REGARDING FINAL-  
23      IZATION OF SUNSCREEN MONOGRAPH.—

24          (1) IN GENERAL.—

1           (A) REVISION OF FINAL SUNSCREEN  
2 ORDER.—The Secretary of Health and Human  
3 Services (referred to in this subsection as the  
4 “Secretary”) shall amend and revise the final  
5 administrative order concerning nonprescription  
6 sunscreen (referred to in this subsection as the  
7 “sunscreen order”) for which the content, prior  
8 to the date of enactment of this Act, was rep-  
9 resented by the final monograph for sunscreen  
10 drug products set forth in part 352 of title 21,  
11 Code of Federal Regulations (as in effect on  
12 May 21, 1999).

13           (B) ISSUANCE OF REVISED SUNSCREEN  
14 ORDER; EFFECTIVE DATE.—A revised sunscreen  
15 order described in subparagraph (A) shall be—

16           (i) issued in accordance with the pro-  
17 cedures described in section 505G(b)(2) of  
18 the Federal Food, Drug, and Cosmetic  
19 Act;

20           (ii) issued in proposed form not later  
21 than 18 months after the date of enact-  
22 ment of this Act; and

23           (iii) issued by the Secretary at least 1  
24 year prior to the effective date of the re-  
25 vised order.



1           (2) REPORTS.—If a revised sunscreen order  
 2           issued under paragraph (1) does not include provi-  
 3           sions related to the effectiveness of various sun pro-  
 4           tection factor levels, and does not address all dosage  
 5           forms known to the Secretary to be used in sun-  
 6           screens marketed in the United States without a  
 7           new drug application approved under section 505 of  
 8           the Federal Food, Drug, and Cosmetic Act (21  
 9           U.S.C. 355), the Secretary shall submit a report to  
 10          the Committee on Energy and Commerce of the  
 11          House of Representatives and the Committee on  
 12          Health, Education, Labor, and Pensions of the Sen-  
 13          ate on the rationale for omission of such provisions  
 14          from such order, and a plan and timeline to compile  
 15          any information necessary to address such provisions  
 16          through such order.

17          (d) TREATMENT OF NON-SUNSCREEN TIME AND EX-  
 18          TENT APPLICATIONS.—

19               (1) IN GENERAL.—Any application described in  
 20               section 586F of the Federal Food, Drug, and Cos-  
 21               metic Act (21 U.S.C. 360fff–6) that was submitted  
 22               to the Secretary pursuant to section 330.14 of title  
 23               21, Code of Federal Regulations, as such provisions  
 24               were in effect immediately prior to the date of enact-

1       ment date of this Act, shall be extinguished as of  
2       such date of enactment, subject to paragraph (2).

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

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

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

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

23               (2) as appropriate, revising such cough and cold  
24       monograph to address such children through the  
25       order process under section 505G(b) of the Federal

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

3 (b) COUGH AND COLD MONOGRAPH DESCRIBED.—

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

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

23 **SEC. 106. TECHNICAL CORRECTIONS.**

24 (a) IMPORTS AND EXPORTS.—Section  
25 801(e)(4)(E)(iii) of the Federal Food, Drug, and Cosmetic

1 Act (21 U.S.C. 381(e)(4)(E)(iii)) is amended by striking  
 2 “subparagraph” each place such term appears and insert-  
 3 ing “paragraph”.

4 (b) FDA REAUTHORIZATION ACT OF 2017.—

5 (1) IN GENERAL.—Section 905(b)(4) of the  
 6 FDA Reauthorization Act of 2017 (Public Law 115–  
 7 52) is amended by striking “Section 744H(e)(2)(B)”  
 8 and inserting “Section 744H(f)(2)(B)”.

9 (2) EFFECTIVE DATE.—The amendment made  
 10 by paragraph (1) shall take effect as of the enact-  
 11 ment of the FDA Reauthorization Act of 2017  
 12 (Public Law 115–52).

## 13 **TITLE II—USER FEES**

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

15 (a) SHORT TITLE.—This title may be cited as the  
 16 “Over-the-Counter Monograph User Fee Act of 2019”.

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

1 of the House of Representatives, as set forth in the Con-  
 2 gressional Record.

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

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

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

9 **“SEC. 744L. DEFINITIONS.**

10 “In this part:

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

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

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

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

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

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

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

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

19                  “(D) collecting fees under section 744M  
20                  and accounting for resources allocated for OTC  
21                  monograph drug activities.

22           “(4) The term ‘FDA establishment identifier’ is  
23           the unique number automatically generated by Food  
24           and Drug Administration’s Field Accomplishments

1 and Compliance Tracking System (FACTS) (or any  
2 successor system).

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

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

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

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

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

23 “(iii) all OTC monograph drug devel-  
24 opment and review activities, including  
25 intra-agency 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 including 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 order submitted under sec-  
11 tion 505G(b)(5).

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 information  
20 in the drug facts label of an OTC monograph  
21 drug;

22 “(ii) the addition of information to the  
23 other information section of the drug facts label  
24 of an OTC monograph drug, as limited by sec-

1           tion 201.66(c)(7) of title 21, Code of Federal  
2           Regulations (or any successor regulations);

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

7           “(iv) the standardization of the concentra-  
8           tion or dose of a specific finalized ingredient  
9           within a particular finalized monograph;

10          “(v) a change to ingredient nomenclature  
11          to align with nomenclature of a standards-set-  
12          ting organization; or

13          “(vi) addition of an interchangeable term  
14          in accordance with section 330.1 of title 21,  
15          Code of Federal Regulations (or any successor  
16          regulations).

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

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

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

11                       “(ii) includes a finished dosage form man-  
12                       ufacturer facility in a contractual relationship  
13                       with the sponsor of one or more OTC mono-  
14                       graph drugs to manufacture or process such  
15                       drugs; and

16                       “(iii) does not include a business or other  
17                       entity whose only manufacturing or processing  
18                       activities are one or more of the following: pro-  
19                       duction of clinical research supplies, testing, or  
20                       placement of outer packaging on packages con-  
21                       taining multiple products, for such purposes as  
22                       creating multipacks, when each monograph  
23                       drug product contained within the overpack-  
24                       aging is already in a final packaged form prior  
25                       to placement in the outer overpackaging.

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

6           “(i) closely related to the same business  
7       enterprise;

8           “(ii) under the supervision of the same  
9       local management; and

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

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

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

23          “(12) The term ‘person’ includes an affiliate of  
24       a person.

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

3   **“SEC. 744M. AUTHORITY TO ASSESS AND USE OTC MONO-**  
4                           **GRAPH FEES.**

5           “(a) TYPES OF FEES.—Beginning with fiscal year  
6   2021, the Secretary shall assess and collect fees in accord-  
7   ance with this section as follows:

8           “(1) FACILITY FEE.—

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

16                  “(B) EXCEPTIONS.—

17                          “(i) FACILITIES THAT CEASE ACTIVI-  
18                          TIES.—A fee shall not be assessed under  
19                          subparagraph (A) if the identified OTC  
20                          monograph drug facility—

21                                  “(I) has ceased all activities re-  
22                                  lated to OTC monograph drugs prior  
23                                  to December 31 of the year imme-  
24                                  diately preceding the applicable fiscal  
25                                  year; and

1 “(II) has updated its registration  
 2 to reflect such change under the re-  
 3 quirements for drug establishment  
 4 registration set forth in section 510.

5 “(ii) CONTRACT MANUFACTURING OR-  
 6 GANIZATIONS.—The amount of the fee for  
 7 a contract manufacturing organization fa-  
 8 cility shall be equal to two-thirds of the  
 9 amount of the fee for an OTC monograph  
 10 drug facility that is not a contract manu-  
 11 facturing organization facility.

12 “(C) AMOUNT.—The amount of fees estab-  
 13 lished under subparagraph (A) shall be estab-  
 14 lished under subsection (c).

15 “(D) DUE DATE.—

16 “(i) FOR FIRST PROGRAM YEAR.—For  
 17 fiscal year 2021, the facility fees required  
 18 under subparagraph (A) shall be due on  
 19 the later of—

20 “(I) the first business day of  
 21 June of 2020; or

22 “(II) 45 calendar days after pub-  
 23 lication of the Federal Register notice  
 24 provided for under subsection  
 25 (c)(4)(A).

1 “(ii) SUBSEQUENT FISCAL YEARS.—

2 For each fiscal year after fiscal year 2021,  
3 the facility fees required under subpara-  
4 graph (A) shall be due on the later of—

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

8 “(3) REFUNDS.—

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

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

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

24 “(b) FEE REVENUE AMOUNTS.—

1           “(1) FISCAL YEAR 2021.—For fiscal year 2021,  
2       fees under subsection (a)(1) shall be established to  
3       generate a total facility fee revenue amount equal to  
4       the sum of—

5           “(A) the annual base revenue for fiscal  
6       year 2021 (as determined under paragraph  
7       (3));

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

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

14          “(2) SUBSEQUENT FISCAL YEARS.—For each of  
15      the fiscal years 2022 through 2025, fees under sub-  
16      section (a)(1) shall be established to generate a total  
17      facility fee revenue amount equal to the sum of—

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

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

23          “(C) the dollar amount equal to the oper-  
24      ating reserve adjustment for the fiscal year, if

1 applicable (as determined under subsection  
2 (c)(2));

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

5 “(E) additional dollar amounts for each  
6 fiscal year as follows:

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

8 “(ii) \$6,000,000 for fiscal year 2023.

9 “(iii) \$7,000,000 for fiscal year 2024.

10 “(iv) \$3,000,000 for fiscal year 2025.

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

15 “(A) for fiscal year 2021, \$8,000,000; and

16 “(B) for fiscal years 2022 through 2025,  
17 the dollar amount of the total revenue amount  
18 established under this subsection for the pre-  
19 vious fiscal year, not including any adjustments  
20 made under subsection (c)(2) or (c)(3).

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

22 “(1) INFLATION ADJUSTMENT.—

23 “(A) IN GENERAL.—For purposes of sub-  
24 section (b)(2)(B), the dollar amount of the in-  
25 flation adjustment to the annual base revenue

for fiscal year 2022 and each subsequent fiscal year shall be equal to the product of—

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

“(ii) the inflation adjustment percentage under subparagraph (C).

“(B) OTC MONOGRAPH ORDER REQUEST FEES.—For purposes of subsection (a)(2), the dollar amount of the inflation adjustment to the fee for OTC monograph order requests for fiscal year 2022 and each subsequent fiscal year shall be equal to the product of—

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

“(ii) the inflation adjustment percentage under subparagraph (C).

“(C) INFLATION ADJUSTMENT PERCENTAGE.—The inflation adjustment percentage under this subparagraph for a fiscal year is equal to—

“(i) for each of fiscal years 2022 and 2023, the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Balti-

1 more, DC–MD–VA–WV; Not Seasonally  
2 Adjusted; All items; Annual Index) for the  
3 first 3 years of the preceding 4 years of  
4 available data; and

5 “(ii) for each of fiscal years 2024 and  
6 2025, the sum of—

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

20 “(II) the average annual percent  
21 change that occurred in the Consumer  
22 Price Index for urban consumers  
23 (Washington-Baltimore, DC–MD–VA–  
24 WV; Not Seasonally Adjusted; All  
25 items; Annual Index) for the first 3

years of the preceding 4 years of  
 available data multiplied by the pro-  
 portion of all costs other than per-  
 sonnel compensation and benefits  
 costs to total costs of OTC mono-  
 graph drug activities for the first 3  
 years of the preceding 4 fiscal years.

“(2) OPERATING RESERVE ADJUSTMENT.—

“(A) IN GENERAL.—For fiscal year 2021  
 and subsequent fiscal years, for purposes of  
 subsections (b)(1)(B) and (b)(2)(C), the Sec-  
 retary may, in addition to adjustments under  
 paragraph (1), further increase the fee revenue  
 and fees if such an adjustment is necessary to  
 provide operating reserves of carryover user  
 fees for OTC monograph drug activities for not  
 more than the number of weeks specified in  
 subparagraph (B).

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

“(i) 3 weeks for fiscal year 2021;

“(ii) 7 weeks for fiscal year 2022;

“(iii) 10 weeks for fiscal year 2023;

“(iv) 10 weeks for fiscal year 2024;

and

1 “(v) 10 weeks for fiscal year 2025.

2 “(C) DECREASE.—If the Secretary has  
3 carryover balances for such process in excess of  
4 10 weeks of the operating reserves referred to  
5 in subparagraph (A), the Secretary shall de-  
6 crease the fee revenue and fees referred to in  
7 such subparagraph to provide for not more than  
8 10 weeks of such operating reserves.

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

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

21 “(A) \$14,000,000 for fiscal year 2021;

22 “(B) \$7,000,000 for fiscal year 2022;

23 “(C) \$4,000,000 for fiscal year 2023;

24 “(D) \$3,000,000 for fiscal year 2024; and

25 “(E) \$3,000,000 for fiscal year 2025.



1 “(4) ANNUAL FEE SETTING.—

2 “(A) FISCAL YEAR 2021.—The Secretary  
3 shall, not later than the second Monday in  
4 March of 2020—

5 “(i) establish OTC monograph drug  
6 facility fees for fiscal year 2021 under sub-  
7 section (a), based on the revenue amount  
8 for such year under subsection (b) and the  
9 adjustments provided under this sub-  
10 section; and

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

14 “(B) SUBSEQUENT FISCAL YEARS.—The  
15 Secretary shall, for each fiscal year that begins  
16 after September 30, 2021, not later than the  
17 second Monday in March that precedes such fis-  
18 cal year—

19 “(i) establish for such fiscal year,  
20 based on the revenue amounts under sub-  
21 section (b) and the adjustments provided  
22 under this subsection—

23 “(I) OTC monograph drug facil-  
24 ity fees under subsection (a)(1); and

1 “(II) OTC monograph order re-  
 2 quest fees under subsection (a)(2);  
 3 and

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

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

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

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

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

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

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

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

3 “(ii) All OTC monograph drugs man-  
 4 ufactured in such a facility or containing  
 5 an ingredient manufactured in such a facil-  
 6 ity shall be deemed misbranded under sec-  
 7 tion 502(ff).

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.—Fees authorized under sub-  
 23 section (a) shall be collected and available for obliga-  
 24 tion only to the extent and in the amount provided  
 25 in advance in appropriations Acts. Such fees are au-

1       thorized to remain available until expended. Such  
 2       sums as may be necessary may be transferred from  
 3       the Food and Drug Administration salaries and ex-  
 4       penses appropriation account without fiscal year lim-  
 5       itation to such appropriation account for salaries  
 6       and expenses with such fiscal year limitation. The  
 7       sums transferred shall be available solely for OTC  
 8       monograph drug activities.

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

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

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

ties), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than \$12,000,000, multiplied by the adjustment factor applicable to the fiscal year involved under subsection (c)(1).

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

“(D) PROVISION FOR EARLY PAYMENTS IN SUBSEQUENT YEARS.—Payment of fees authorized under this section for a fiscal year (after fiscal year 2021), prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

“(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2021 through 2025, there is authorized to be appropriated for fees under this section an amount equal to the total amount of fees assessed for such fiscal year under this section.

14 "SEC. 744N. REAUTHORIZATION; REPORTING REQUIRE-  
15 MENTS.

**•S 2740 IS**

1 graph Safety, Innovation, and Reform Act of 2019 during  
2 such fiscal year and the future plans of the Food and  
3 Drug Administration for meeting such goals.

4 “(b) FISCAL REPORT.—Not later than 120 calendar  
5 days after the end of fiscal year 2021 and each subsequent  
6 fiscal year for which fees are collected under this part,  
7 the Secretary shall prepare and submit to the Committee  
8 on Energy and Commerce of the House of Representatives  
9 and the Committee on Health, Education, Labor, and  
10 Pensions of the Senate a report on the implementation  
11 of the authority for such fees during such fiscal year and  
12 the use, by the Food and Drug Administration, of the fees  
13 collected for such fiscal year.

14 “(c) PUBLIC AVAILABILITY.—The Secretary shall  
15 make the reports required under subsections (a) and (b)  
16 available to the public on the internet website of the Food  
17 and Drug Administration.

18 “(d) REAUTHORIZATION.—

19 “(1) CONSULTATION.—In developing rec-  
20 ommendations to present to the Congress with re-  
21 spect to the goals described in subsection (a), and  
22 plans for meeting the goals, for OTC monograph  
23 drug activities for the first 5 fiscal years after fiscal  
24 year 2025, and for the reauthorization of this part

1 for such fiscal years, the Secretary shall consult  
2 with—

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

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

7 “(C) scientific and academic experts;

8 “(D) health care professionals;

9 “(E) representatives of patient and con-  
10 sumer advocacy groups; and

11 “(F) the regulated industry.

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

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

18 “(B) publish such recommendations in the  
19 Federal Register;

20 “(C) provide for a period of 30 calendar  
21 days for the public to provide written comments  
22 on such recommendations;

23 “(D) hold a meeting at which the public  
24 may present its views on such recommenda-  
25 tions; and



1           “(E) after consideration of such public  
2           views and comments, revise such recommenda-  
3           tions as necessary.

4           “(3) TRANSMITTAL OF RECOMMENDATIONS.—  
5           Not later than January 15, 2025, the Secretary  
6           shall transmit to the Congress the revised rec-  
7           ommendations under paragraph (2), a summary of  
8           the views and comments received under such para-  
9           graph, and any changes made to the recommenda-  
10          tions in response to such views and comments.”.

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