

*Bob Casey, Jr.*

AMENDMENT NO. 1 Calendar No. \_\_\_\_\_

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

IN THE SENATE OF THE UNITED STATES—116th Cong., 1st Sess.

**S. 1895**

To lower health care costs.

Referred to the Committee on Health, Education, Labor, & Pensions and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Senator Casey

Viz:

- 1 At the end, add the following:
- 2 **TITLE VI—OTC DRUG REVIEW**
- 3 **SEC. 600. SHORT TITLE.**
- 4 This title may be cited as the “Over-the-Counter
- 5 Monograph Safety, Innovation, and Reform Act of 2019”.



1 monograph issued under part 330 of title  
2 21, Code of Federal Regulations (except as  
3 provided in paragraph (2)), the general re-  
4 quirements for nonprescription drugs, and  
5 conditions or requirements under sub-  
6 sections (b), (c), and (k); and

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

16 “(B) the drug is—

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

23 “(ii) in conformity with the proposed  
24 requirements for nonprescription use of  
25 such tentative final monograph, any appli-

1 cable subsequent determination by the Sec-  
2 retary, the general requirements for non-  
3 prescription drugs, and conditions or re-  
4 quirements under subsections (b), (c), and  
5 (k); and

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

15 “(2) TREATMENT OF SUNSCREEN DRUGS.—  
16 With respect to sunscreen drugs subject to this sec-  
17 tion, the applicable requirements in terms of con-  
18 formity with a final monograph, for purposes of  
19 paragraph (1)(A)(i), shall be the requirements speci-  
20 fied in part 352 of title 21, Code of Federal Regula-  
21 tions, as published on May 21, 1999, beginning on  
22 page 27687 of volume 64 of the Federal Register,  
23 except that the applicable requirements governing ef-  
24 fectiveness and labeling shall be those specified in

1 section 201.327 of title 21, Code of Federal Regula-  
2 tions.

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

11 “(A) the drug is—

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

19 “(ii) in conformity with—

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

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

9                   “(III) the general requirements  
10                  for nonprescription drugs and condi-  
11                  tions or requirements under sub-  
12                  section (b) or (k); and

13                  “(iii) in a dosage form that, imme-  
14                  diately prior to the date of the enactment  
15                  of this section, had been used to a material  
16                  extent and for a material time under sec-  
17                  tion 201(p)(2); or

18                  “(B) the drug is—

19                  “(i) classified in category I for safety  
20                  and effectiveness under a proposed mono-  
21                  graph or advance notice of proposed rule-  
22                  making that is the most recently applicable  
23                  proposal or determination for such drug  
24                  issued under part 330 of title 21, Code of  
25                  Federal Regulations;

1           “(ii) in conformity with the require-  
2           ments for nonprescription use of such pro-  
3           posed monograph or advance notice of pro-  
4           posed rulemaking, any applicable subse-  
5           quent determination by the Secretary, the  
6           general requirements for nonprescription  
7           drugs, and conditions or requirements  
8           under subsection (b) or (k); and

9           “(iii) in a dosage form that, imme-  
10          diately prior to the date of the enactment  
11          of this section, has been used to a material  
12          extent and for a material time under sec-  
13          tion 201(p)(2).

14          “(4) CATEGORY II DRUGS DEEMED NEW  
15          DRUGS.—A drug that is classified in category II for  
16          safety or effectiveness under a tentative final mono-  
17          graph or that is subject to a determination to be not  
18          generally recognized as safe and effective in a pro-  
19          posed rule that is the most recently applicable pro-  
20          posal issued under part 330 of title 21, Code of Fed-  
21          eral Regulations, shall be deemed to be a new drug  
22          under section 201(p), misbranded under section  
23          502(ee), and subject to the requirement for an ap-  
24          proved new drug application under section 505 be-  
25          ginning on the day that is 180 calendar days after

1 the date of the enactment of this section, unless, be-  
2 fore such day, the Secretary determines that it is in  
3 the interest of public health to extend the period  
4 during which the drug may be marketed without  
5 such an approved new drug application.

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

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

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

20 and

21 “(B) is not described in paragraph (1),  
22 (2), (3), (4), or (5), or subsection (b)(1)(B).

23 “(b) ADMINISTRATIVE ORDERS.—

24 “(1) IN GENERAL.—



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

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

9                     and

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

12           “(B) EFFECT.—A drug or combination of  
13           drugs shall be deemed to not require approval  
14           under section 505 if such drug or combination  
15           of drugs—

16                    “(i) is determined by the Secretary to  
17                    meet the conditions specified in clauses (i)  
18                    and (ii) of subparagraph (A);

19                    “(ii) is marketed in conformity with  
20                    an administrative order under this sub-  
21                    section;

22                    “(iii) meets the general requirements  
23                    for nonprescription drugs; and

24                    “(iv) meets the requirements under  
25                    subsections (c) and (k).

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

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

7           “(ii) the evidence is inadequate to  
8 show that the drug is generally recognized  
9 as safe and effective under section  
10 201(p)(1).

11           “(2) ADMINISTRATIVE ORDERS INITIATED BY  
12 THE SECRETARY.—

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

16           “(i) make reasonable efforts to notify  
17 informally, not later than 2 business days  
18 before the issuance of the proposed order,  
19 the sponsors of drugs who have a listing in  
20 effect under section 510(j) for the drugs or  
21 combination of drugs that will be subject  
22 to the administrative order;

23           “(ii) after any such reasonable efforts  
24 of notification—

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

7                   “(II) publish a notice of avail-  
8                   ability of such proposed order in the  
9                   Federal Register;

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

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

19                  “(I) issue the final administrative  
20                  order, together with a detailed state-  
21                  ment of reasons, which order shall not  
22                  take effect until the time for request-  
23                  ing judicial review under paragraph  
24                  (3)(D)(ii) has expired;

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

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

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

22                  “(B) EXCEPTIONS.—When issuing an ad-  
23                  ministrative order under paragraph (1) on the  
24                  Secretary’s initiative proposing to determine  
25                  that a drug described in subsection (a)(3) is not

1 generally recognized as safe and effective under  
2 section 201(p)(1), the Secretary shall follow the  
3 procedures in subparagraph (A), except that—

4 “(i) the proposed order shall include  
5 notice of—

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

11 “(II) the format for submissions  
12 by interested persons;

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

19 “(iii) any person who submits data in  
20 such comment period shall include a cer-  
21 tification that the person has submitted all  
22 evidence created, obtained, or received by  
23 that person that is both within the cat-  
24 egories of data identified in the proposed  
25 order and relevant to a determination as to

1           whether the drug is generally recognized as  
2           safe and effective under section 201(p)(1).

3           “(3) HEARINGS; JUDICIAL REVIEW.—

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

18          “(B) NO HEARING REQUIRED WITH RE-  
19          SPECT TO ORDERS RELATING TO CERTAIN  
20          DRUGS.—

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

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

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

11 “(ii) HUMAN DATA STUDIES AND  
12 NON-HUMAN DATA DEFINED.—In this sub-  
13 paragraph:

14 “(I) The term ‘human data stud-  
15 ies’ means clinical trials of safety or  
16 effectiveness (including actual use  
17 studies), pharmacokinetics studies, or  
18 bioavailability studies.

19 “(II) The term ‘non-human data’  
20 means data from testing other than  
21 with human subjects which provides  
22 information concerning safety or ef-  
23 fectiveness.

24 “(C) HEARING PROCEDURES.—

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

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

22                  “(iii) PRESIDING OFFICER.—The pre-  
23                  siding officer of a hearing requested under  
24                  subparagraph (A) shall—



1                   “(I) be designated by the Sec-  
2                   retary;

3                   “(II) not be an employee of the  
4                   Center for Drug Evaluation and Re-  
5                   search; and

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

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

22                  “(v) FINAL DECISION.—

23                  “(I) At the conclusion of a hear-  
24                  ing requested under subparagraph  
25                  (A), the presiding officer of the hear-

1           ing shall issue a decision containing  
2           findings of fact and conclusions of  
3           law. The decision of the presiding offi-  
4           cer shall be final.

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

10                   “(D) JUDICIAL REVIEW OF FINAL ADMIN-  
11           ISTRATIVE ORDER.—

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

23                   “(ii) PERIOD TO SUBMIT A REQUEST  
24           FOR JUDICIAL REVIEW.—A person eligible  
25           to request a hearing under this paragraph

1 and seeking judicial review of a final ad-  
2 ministrative order issued under this sub-  
3 section shall file such request for judicial  
4 review not later than 60 calendar days  
5 after the latest of—

6 “(I) the date on which notice of  
7 such order is published;

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

11 “(III) the date on which a final  
12 decision is made following a hearing  
13 under subparagraph (C)(v); or

14 “(IV) if no hearing is requested,  
15 the date on which the time for re-  
16 questing a hearing expires.

17 “(4) EXPEDITED PROCEDURE WITH RESPECT  
18 TO ADMINISTRATIVE ORDERS INITIATED BY THE  
19 SECRETARY.—

20 “(A) IMMINENT HAZARD TO THE PUBLIC  
21 HEALTH.—

22 “(i) IN GENERAL.—In the case of a  
23 determination by the Secretary that a  
24 drug, class of drugs, or combination of  
25 drugs subject to this section poses an im-

1           minent hazard to the public health, the  
2           Secretary, after first making reasonable ef-  
3           forts to notify, not later than 48 hours be-  
4           fore issuance of such order under this sub-  
5           paragraph, sponsors who have a listing in  
6           effect under section 510(j) for such drug  
7           or combination of drugs—

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

14                  “(II) shall publish in the Federal  
15                  Register a notice of availability of any  
16                  such order; and

17                  “(III) shall provide for a public  
18                  comment period of at least 45 cal-  
19                  endar days with respect to such in-  
20                  terim final order.

21                  “(ii) NONDELEGATION.—The Sec-  
22                  retary may not delegate the authority to  
23                  issue an interim final administrative order  
24                  under this subparagraph.

25                  “(B) SAFETY LABELING CHANGES.—

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

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

16                  “(II) after reasonable efforts of  
17                  notification, issue an interim final ad-  
18                  ministrative order in accordance with  
19                  paragraph (1) to require such change,  
20                  together with a detailed statement of  
21                  the reasons for such order;

22                  “(III) publish in the Federal  
23                  Register a notice of availability of  
24                  such order; and

1                   “(IV) provide for a public com-  
2                   ment period of at least 45 calendar  
3                   days with respect to such interim final  
4                   order.

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

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

14                  “(D) FINAL ORDER.—After the completion  
15                  of the proceedings in subparagraph (A) or (B),  
16                  the Secretary shall—

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

19                         “(ii) publish a notice of availability of  
20                         such final administrative order in the Fed-  
21                         eral Register; and

22                         “(iii) afford sponsors of such drugs  
23                         that will be subject to such an order the  
24                         opportunity for formal dispute resolution  
25                         up to the level of the Director of the Cen-



1 or (B), issue a final order in accord-  
2 ance with paragraph (1); and

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

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

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

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

21 “(A) IN GENERAL.—In issuing an adminis-  
22 trative order under paragraph (1) at the re-  
23 quest of a requestor with respect to certain  
24 drugs, classes of drugs, or combinations of  
25 drugs—



1                   “(i) the Secretary shall, after receiv-  
2                   ing a request under this subparagraph, de-  
3                   termine whether the request is sufficiently  
4                   complete and formatted to permit a sub-  
5                   stantive review;

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

10                   “(I) file the request; and

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

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

24                   “(B) REQUEST TO INITIATE PRO-  
25                   CEEDINGS.—

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

11                   “(I) determining whether a drug  
12                   is generally recognized as safe and ef-  
13                   fective under section 201(p)(1), ex-  
14                   empt from section 503(b)(1), and not  
15                   required to be the subject of an ap-  
16                   proved application under section 505;  
17                   or

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

1 if, absent such a changed condition of  
2 use, such drug is—

3 “(aa) generally recognized  
4 as safe and effective under sec-  
5 tion 201(p)(1) in accordance with  
6 subsection (a)(1), (a)(2), or an  
7 order under this subsection; or

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

18 “(ii) EXCEPTION.—The Secretary is  
19 not required to complete review of a re-  
20 quest for a change described in clause  
21 (i)(II) if the Secretary determines that  
22 there is an inadequate basis to find the  
23 drug is generally recognized as safe and ef-  
24 fective under section 201(p)(1) under para-

1 graph (1) and issues a final order an-  
2 nouncing that determination.

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

11 “(C) EXCLUSIVITY.—

12 “(i) IN GENERAL.—A final adminis-  
13 trative order issued in response to a re-  
14 quest under this section shall have the ef-  
15 fect of authorizing solely the order re-  
16 questor (or the licensees, assignees, or suc-  
17 cessors in interest of such requestor with  
18 respect to the subject of such order), for a  
19 period of 18 months following the effective  
20 date of such final order and beginning on  
21 the date the requestor may lawfully market  
22 such drugs pursuant to the order, to mar-  
23 ket drugs—

24 “(I) incorporating changes de-  
25 scribed in clause (ii); and

1                   “(II) subject to the limitations  
2                   under clause (iv).

3                   “(ii) CHANGES DESCRIBED.—A  
4                   change described in this clause is a change  
5                   subject to an order specified in clause (i),  
6                   which—

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

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

19                  “(iii) DRUGS DESCRIBED.—The drugs  
20                  described in this clause are drugs—

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

23                  “(II) subject to a final order  
24                  issued under this section;

1 “(III) subject to a final sun-  
2 screen order (as defined in section  
3 586(2)(A)); or

4 “(IV) described in subsection  
5 (m)(1), other than drugs subject to an  
6 active enforcement action under chap-  
7 ter III of this Act.

8 “(iv) LIMITATIONS ON EXCLU-  
9 SIVITY.—

10 “(I) IN GENERAL.—Only one 18-  
11 month period under this subpara-  
12 graph shall be granted, under each  
13 order described in clause (i), with re-  
14 spect to changes (to the drug subject  
15 to such order) which are either—

16 “(aa) changes described in  
17 clause (ii)(I), relating to active  
18 ingredients; or

19 “(bb) changes described in  
20 clause (ii)(II), relating to condi-  
21 tions of use.

22 “(II) NO EXCLUSIVITY AL-  
23 LOWED.—No exclusivity shall apply to  
24 changes to a drug which are—

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

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

9                   “(cc) changes related to  
10 methods of testing safety or effi-  
11 cacy.

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

19                   “(I) have not been relied on by  
20 the Secretary to support—

21                   “(aa) a proposed or final de-  
22 termination that a drug described  
23 in subclause (I), (II), or (III) of  
24 clause (iii) is generally recognized

1 as safe and effective under sec-  
2 tion 201(p)(1); or

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

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

9 “(aa) a proposed or final de-  
10 termination that a drug described  
11 in subclause (I), (II), or (III) of  
12 clause (iii) is generally recognized  
13 as safe and effective under sec-  
14 tion 201(p)(1); or

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

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

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



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

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

12          “(B) DRUG DESCRIBED.—A drug de-  
13          scribed in this subparagraph is a nonprescrip-  
14          tion drug which contains an active ingredient  
15          not previously incorporated in a drug—

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

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

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

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

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

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

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

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

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

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

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

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

18                  “(i) the drug is marketed as a non-  
19                  prescription drug, under conditions of use  
20                  comparable to the conditions specified in  
21                  the request, for such period as the Sec-  
22                  retary determines appropriate (not to ex-  
23                  ceed 5 consecutive years) pursuant to an  
24                  application approved under section 505;  
25                  and

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

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

14                  “(7) PACKAGING.—An administrative order  
15                  issued under paragraph (2), (4)(A), or (5) may in-  
16                  clude requirements for the packaging of a drug to  
17                  encourage use in accordance with labeling. Such re-  
18                  quirements may include unit dose packaging, re-  
19                  quirements for products intended for use by pedi-  
20                  atric populations, requirements to reduce risk of  
21                  harm from unsupervised ingestion, and other appro-  
22                  priate requirements. This paragraph does not au-  
23                  thorize the Food and Drug Administration to re-  
24                  quire standards or testing procedures as described in  
25                  part 1700 of title 16, Code of Federal Regulations.

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

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

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

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

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

22                   “(C) DEEMED ORDERS INCLUDE HARMO-  
23          NIZING TECHNICAL AMENDMENTS.—The  
24          deemed establishment of a final administrative  
25          order under subparagraph (A) shall be con-

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

8           “(c) PROCEDURE FOR MINOR CHANGES.—

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

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

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

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

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

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

3 “(2) ADDITIONAL INFORMATION.—

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

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

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

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

23 “(C) FAILURE TO SUBMIT SUFFICIENT IN-  
24 FORMATION.—If the sponsor fails to provide  
25 such additional information within a time pre-

1           scribed by the Secretary, or if the Secretary de-  
2           termines that such additional information does  
3           not demonstrate that the change does not—

4                   “(i) affect the safety or effectiveness  
5                   of the drug; or

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

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

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

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



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

8           “(d) CONFIDENTIALITY OF INFORMATION SUB-  
9           MITTED TO THE SECRETARY.—

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

21           “(2) PUBLIC AVAILABILITY.—

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

24           “(i) make any information submitted  
25           by a requestor in support of a request

1 under subsection (b)(5)(A) available to the  
2 public not later than the date on which the  
3 proposed order is issued; and

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

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

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

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

24 “(iii) the Secretary requests and ob-  
25 tains the information under subsection (c)

1                   and such information is not submitted in  
2                   relation to an order under subsection (b);  
3                   or

4                   “(iv) the information is of the type  
5                   contained in raw datasets.

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

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

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

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

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

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

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

16 “(A) a brief description of each such order;  
17 and

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

21 “(h) DEVELOPMENT ADVICE TO SPONSORS OR RE-  
22 QUESTORS.—The Secretary shall establish procedures  
23 under which sponsors or requestors may meet with appro-  
24 priate officials of the Food and Drug Administration to  
25 obtain advice on the studies and other information nec-

1 essary to support submissions under this section and other  
2 matters relevant to the regulation of nonprescription  
3 drugs and the development of new nonprescription drugs  
4 under this section.

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

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

14       “(k) EFFECT ON EXISTING REGULATIONS GOV-  
15 ERNING NONPRESCRIPTION DRUGS.—

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

1 of rulemaking in accordance with section 553 of title  
2 5, United States Code.

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

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

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

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

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

23 “(3) WITHDRAWAL OF REGULATIONS.—The  
24 Secretary shall withdraw regulations establishing  
25 final monographs and the procedures governing the

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

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

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

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

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

22 “(4) consolidated proceedings for appeal and  
23 the procedures for such proceedings where appro-  
24 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 paragraphs (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. 602. 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. 603. 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 601 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. 604. 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 601 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 601 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           (Λ)—

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 601  
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.—Not later than November 26, 2019,  
3 the Secretary of Health and Human Services  
4 (referred to in this subsection as the “Sec-  
5 retary”) shall amend and revise the final ad-  
6 ministrative order concerning nonprescription  
7 sunscreen (referred to in this subsection as the  
8 “sunscreen order”) for which the content, prior  
9 to the date of enactment of this Act, was rep-  
10 resented by the final monograph for sunscreen  
11 drug products set forth in part 352 of title 21,  
12 Code of Federal Regulations (as in effect on  
13 May 21, 1999).

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

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

21                   (ii) issued in proposed form not later  
22 than May 28, 2019;

23                   (iii) effective not later than November  
24 26, 2020; and

1 (iv) issued by the Secretary at least 1  
2 year prior to the effective date of the re-  
3 vised order.

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

20 (d) TREATMENT OF NON-SUNSCREEN TIME AND EX-  
21 TENT APPLICATIONS.—

22 (1) IN GENERAL.—Any application described in  
23 section 586F of the Federal Food, Drug, and Cos-  
24 metic Act (21 U.S.C. 360fff-6) that was submitted  
25 to the Secretary pursuant to section 330.14 of title



1 21, Code of Federal Regulations, as such provisions  
2 were in effect immediately prior to the date of enact-  
3 ment date of this Act, shall be extinguished as of  
4 such date of enactment, subject to paragraph (2).

5 (2) ORDER REQUEST.—Nothing in paragraph  
6 (1) precludes the submission of an order request  
7 under section 505G(b) of the Federal Food, Drug,  
8 and Cosmetic Act, as added by section 601 of this  
9 Act, with respect to a drug that was the subject of  
10 an application extinguished under paragraph (1).

11 **SEC. 605. ANNUAL UPDATE TO CONGRESS ON APPRO-**  
12 **PRIATE PEDIATRIC INDICATION FOR CER-**  
13 **TAIN OTC COUGH AND COLD DRUGS.**

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

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

1           (2) as appropriate, revising such cough and cold  
2           monograph to address such children through the  
3           order process under section 505G(b) of the Federal  
4           Food, Drug, and Cosmetic Act, as added by section  
5           601 of this Act.

6           (b) COUGH AND COLD MONOGRAPH DESCRIBED.—

7           The cough and cold monograph described in this sub-  
8           section consists of the conditions under which nonprescrip-  
9           tion drugs containing antitussive, expectorant, nasal de-  
10          congestant, or antihistamine active ingredients (or com-  
11          binations thereof) are generally recognized as safe and ef-  
12          fective, as specified in part 341 of title 21, Code of Federal  
13          Regulations (as in effect immediately prior to the date of  
14          enactment of this Act), and included in an order deemed  
15          to be established under section 505G(b) of the Federal  
16          Food, Drug, and Cosmetic Act, as added by section 601  
17          of this Act.

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

1 **SEC. 606. TECHNICAL CORRECTIONS.**

2 (a) IMPORTS AND EXPORTS.—Section  
3 801(e)(4)(E)(iii) of the Federal Food, Drug, and Cosmetic  
4 Act (21 U.S.C. 381(e)(4)(E)(iii)) is amended by striking  
5 “subparagraph” each place such term appears and insert-  
6 ing “paragraph”.

7 (b) FDA REAUTHORIZATION ACT OF 2017.—

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

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

16 **Subtitle B—User Fees**

17 **SEC. 611. SHORT TITLE; FINDING.**

18 (a) SHORT TITLE.—This subtitle may be cited as the  
19 “‘Over-the-Counter Monograph User Fee Act of 2019’”.

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

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

5 **SEC. 612. FEES RELATING TO OVER-THE-COUNTER DRUGS.**

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

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

11 **“SEC. 744L. DEFINITIONS.**

12 “In this part:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

17                  “(B) Inspections related to OTC mono-  
18                  graph drugs.

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

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

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

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

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

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

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

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

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



1           “(i) the reordering of existing information  
2 in the drug facts label of an OTC monograph  
3 drug;

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

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

13           “(iv) the standardization of the concentra-  
14 tion or dose of a specific finalized ingredient  
15 within a particular finalized monograph;

16           “(v) a change to ingredient nomenclature  
17 to align with nomenclature of a standards-set-  
18 ting organization; or

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

23           “(B) The Secretary may, based on program im-  
24 plementation experience or other factors found ap-  
25 propriate by the Secretary, characterize any OTC

1 monograph order request as a Tier 2 OTC mono-  
2 graph order request (including recharacterizing a re-  
3 quest from Tier 1 to Tier 2) and publish such deter-  
4 mination in a proposed order issued pursuant to sec-  
5 tion 505G.

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

9 “(i) is—

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

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

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

21 “(iii) does not include a business or other  
22 entity whose only manufacturing or processing  
23 activities are one or more of the following: pro-  
24 duction of clinical research supplies, testing, or  
25 placement of outer packaging on packages con-

1           taining multiple products, for such purposes as  
2           creating multipacks, when each monograph  
3           drug product contained within the overpack-  
4           aging is already in a final packaged form prior  
5           to placement in the outer overpackaging.

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

11                 “(i) closely related to the same business  
12                 enterprise;

13                 “(ii) under the supervision of the same  
14                 local management; and

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

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

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

4           “(12) The term ‘person’ includes an affiliate of  
5           a person.

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

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

10          “(a) TYPES OF FEES.—Beginning with fiscal year  
11          2019, the Secretary shall assess and collect fees in accord-  
12          ance with this section as follows:

13               “(1) FACILITY FEE.—

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

21                       “(B) EXCEPTIONS.—

22                               “(i) A fee shall not be assessed under  
23                               subparagraph (A) if the identified OTC  
24                               monograph drug facility—

1           “(I) has ceased all activities re-  
2           lated to OTC monograph drugs prior  
3           to the date that is 30 days after the  
4           date of enactment of the Over-the-  
5           Counter Monograph Safety, Innova-  
6           tion, and Reform Act of 2019, for the  
7           first program year, and December 31  
8           of the fiscal year for subsequent fiscal  
9           years; and

10           “(II) has updated its registration  
11           to reflect such change under the re-  
12           quirements for drug establishment  
13           registration set forth in section 510.

14           “(ii) The amount of the fee for a con-  
15           tract manufacturing organization facility  
16           shall be equal to two-thirds of the amount  
17           of the fee for an OTC monograph drug fa-  
18           cility that is not a contract manufacturing  
19           organization facility.

20           “(C) AMOUNT.—The amount of fees estab-  
21           lished under subparagraph (A) shall be estab-  
22           lished under subsection (c).

23           “(D) DUE DATE.—

24           “(i) FOR FIRST PROGRAM YEAR.—For  
25           fiscal year 2019, the facility fees required

1 under subparagraph (A) shall be due 45  
2 calendar days after publication of the Fed-  
3 eral Register notice provided for under  
4 subsection (c)(4)(A).

5 “(ii) SUBSEQUENT FISCAL YEARS.—  
6 For each fiscal year after fiscal year 2019,  
7 the facility fees required under subpara-  
8 graph (A) shall be due on the later of—

9 “(I) the first business day of  
10 June of such year; or

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

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

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

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

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

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

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

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

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

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

24                   “(D) REFUND OF FEE IF ORDER REQUEST  
25                   IS RECATEGORIZED AS A TIER 2 OTC MONO-

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

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

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



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

12          “(3) REFUNDS.—

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

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

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

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

3 “(b) FEE REVENUE AMOUNTS.—

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

8 “(A) the annual base revenue for fiscal  
9 year 2019 (as determined under paragraph  
10 (3));

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24                   “(1) INFLATION ADJUSTMENT.—

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

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

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

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

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

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

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

1                   “(i) for each of fiscal years 2020 and  
2                   2021, the average annual percent change  
3                   that occurred in the Consumer Price Index  
4                   for urban consumers (Washington-Balti-  
5                   more, DC–MD–VA–WV; Not Seasonally  
6                   Adjusted; All items; Annual Index) for the  
7                   first 3 years of the preceding 4 years of  
8                   available data; and

9                   “(ii) for each of fiscal years 2022 and  
10                  2023, the sum of—

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

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

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

12 “(2) OPERATING RESERVE ADJUSTMENT.—

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

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

25 “(i) 3 weeks for fiscal year 2019;

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

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

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

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

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

1 “(B) \$7,000,000 for fiscal year 2020;  
2 “(C) \$4,000,000 for fiscal year 2021;  
3 “(D) \$3,000,000 for fiscal year 2022; and  
4 “(E) \$3,000,000 for fiscal year 2023.

5 “(4) ANNUAL FEE SETTING.—

6 “(A) FISCAL YEAR 2019.—The Secretary  
7 shall, not later than 75 days after the date of  
8 enactment of the Over-the-Counter Monograph  
9 Safety, Innovation, and Reform Act of 2019—

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

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

19 “(B) SUBSEQUENT FISCAL YEARS.—The  
20 Secretary shall, not later than the second Mon-  
21 day in March of each fiscal year that begins  
22 after September 30, 2019—

23 “(i) establish for each such fiscal  
24 year, based on the revenue amounts under



1 subsection (b) and the adjustments pro-  
2 vided under this subsection—

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

5 “(II) OTC monograph order re-  
6 quest fees under subsection (a)(2);  
7 and

8 “(ii) publish such fee revenue  
9 amounts, facility fees, and OTC mono-  
10 graph order request fees in the Federal  
11 Register.

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

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

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

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

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

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

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

8                     “(ii) All OTC monograph drugs man-  
9                     ufactured in such a facility or containing  
10                    an ingredient manufactured in such a facil-  
11                    ity shall be deemed misbranded under sec-  
12                    tion 502(ff).

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

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

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

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

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

14 “(2) COLLECTIONS AND APPROPRIATION  
15 ACTS.—

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

23 “(B) USE OF FEES AND LIMITATION.—  
24 The fees authorized by this section shall be  
25 available to defray increases in the costs of the

1 resources allocated for OTC monograph drug  
2 activities (including increases in such costs for  
3 an additional number of full-time equivalent po-  
4 sitions in the Department of Health and  
5 Human Services to be engaged in such activi-  
6 ties), only if the Secretary allocates for such  
7 purpose an amount for such fiscal year (exclud-  
8 ing amounts from fees collected under this sec-  
9 tion) no less than \$12,000,000, multiplied by  
10 the adjustment factor applicable to the fiscal  
11 year involved under subsection (c)(1).

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

19 “(D) PROVISION FOR EARLY PAYMENTS IN  
20 SUBSEQUENT YEARS.—Payment of fees author-  
21 ized under this section for a fiscal year (after  
22 fiscal year 2019), prior to the due date for such  
23 fees, may be accepted by the Secretary in ac-  
24 cordance with authority provided in advance in  
25 a prior year appropriations Act.



1 House of Representatives and the Committee on Health,  
2 Education, Labor, and Pensions of the Senate a report  
3 concerning the progress of the Food and Drug Adminis-  
4 tration in achieving the goals identified in the letters de-  
5 scribed in section 2001(b) of the Over-the-Counter Mono-  
6 graph Safety, Innovation, and Reform Act of 2019 during  
7 such fiscal year and the future plans of the Food and  
8 Drug Administration for meeting such goals.

9       “(b) FISCAL REPORT.—Not later than 120 calendar  
10 days after the end of fiscal year 2019 and each subsequent  
11 fiscal year for which fees are collected under this part,  
12 the Secretary shall prepare and submit to the Committee  
13 on Energy and Commerce of the House of Representatives  
14 and the Committee on Health, Education, Labor, and  
15 Pensions of the Senate a report on the implementation  
16 of the authority for such fees during such fiscal year and  
17 the use, by the Food and Drug Administration, of the fees  
18 collected for such fiscal year.

19       “(c) PUBLIC AVAILABILITY.—The Secretary shall  
20 make the reports required under subsections (a) and (b)  
21 available to the public on the internet website of the Food  
22 and Drug Administration.

23       “(d) REAUTHORIZATION.—

24               “(1) CONSULTATION.—In developing rec-  
25 ommendations to present to the Congress with re-

1       spect to the goals described in subsection (a), and  
2       plans for meeting the goals, for OTC monograph  
3       drug activities for the first 5 fiscal years after fiscal  
4       year 2023, and for the reauthorization of this part  
5       for such fiscal years, the Secretary shall consult  
6       with—

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

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

11              “(C) scientific and academic experts;

12              “(D) health care professionals;

13              “(E) representatives of patient and con-  
14              sumer advocacy groups; and

15              “(F) the regulated industry.

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

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

22              “(B) publish such recommendations in the  
23              Federal Register;

1           “(C) provide for a period of 30 calendar  
2 days for the public to provide written comments  
3 on such recommendations;

4           “(D) hold a meeting at which the public  
5 may present its views on such recommenda-  
6 tions; and

7           “(E) after consideration of such public  
8 views and comments, revise such recommenda-  
9 tions as necessary.

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