

115TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

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

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IN THE SENATE OF THE UNITED STATES

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Mr. ISAKSON (for himself and Mr. CASEY) introduced the following bill; which was read twice and referred to the Committee on \_\_\_\_\_

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**A BILL**

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

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

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “\_\_\_\_\_ Act of  
5       \_\_\_\_\_”.

1 **SEC. 2. REGULATION OF CERTAIN NONPRESCRIPTION**  
2 **DRUGS THAT ARE MARKETING WITHOUT AN**  
3 **APPROVED NEW DRUG APPLICATION.**

4 Chapter V of the Federal Food, Drug, and Cosmetic  
5 Act is amended by inserting after section 505F of such  
6 Act (21 U.S.C. 355g) the following:

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

10 “(a) DEFINITIONS.—In this section:

11 “(1) NONPRESCRIPTION DRUG.—The term  
12 ‘nonprescription drug’ means a drug that is not sub-  
13 ject to the requirements of section 503(b)(1).

14 “(2) REQUESTOR.—The term ‘requestor’ means  
15 a person or group of persons marketing, manufac-  
16 turing, processing, or developing a drug.

17 “(3) SPONSOR.—The term ‘sponsor’ means a  
18 person or group of persons marketing, manufac-  
19 turing, or processing a drug and who has a listing  
20 in effect under section 510(j) for such drug.

21 “(b) CERTAIN NONPRESCRIPTION DRUGS.—With re-  
22 spect to a drug that, on or after the date of enactment  
23 of the \_\_\_\_\_ Act of \_\_\_\_\_, is offered in inter-  
24 state commerce as a nonprescription drug, the following  
25 shall apply:

“(1) A drug is deemed to be generally recognized as safe and effective within the meaning of section 201(p)(1), not a new drug under section 201(p), and not subject to section 503(b)(1), and is referred to in this section as a ‘Category I drug’ if—

“(A) the drug is—

“(i)(I) subject to a final monograph issued under part 330 of title 21, Code of Federal Regulations, as of the date of enactment of the \_\_\_\_\_ Act of \_\_\_\_\_;

“(II) in conformity with the conditions for nonprescription use of such monograph and the general conditions specified for nonprescription drugs, including any modifications to those conditions made under subsections (c), (d), and **[(l)]**/***[should this be (g)?]***; and

“(III) except as permitted by an administrative order issued under subsection (c) or a minor change in the drug in conformity with subsection (d), is in a dosage form that has been used to a material extent and for a material time within the meaning of section 201(p)(2); or

1 “(ii)(I) the subject of a tentative final  
2 monograph that is the most recently appli-  
3 cable proposal or determination issued  
4 under part 330 of title 21, Code of Federal  
5 Regulations, as of the date of enactment of  
6 the \_\_\_\_\_ Act of \_\_\_\_\_;

7 “(II) classified in category I for safety  
8 and effectiveness under such tentative final  
9 monograph;

10 “(III) in conformity with the condi-  
11 tions for nonprescription use of such ten-  
12 tative final monograph, any applicable final  
13 order under subsection (c)(5)(D), and the  
14 general conditions for nonprescription  
15 drugs, including any modifications of those  
16 conditions under subsections (c), (d), and  
17 **[(l)] [(g)?]**; and

18 “(IV) except as permitted by an ad-  
19 ministrative order issued under subsection  
20 (c) or a minor change in the drug in con-  
21 formity with subsection (d), is in a dosage  
22 form that has been used to a material ex-  
23 tent and for a material time within the  
24 meaning of section 201(p)(2); or

25 “(B) the drug is in conformity with—

1 “(i) the conditions of a final adminis-  
2 trative order issued under subsection (c)  
3 determining that the active ingredients in  
4 such drug are generally recognized as safe  
5 and effective within the meaning of section  
6 201(p)(1); and

7 “(ii) the general conditions for non-  
8 prescription drugs, including any modifica-  
9 tions of the requirements and conditions  
10 under subsections (c), (d), and **[(l)]/**  
11 **[(g)?]**.

12 “(2) A drug that is not a Category I drug may  
13 be lawfully marketed without an approved new drug  
14 application under section 505, is not subject to sec-  
15 tion 503(b)(1), and is referred to in this section as  
16 a ‘lawfully marketed drug’ if the drug is—

17 “(A)(i) the subject of a tentative final  
18 monograph that is the most recently applicable  
19 proposal or determination issued under part  
20 330 of title 21, Code of Federal Regulations;

21 “(ii) classified in category III for safety or  
22 effectiveness under such tentative final mono-  
23 graph;

24 “(iii) in conformity with the most recently  
25 proposed or final rule establishing conditions of

1 nonprescription use published in the Federal  
2 Register related to such tentative final mono-  
3 graph and the general conditions for non-  
4 prescription drugs, including any modifications  
5 of those requirements and conditions under  
6 subsections (c) and **[(l)]/[(g)?]**; and

7 “(iv) in a dosage form that has been used  
8 to a material extent and for a material time  
9 within the meaning of section 201(p)(2); or

10 “(B)(i) the subject of a proposed mono-  
11 graph or advance notice of proposed rulemaking  
12 that is the most recently applicable proposal or  
13 determination issued under part 330 of title 21,  
14 Code of Federal Regulations;

15 “(ii) classified in category I for safety and  
16 effectiveness under such proposed monograph  
17 or advance notice of proposed rulemaking;

18 “(iii) in conformity with the most recently  
19 proposed or final rule establishing conditions of  
20 nonprescription use published in the Federal  
21 Register related to such proposed monograph or  
22 advance notice of proposed rulemaking and the  
23 general conditions for nonprescription drugs, in-  
24 cluding any modifications of those requirements

1 and conditions under subsections (c) and **[(l)]**/  
2 **[(g)?]**; and

3 “(iv) in a dosage form that has been used  
4 to a material extent and for a material time  
5 within the meaning of section 201(p)(2).

6 “(3) A drug that is classified in category II for  
7 safety or effectiveness under a tentative final mono-  
8 graph or that the Secretary has determined not to  
9 be safe and effective in a final monograph or pre-  
10 amble to a rule that is the most recently applicable  
11 proposal or determination issued under part 330 of  
12 title 21, Code of Federal Regulations shall be  
13 deemed to be a new drug within the meaning of sec-  
14 tion 201(p), misbranded under section 502(ee), and  
15 subject to the requirement for an approved new drug  
16 application under section 505 beginning 180 days  
17 after the date of enactment of the \_\_\_\_\_  
18 Act of \_\_\_\_\_, unless, before such day, the Sec-  
19 retary determines that it is in the interest of public  
20 health to extend the period during which the drug  
21 may be marketed without an approved new drug ap-  
22 plication under section 505. Such drug shall be re-  
23 ferred to in this section as a ‘Category II drug’.

1           “(4)(A) This section shall not affect the treat-  
2           ment or status of a nonprescription drug subject to  
3           section 505—

4                   “(i) that, on the date of enactment of the  
5                   \_\_\_\_\_ Act of \_\_\_\_\_, is marketed  
6                   without an application approved under section  
7                   505; and

8                   “(ii) to which paragraphs (1), (2), and (3)  
9                   do not apply.

10           “(B) Nothing in this paragraph shall be con-  
11           strued to preclude or limit the applicability of any  
12           other provision of this Act.

13           “(5) A drug that is subject to the final mono-  
14           graph for sunscreen drug products set forth at part  
15           352 of title 2, Code of Federal Regulations (as in ef-  
16           fect on the date of enactment of the \_\_\_\_\_  
17           Act of \_\_\_\_\_), shall comply with the require-  
18           ments of that monograph, except that the testing re-  
19           quirements for effectiveness and the provisions gov-  
20           erning labeling shall be in accordance with section  
21           201.327 of title 21, Code of Federal Regulations (as  
22           in effect on the date of enactment of the  
23           \_\_\_\_\_ Act of \_\_\_\_\_), or such changes to  
24           those requirements as may be made under sub-  
25           section [(c) or (d)] [*should this be (j)?*].



1           “(6) A nonprescription drug that is not de-  
2       scribed in paragraph (1), (2), (3), or (4) and that  
3       is not in conformity with subsection (d) and that is  
4       not the subject of an application approved under sec-  
5       tion 505 is deemed to be a new drug within the  
6       meaning of section 201(p) and misbranded under  
7       section 502(ee).

8           “(c) ADMINISTRATIVE ORDERS.—**[***Note: I think this*  
9       *subsection should be restructured to separate out the proc-*  
10      *esses for hearing and judicial review, which are currently*  
11      *drafted in reference to paragraph (3), but have broader ap-*  
12      *plicability. I would propose creating a new subsection for*  
13      *hearings and review, to separate that concept from the*  
14      *issuance of orders. This would be a large structural change,*  
15      *so please advise on whether you would want that in the*  
16      *next draft.***]**

17           “(1) IN GENERAL.—

18           “(A) GENERALLY RECOGNIZED AS SAFE  
19       AND EFFECTIVE.—The Secretary may, on the  
20       initiative of the Secretary or at the request of  
21       one or more requestors, issue an administrative  
22       order determining whether there are conditions  
23       under which a specific drug, class of such  
24       drugs, or combination of such drugs is deter-  
25       mined to be—

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

2 “(ii) generally recognized as safe and  
3 effective within the meaning of section  
4 201(p)(1); and

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

7 “(B) NOT GENERALLY RECOGNIZED AS  
8 SAFE AND EFFECTIVE.—The Secretary shall  
9 **【find】/【issue an order determining】** that a  
10 drug is not generally recognized as safe and ef-  
11 fective within the meaning of section 201(p)(1)  
12 for the specified conditions if—

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

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

21 “(2) NONAPPLICATION OF CERTAIN REQUIRE-  
22 MENTS.—The requirements of subchapter II of  
23 chapter 5 of title 5, United States Code shall not  
24 apply with respect to administrative orders issued  
25 under this subsection.

1           “(3) ADMINISTRATIVE ORDERS INITIATED BY  
2       THE SECRETARY.—

3           “(A) IN GENERAL.—Except as provided in  
4       paragraph (5), in issuing an administrative  
5       order under paragraph (1) on the initiative of  
6       the Secretary, the Secretary shall—

7           “(i) post on the Internet website of  
8       the Food and Drug Administration, not  
9       later than 2 business days before the  
10      issuance of the proposed order, information  
11      for sponsors of drugs that will be subject  
12      to the administrative order;

13          “(ii) after any such posting—

14               “(I) issue such a proposed ad-  
15              ministrative order by publishing it on  
16              the Internet website of the Food and  
17              Drug Administration and include in  
18              such order the reasons for the  
19              issuance of such order; and

20               “(II) publish notice of availability  
21              of such proposed order in the Federal  
22              Register;

23               “(iii) except as provided in subpara-  
24              graph (B), provide for a public comment

1 period with respect to such proposed order  
2 of not less than 45 days; and

3 “(iv) if, after satisfying the require-  
4 ments of clauses (i) through (iii), the Sec-  
5 retary determines that it is appropriate to  
6 issue a final administrative order, the Sec-  
7 retary shall—

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

14 “(II) publish a notice of avail-  
15 ability of such final administrative  
16 order in the Federal Register;

17 “(III) afford sponsors of prod-  
18 ucts that will be subject to such order  
19 the opportunity for formal dispute  
20 resolution up to the level of the Direc-  
21 tor of the Center for Drug Evaluation  
22 and Research, which initially shall be  
23 requested within 45 days of the  
24 issuance of the order, and, for subse-

1           quent levels of appeal, within 30 days  
2           of the prior decision; and

3                   “(IV) except with respect to  
4           drugs described in paragraph (4)(B),  
5           upon completion of the formal dispute  
6           resolution procedure, inform the per-  
7           son or persons which sought such dis-  
8           pute resolution of their right to re-  
9           quest a hearing.

10                   “(B) SPECIAL REQUIREMENTS WITH RE-  
11           SPECT TO LAWFULLY MARKETED DRUGS.—  
12           When issuing an administrative order under  
13           paragraph (1) on the initiative of the Secretary  
14           (except as provided under paragraph (5)) pro-  
15           posing to determine that a lawfully marketed  
16           drug is not generally recognized as safe and ef-  
17           fective within the meaning of section 201(p)(1),  
18           the Secretary shall follow the procedures in sub-  
19           paragraph (A) except that—

20                   “(i) the proposed order shall include  
21           notice of—

22                   “(I) the general categories of  
23           data the Secretary has determined  
24           necessary to establish that the drug is  
25           generally recognized as safe and effec-

1                   tive within the meaning of section  
2                   201(p)(1); and

3                   “(II) the format for submissions  
4                   by interested persons;

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

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

21                  “(4) HEARINGS; JUDICIAL REVIEW.—

22                  “(A) IN GENERAL.—A person who partici-  
23                  pated in each level of formal dispute resolution  
24                  under paragraph (3)(A)(iv)(III) of an adminis-  
25                  trative order with respect to a drug may re-

1           quest a hearing concerning a final administra-  
2           tive order issued under paragraph (3)(A)(iv)  
3           with respect to such drug. Such person may  
4           submit a request for a hearing, which shall be  
5           based solely on the information in the adminis-  
6           trative record, to the Secretary not later than  
7           30 days after receiving notice of the final deci-  
8           sion of the formal dispute resolution procedure.

9           “(B) NO HEARING REQUIRED WITH RE-  
10          SPECT TO ORDERS RELATING TO CERTAIN  
11          DRUGS.—The Secretary is not required to pro-  
12          vide notice and an opportunity for a hearing  
13          pursuant to paragraph (3)(A)(iv) if the final  
14          administrative order involved relates to a  
15          drug—

16               “(i) that is described in subsection  
17               (b)(2)(A); and

18               “(ii) with respect to which no data  
19               relevant to the safety or effectiveness of  
20               such drug have been submitted to the ad-  
21               ministrative record since the issuance of  
22               the most recent tentative final monograph  
23               relating to such drug.

24          “(C) HEARING PROCEDURES.—

1 “(i) DENIAL OF REQUEST FOR HEAR-  
2 ING.—If the Secretary determines that a  
3 request for a hearing under subparagraph  
4 (A) with respect to a final administrative  
5 order issued under paragraph (3)(A)(iv),  
6 does not establish the existence of a gen-  
7 uine and substantial question of material  
8 fact, the Secretary may deny such request.  
9 In making such a determination, the Sec-  
10 retary may consider only information and  
11 data that are based on relevant and reli-  
12 able scientific principles and methodolo-  
13 gies.

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  
23 Commissioner of Food and Drugs shall ap-  
24 point a presiding officer of a hearing re-  
25 quested under subparagraph (A) who—



1                   “(I) is not an employee of the  
2                   Center for Drug Evaluation and Re-  
3                   search; and

4                   “(II) has not previously been in-  
5                   volved in the development of the appli-  
6                   cable administrative order or in the  
7                   proceedings relating to that adminis-  
8                   trative order.

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

20                  “(v) FINAL DECISION.—At the conclu-  
21                  sion of a hearing requested under subpara-  
22                  graph (A), the presiding officer of the  
23                  hearing shall issue a decision containing  
24                  findings of fact and conclusions of law.  
25                  The decision of the presiding officer shall

1 be final. The final decision may not take  
2 effect until the period under subparagraph  
3 (D)(ii) for submitting a request for judicial  
4 review of such decision expires.

5 “(D) JUDICIAL REVIEW OF FINAL ADMIN-  
6 ISTRATIVE ORDER.—

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

18 “(ii) TIME TO SUBMIT A REQUEST  
19 FOR JUDICIAL REVIEW.—A person eligible  
20 to request a hearing under this paragraph  
21 and seeking judicial review of a final ad-  
22 ministrative order issued under this sub-  
23 section shall file such appeal not later than  
24 60 days after the latest of—

1 “(I) the date on which notice of  
2 such order is published;

3 “(II) the date on which any hear-  
4 ing with respect to such order is de-  
5 nied under subparagraph **[(B)]** *[(This*  
6 *does not allow for a denial, but only*  
7 *explains when a hearing is not avail-*  
8 *able--strike?]* or (C)(i);

9 “(III) the date on which a final  
10 decision is made following any hearing  
11 with respect to such order under sub-  
12 paragraph (C)(v); or

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

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

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

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

1 Secretary may, after notifying any sponsor  
2 that will be the subject of such determina-  
3 tion, not later than 48 hours before  
4 issuance of an order under this subpara-  
5 graph—

6 “(I) issue an interim final admin-  
7 istrative order for such drug or com-  
8 bination of drugs under paragraph  
9 (1), together with a detailed state-  
10 ment of the reasons for such order;

11 “(II) publish in the Federal Reg-  
12 ister a notice of availability of such  
13 order; and

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

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

22 “(B) SAFETY LABELING CHANGES.—

23 “(i) IN GENERAL.—In the case of a  
24 determination by the Secretary that a  
25 change in the labeling of a drug, class of

1 drugs, or combination of drugs subject to  
2 this section is reasonably expected to miti-  
3 gate a significant or unreasonable risk of  
4 a serious adverse event associated with use  
5 of the drug, the Secretary may—

6 “(I) notify, not later than 48  
7 hours before the issuance of the in-  
8 terim final order, the sponsor or  
9 group of sponsors of any drug that  
10 will be the subject of such determina-  
11 tion;

12 “(II) after notification, issue an  
13 interim final administrative order in  
14 accordance with paragraph (1) to re-  
15 quire such change, together with a de-  
16 tailed statement of the reasons for  
17 such order;

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

21 “(IV) provide for a public com-  
22 ment period of at least 45 calendar  
23 days with respect to such interim final  
24 order.

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

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

10                  “(D) FINAL ORDER.—After the completion  
11                  of the proceedings in subparagraph (A) or (B),  
12                  the Secretary shall—

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

15                         “(ii) publish a notice of availability of  
16                         such final administrative order in the Fed-  
17                         eral Register; and

18                         “(iii) afford sponsors of drugs that  
19                         will be subject to such an order the oppor-  
20                         tunity for formal dispute resolution up to  
21                         the level of the Director of the Center for  
22                         Drug Evaluation and Research, which ini-  
23                         tially shall be within 45 days of the  
24                         issuance of the order; and, for subsequent

1 levels of appeal, within 30 days of the prior  
2 decision.

3 “(E) HEARINGS.—

4 “(i) IN GENERAL.—A sponsor of a  
5 drug subject to a final order issued under  
6 subparagraph (A) or (B) who participated  
7 in each level of formal dispute resolution  
8 under subparagraph (D)(iii) may request a  
9 hearing on such order. The provisions of  
10 subparagraphs (A), (B), and (C) of para-  
11 graph (4) shall apply with respect to a  
12 hearing on such order in the same manner  
13 and to the same extent as such provisions  
14 apply with respect to a hearing on an ad-  
15 ministrative order issued under paragraph  
16 (3)(A)(iv).

17 “(ii) REFERENCES.—For purposes of  
18 a hearing under this subparagraph, the  
19 references in subparagraphs (A), (B), and  
20 (C) of paragraph (4)—

21 “(I) to ‘each level of dispute reso-  
22 lution under paragraph  
23 (3)(A)(iv)(III)’ shall be deemed to  
24 mean ‘each level of formal dispute res-

1                   olution under subparagraph (D)(iii);  
2                   and  
3                   “(II) to ‘final administrative  
4                   order issued under paragraph  
5                   (3)(A)(iv)’ shall be deemed to mean  
6                   ‘final order under subparagraph  
7                   (D)(i)’.

8                   “(F) FINAL ORDER.—Not later than 1  
9                   year after the date on which an interim final  
10                  order is issued under subparagraph (A) or (B),  
11                  the Secretary shall issue a final order in accord-  
12                  ance with paragraph (1) and complete any re-  
13                  quired hearing.

14                  “(G) JUDICIAL REVIEW.—A final order  
15                  issued pursuant to subparagraph (F) shall be  
16                  subject to judicial review in accordance with  
17                  paragraph (4)(D).

18                  “(H) CLARIFICATION.—Paragraph (3)  
19                  shall not apply to the orders issued under this  
20                  paragraph.

21                  “(6) ADMINISTRATIVE ORDER INITIATED BY  
22                  REQUEST.—

23                  “(A) IN GENERAL.—In issuing an adminis-  
24                  trative order under paragraph (1) at the re-  
25                  quest of a requestor or a group of requestors



1 with respect to certain drugs, classes of drugs,  
2 or combinations of drugs—

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

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

12 “(I) file the request; and

13 “(II) initiate proceedings with re-  
14 spect to issuing an administrative  
15 order in accordance with paragraphs  
16 (3) and (4); and

17 “(iii) except as provided in paragraph  
18 (7), if the Secretary determines that a re-  
19 quest does not meet the requirements for  
20 filing or is not sufficiently complete or for-  
21 matted to permit a substantive review, the  
22 requestor may elect that the Secretary file  
23 the request over protest, and the Secretary  
24 shall initiate proceedings to review the re-  
25 quest in accordance with paragraph (3)(A).

1                   “(B) REQUEST TO INITIATE PRO-  
2 CEEDINGS.—

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

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

20                   “(II) determining whether a  
21 change to a condition of use of a drug  
22 is generally recognized as safe and ef-  
23 fective within the meaning of section  
24 201(p)(1), exempt from section  
25 503(b)(1), and not required to be the

1 subject of an approved application  
2 under section 505, if such drug is—

3 “(aa) a Category I drug; or

4 “(bb) a lawfully marketed

5 drug, but only if such requestor

6 initiates such request in conjunc-

7 tion with a request for the Sec-

8 retary to determine whether such

9 drug is generally recognized as

10 safe and effective within the

11 meaning of section 201(p)(1),

12 which is filed by the Secretary

13 under subparagraph (A)(ii)(I).

14 The Secretary is not required to complete

15 review of the request for a change de-

16 scribed in subclause (II) if the Secretary

17 determines that there is an inadequate

18 basis to find the drug is generally recog-

19 nized as safe and effective under para-

20 graph (1) and issues a final order an-

21 nouncing that determination.

22 “(ii) WITHDRAWAL OF REQUEST.—

23 The requestor may withdraw a request

24 under this paragraph, according to the

25 procedures established by the Secretary.

1 Notwithstanding any other provision of  
2 this section, if such request is withdrawn,  
3 the Secretary may cease proceedings under  
4 this subparagraph.

5 “(C) PRODUCT DIFFERENTIATION.—

6 “(i) IN GENERAL.—In the case of a  
7 final order issued under this paragraph  
8 providing for a change in the conditions of  
9 use of a drug with respect to which origi-  
10 nal human data submitted by the requestor  
11 of the drug were essential to the issuance  
12 of such order, the administrative order  
13 shall, for a period of **【2 years】** after the  
14 date on which the order is issued, be effec-  
15 tive only with respect to drugs marketed  
16 by the requestor that submitted the re-  
17 quest under subparagraph (A) (or the li-  
18 censees, assignees, or successors in interest  
19 of such requestor ) with respect to such  
20 drug. Only one **【2-year】** period shall be  
21 provided for the same change in the formu-  
22 lation or conditions of use of the same  
23 drug.

24 “(ii) HUMAN DATA DEFINED.—For  
25 purposes of this subparagraph, the term

1           ‘human data’ means data from any testing  
2           with human subjects, including clinical  
3           trials of safety or effectiveness (including  
4           actual use studies), pharmacokinetics, or  
5           bioavailability.

6           “(7) INFORMATION REGARDING SAFE NON-  
7           PRESCRIPTION MARKETING AND USE AS A CONDI-  
8           TION FOR FILING A GRASE REQUEST.—**【Should this**  
9           *be under paragraph (6)?】*

10           “(A) IN GENERAL.—In response to a re-  
11           quest under paragraph (6) that a drug de-  
12           scribed in subparagraph (B) be generally recog-  
13           nized as safe and effective, the Secretary—

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

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

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

5           “(i) marketed in accordance with a  
6           final monograph issued under section 330  
7           of title 21, Code of Federal Regulations  
8           (including conditions of use under such  
9           section), as in effect on the date of enact-  
10          ment of this section;

11          “(ii) marketed as category I in ac-  
12          cordance with a tentative final monograph  
13          issued under [section 330 of title 21, Code  
14          of Federal Regulations] [*Check citation--*  
15          *this appears to be incorrect*] (including  
16          conditions of use and any applicable subse-  
17          quent determinations under such section),  
18          as in effect on the date of enactment of  
19          this section; or

20          “(iii) marketed in accordance with a  
21          final order issued under this section.

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 to dem-  
4                   onstrate that the drug subject to such re-  
5                   quest has a verifiable history of being mar-  
6                   keted and safely used by consumers in the  
7                   United States as a nonprescription drug  
8                   under comparable conditions of use; or

9                   “(ii) if the drug has not been pre-  
10                  viously marketed in the United States as a  
11                  nonprescription drug, information suffi-  
12                  cient to demonstrate that the drug was  
13                  marketed and safely used in a foreign  
14                  country under comparable conditions of  
15                  marketing and use—

16                   “(I) for such period of time as  
17                   needed to provide reasonable assur-  
18                   ances concerning the safe nonprescrip-  
19                   tion use of the drug; and

20                   “(II) during such period of time,  
21                   was subject to sufficient monitoring  
22                   by a regulatory body considered ac-  
23                   ceptable by the Secretary for such  
24                   monitoring purposes, including for ad-

1                   verse events associated with non-  
2                   prescription use of the drug.

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

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

16                  “(ii) during such period of time,  
17                  1,000,000 retail packages of the drug were  
18                  distributed for retail sale, as determined in  
19                  such manner as the Secretary may require.

20                  “(E) RULE OF APPLICATION.—If the Sec-  
21                  retary refuses to file a request under this para-  
22                  graph, the requestor may not file over protest  
23                  under paragraph (6)(A)(iii).

24                  “(8) FINAL AND TENTATIVE FINAL MONO-  
25                  GRAPHS FOR CATEGORY I DRUGS.—A final mono-



1 graph or tentative final monograph establishing con-  
2 ditions of use for a Category I drug shall be deemed  
3 to be a final administrative order under this sub-  
4 section and may be amended, revoked, or otherwise  
5 modified in accordance with the procedures of this  
6 subsection.

7 “(d) PROCEDURE FOR MINOR CHANGES.—

8 “(1) IN GENERAL.—Minor changes in the dos-  
9 age form of a drug that is described in subpara-  
10 graph (A) or (B) of subsection (b)(1) may be made  
11 by a requestor without the issuance of an adminis-  
12 trative order under subsection (c) if—

13 “(A) the requestor maintains information  
14 necessary to demonstrate that the change—

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

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

21 “(B) the requestor submits updated drug  
22 listing information for the drug in accordance  
23 with the requirements of section 510(j) within  
24 30 days of the date on which the drug is first

1 introduced into interstate commerce with the  
2 change;

3 “(C) the change is in conformity with the  
4 requirements of an applicable administrative  
5 order issued by the Secretary under paragraph  
6 (3).

7 “(2) ADDITIONAL INFORMATION.—

8 “(A) ACCESS TO RECORDS.—The requestor  
9 shall submit records requested related to a  
10 minor change under section 704 to the Sec-  
11 retary within 15 business days of receiving such  
12 request, or such longer period as the Secretary  
13 may provide.

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

21 “(i) may so inform the requestor of  
22 the drug in writing; and

23 “(ii) provide the requestor of the drug  
24 with a reasonable opportunity to provide  
25 additional information.

1           “(C) FAILURE TO SUBMIT SUFFICIENT IN-  
2           FORMATION.—If the requestor fails to provide  
3           such additional information within the pre-  
4           scribed time, or if the Secretary determines that  
5           such additional information does not dem-  
6           onstrate that the change does not affect the  
7           safety or effectiveness of the drug or materially  
8           affect the extent of absorption or other expo-  
9           sure to the active ingredient, the drug as modi-  
10          fied is a new drug within the meaning of sec-  
11          tion 201(p) and shall be deemed to be mis-  
12          branded under section 502(ee).

13          “(3) DETERMINING WHETHER 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 requestor 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 drug products.

6                   “(e) INFORMATION SUBMITTED BY REQUESTORS.—

7                   “(1) CONFIDENTIAL INFORMATION.—Any infor-  
8                   mation, including reports of testing conducted on the  
9                   drug or drugs involved, that is submitted by a re-  
10                  questor in connection with proceedings on an admin-  
11                  istrative order under this section (or any minor  
12                  change under subsection (d)) and is a trade secret  
13                  or confidential information subject to section  
14                  552(b)(4) of title 5, United States Code, or section  
15                  1905 of title 18, United States Code, shall not be  
16                  disclosed to the public unless the requestor consents  
17                  to that disclosure.

18                  “(2) PUBLIC AVAILABILITY LIMITATIONS.—The  
19                  Secretary shall make available to the public any in-  
20                  formation submitted by a requestor in support of a  
21                  request under subsection (c)(6)(A) as of the date on  
22                  which the proposed order is issued unless—

23                  “(A) the information pertains to pharma-  
24                  ceutical quality information which is necessary  
25                  to establish standards under which a drug is

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

3 “(B) the information is submitted in a re-  
4 questor-initiated request, but the requestor  
5 withdraws such request before the Secretary  
6 issues the proposed order in accordance with  
7 withdrawal procedures established by the Sec-  
8 retary; or

9 “(C) the Secretary otherwise obtains the  
10 information under subsection (d).

11 “(f) PUBLIC AVAILABILITY OF ADMINISTRATIVE OR-  
12 DERS.—The Secretary shall establish, maintain, update  
13 (as the Secretary determines necessary, but not less fre-  
14 quently than annually), and make available on the Inter-  
15 net website of the Food and Drug Administration—

16 “(1) a repository of each final administrative  
17 order and interim final order [under subsection (c)  
18 that is] in effect, including the complete text of the  
19 administrative order; and

20 “(2) a listing of all administrative orders pro-  
21 posed and under development under this section, in-  
22 cluding—

23 “(A) a brief description of the administra-  
24 tive order; and

1                   “(B) the expectations of the Secretary, for  
2                   issuance of proposed administrative orders over  
3                   a 3 year period.

4           “(g) UPDATES TO DRUG LISTING INFORMATION.—  
5   A sponsor who makes a change to a drug described in  
6   paragraph (1) or (2) of subsection (b) shall submit up-  
7   dated drug listing information for the drug in accordance  
8   with the requirements of section 510(j) within 30 days of  
9   the date on which the drug is first introduced into inter-  
10   state commerce with the change.

11          “(h) APPROVALS UNDER SECTION 505.—This sec-  
12   tion shall not be construed to preclude a sponsor of a drug  
13   or requestor from seeking or maintaining the approval of  
14   an application for such drug under subsection (b)(1),  
15   (b)(2), or (j) of section 505. A determination under this  
16   section that a drug is not subject to section 503(b)(1),  
17   is generally recognized as safe and effective within the  
18   meaning of 201(p)(1), and is not a new drug under section  
19   201(p) shall constitute a finding of safety and effective-  
20   ness for purposes of section 505(b)(2), so that the appli-  
21   cant shall be required to submit only that information  
22   needed to support the modification of the drug that is sub-  
23   ject to the determination under this section.

24          “(i) DEVELOPMENT ADVICE TO REQUESTORS OR  
25   SPONSORS.—

1           “(1) IN GENERAL.—The Secretary may estab-  
2           lish procedures under which requestors may meet  
3           with appropriate officials of the Food and Drug Ad-  
4           ministration to obtain advice on the studies and  
5           other information necessary to support submissions  
6           under this section and other matters relevant to the  
7           regulation of nonprescription drugs and the develop-  
8           ment of new nonprescription drugs under this sec-  
9           tion.

10           “(2) PARTICIPATION OF MULTIPLE SPON-  
11           SORS.—The Secretary shall establish procedures to  
12           facilitate efficient participation by multiple reques-  
13           tors in proceedings under this section, including pro-  
14           vision for joint meetings with multiple requestors or  
15           with organizations nominated by requestors to rep-  
16           resent their interests in a proceeding.

17           “(3) PUBLICATION OF MEETING SUMMARIES.—  
18           The Secretary shall publish a summary of any meet-  
19           ing held under this subsection, in a manner con-  
20           sistent with subsection (e).

21           “(j) EFFECT ON EXISTING REGULATIONS GOV-  
22           ERNING NONPRESCRIPTION DRUGS.—

23           “(1) EXISTING REGULATIONS.—Except as pro-  
24           vided in this subsection, nothing in this section su-  
25           persedes regulations establishing requirements for

1 the labeling or formulation of nonprescription drugs,  
2 or regulations of general applicability contained in  
3 parts 201, 250 and 330 of title 21, Code of Federal  
4 Regulations, or any successor regulations. The Sec-  
5 retary shall establish or modify such regulations by  
6 means of rulemaking in accordance with section 553  
7 of title 5, United States Code.

8 “(2) SPECIAL LABELING REQUIREMENTS.—

9 “(A) IN GENERAL.—The Secretary shall  
10 establish or modify regulations in effect on the  
11 day before the date of enactment of this section  
12 establishing general requirements for non-  
13 prescription drugs and regulations of general  
14 applicability contained in parts 201, 250, and  
15 330 of title 21, Code of Federal Regulations (or  
16 any successor regulations).

17 “(B) EFFECTIVE DATE PERIOD.—Unless  
18 withdrawn or revised by the Secretary, the reg-  
19 ulations described in subparagraph (A) shall re-  
20 main in effect in title 21 of the Code of Federal  
21 Regulations as they apply to drugs not subject  
22 to paragraphs (1) through (4) of subsection (b).

23 “(3) PROCEDURAL REGULATIONS.—The Sec-  
24 retary shall withdraw regulations establishing final  
25 monographs and the procedures governing the over-



1 the-counter drug review under part 330 and other  
2 relevant parts of title 21, Code of Federal Regula-  
3 tions (as in effect on the date immediately before  
4 this section takes effect), or make technical changes  
5 to such regulations to ensure conformity with appro-  
6 priate terminology and cross references, to the ex-  
7 tent needed to effectuate or harmonize the provi-  
8 sions of this section. Notwithstanding subchapter II  
9 of chapter 5 of title 5, United States Code, any such  
10 withdrawal or technical amendments shall be effec-  
11 tive upon publication through notice in the Federal  
12 Register (or upon such date as specified in such no-  
13 tice).

14 “(k) GUIDANCE.—

15 “(1) ISSUANCE.—The Secretary shall issue  
16 guidance that provides—

17 “(A) the procedures and principles for for-  
18 mal meetings between the Secretary and spon-  
19 sors or requestors for drugs subject to this sec-  
20 tion;

21 “(B) the format and content of data sub-  
22 missions to the Secretary under this section;

23 “(C) the format of electronic submissions  
24 to the Secretary under this section;

1 “(D) consolidated proceedings and the pro-  
2 cedures for such proceedings where appropriate;  
3 and

4 “(E) for minor changes in drugs, rec-  
5 ommendations on how to comply with the re-  
6 quirements in administrative orders issued  
7 under subsection (c)(3).

8 “(1) ELECTRONIC FORMAT.—All submissions under  
9 this section shall be in a format specified by the Secretary  
10 after providing a period for public comment.”.

11 **SEC. 3. AUTHORIZATION OF USER FEES.**

12 Subchapter C of chapter VII of the Federal Food,  
13 Drug, and Cosmetic Act (21 U.S.C. 379f et seq.) is  
14 amended by adding at the end the following:

15 **“PART 10—FEES RELATING TO**  
16 **NONPRESCRIPTION DRUGS**

17 **“SEC. 744L. DEFINITIONS.**

18 “For purposes of this part:

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

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

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

3           “(2) The term ‘costs of resources allocated for  
4           nonprescription drug activities’ means the expenses  
5           in connection with nonprescription 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 to contracts with  
12          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 744L–  
22          1] and accounting for resources allocated for  
23          nonprescription drug activities.

24          “(3) The term ‘firm establishment identifier’ is  
25          the unique number automatically generated by the

1       Field Accomplishments and Compliance Tracking  
2       System of the Food and Drug Administration.

3           “(5) The term ‘nonprescription drug activities’  
4       means activities of the Secretary associated with  
5       nonprescription drug products and inspection of fa-  
6       cilities associated with such products, including—

7           “(A) the activities necessary for review and  
8       evaluation of nonprescription drugs and non-  
9       prescription drug order requests, including—

10           “(i) orders proposing or finalizing ap-  
11       plicable conditions of use for nonprescrip-  
12       tion drugs products;

13           “(ii) orders affecting status regarding  
14       general recognition of safety and effective-  
15       ness of a nonprescription drug ingredient  
16       or combination of ingredients under speci-  
17       fied conditions of use;

18           “(iii) all nonprescription drug develop-  
19       ment and review activities, including intra-  
20       agency collaboration;

21           “(iv) regulation and policy develop-  
22       ment activities related to nonprescription  
23       drugs;

1 “(v) development of product standards  
2 for products subject to review and evalua-  
3 tion;

4 “(vi) meetings regarding nonprescrip-  
5 tion drug activities;

6 “(vii) review of labeling prior to  
7 issuance of orders related to nonprescrip-  
8 tion drugs or conditions of use; and

9 “(viii) regulatory science activities re-  
10 lated to nonprescription drugs;

11 “(B) inspections related to nonprescription  
12 drugs;

13 “(C) monitoring of clinical and other re-  
14 search conducted in connection with non-  
15 prescription drugs;

16 “(D) safety activities with respect to non-  
17 prescription drugs, including—

18 “(i) collecting, developing, and review-  
19 ing safety information on nonprescription  
20 drugs, including adverse event reports;

21 “(ii) developing and using improved  
22 adverse event data-collection systems, in-  
23 cluding information technology systems;  
24 and

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

5 “(E) other activities necessary for imple-  
6 mentation of section 505G.

7 “(6)(A) The term ‘nonprescription drug facility’  
8 means a foreign or domestic business or other enti-  
9 ty—

10 “(i) that is under 1 management, either di-  
11 rect or indirect; and

12 “(ii) at 1 geographic location or address  
13 engaged in manufacturing or processing a non-  
14 prescription drug finished dosage form;

15 “(iii) includes a finished dosage form man-  
16 ufacturer facility or an affiliate thereof in a  
17 contractual relationship with a nonprescription  
18 drug requestor or requestors to manufacture or  
19 process nonprescription drugs; and

20 “(iv) does not include a business or other  
21 entity whose only manufacturing or processing  
22 activities relate to—

23 “(I) production of clinical research  
24 supplies; or

25 “(II) testing.

1           “(B) For purposes of subparagraph (A), sepa-  
2           rate buildings or locations within close proximity are  
3           considered to be at 1 geographic location or address  
4           if the activities conducted in them are—

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

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

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

13          “(C) If a business or other entity would meet  
14          the definition of a facility under this paragraph but  
15          for being under multiple management, the business  
16          or other entity is deemed to constitute multiple fa-  
17          cilities, one per management entity, for purposes of  
18          this paragraph.

19          “(7) The term ‘nonprescription drug meeting’  
20          means any meeting regarding the content of a pro-  
21          posed nonprescription drug order request.

22          “(8) The term ‘nonprescription drug product’  
23          means a nonprescription drug product that is mar-  
24          keted without an approved new drug application in  
25          accordance with section 505G(b).

1           “(9) The term ‘nonprescription drug order re-  
2           quest’ means a request for an order under section  
3           505G for the issuance of an administrative order for  
4           a change to the nonprescription drug product.

5           “(10) The term ‘nonprescription drug re-  
6           questor’ means an entity submitting a nonprescrip-  
7           tion drug order request or a nonprescription drug  
8           meeting request or any other inquiry relating to a  
9           request for an order or development of a non-  
10          prescription drug order request.

11          “(11) The term ‘person’ includes an affiliate  
12          thereof.

13          “(12) The term ‘Tier 1 nonprescription drug  
14          order request’ means any nonprescription drug order  
15          request not determined to be a Tier 2 nonprescrip-  
16          tion drug order request.

17          “(13)(A) The term ‘Tier 2 nonprescription drug  
18          order request’ means subject to subparagraph (B), a  
19          nonprescription drug monograph order request for—

20                 “(i) the reordering of existing information  
21                 in the drug facts label of a nonprescription  
22                 drug product;

23                 “(ii) the addition of information to the  
24                 other information section of the drug facts label  
25                 of an nonprescription drug product, as limited



1 by part 201.66(c)(7) of title 21, Code of Fed-  
2 eral Regulations;

3 “(iii) modification to the directions for use  
4 section of the drug facts label of a nonprescrip-  
5 tion drug product, if such changes conform to  
6 changes made pursuant to section 505G(d);

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

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

13 “(vi) addition of an interchangeable term  
14 in accordance with part 330.1 of title 21, Code  
15 of Federal Regulations.

16 “(B) The Secretary may, based on program im-  
17 plementation experience or other factors found ap-  
18 propriate by the Secretary, characterize any non-  
19 prescription drug order request as a Tier 2 non-  
20 prescription drug order request (including re-  
21 characterizing a request from Tier 1 to Tier 2) and  
22 publish such determination in a proposed order  
23 issued pursuant to section **【505G(c)(6)(A)】**.

1 **“SEC. 744L-1. AUTHORITY TO ASSESS AND USE NON-**  
2 **PRESCRIPTION DRUG FEES.**

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

6 “(1) FACILITY FEE.—

7 “(A) IN GENERAL.—Except as provided in  
8 subparagraph (B), each person that owns a fa-  
9 cility identified as a nonprescription drug facil-  
10 ity on December 31 of the fiscal year or at any  
11 time during the preceding 12-month period  
12 shall be assessed an annual fee for each such  
13 facility as determined under subsection (c).

14 “(B) EXCEPTION.—A fee shall not be as-  
15 sessed under subparagraph (A) if the identified  
16 nonprescription drug facility has ceased all ac-  
17 tivities related to nonprescription drug products  
18 prior to the publication of the Notice under  
19 subparagraph C and has updated its registra-  
20 tion to reflect such change under the require-  
21 ments for drug establishment registration set  
22 forth in section 510.

23 “(C) DUE DATE.—For each fiscal year, the  
24 facility fees required under subparagraph (A)  
25 shall be due on the later of—

1 “(i) the first business day of April of  
2 such year; and

3 “(ii) the first business day after the  
4 enactment of an appropriations Act pro-  
5 viding for the collection and obligation of  
6 fees under this section for such year.

7 “(2) NONPRESCRIPTION DRUG ORDER REQUEST  
8 FEE.—

9 “(A) IN GENERAL.—Each person that sub-  
10 mits a nonprescription drug order request shall  
11 be subject to a fee for a nonprescription drug  
12 order request. The nonprescription drug order  
13 request fee under paragraph (2) shall be—

14 “(i) for a tier 1 nonprescription drug  
15 order request, \$500,000, adjusted for in-  
16 flation for the fiscal year (as determined  
17 under subsection (c)(1)); and

18 “(ii) for a tier 2 nonprescription drug  
19 order request other than a tier 1 request,  
20 \$100,000 adjusted for inflation for the fis-  
21 cal year (as determined under subsection  
22 (c)(1)).

23 “(B) DUE DATE.—The nonprescription  
24 drug order request fees required under subpara-

1 graph (A) shall be due on the date of submis-  
2 sion of the nonprescription drug order request.

3 “(C) EXCEPTION FOR CERTAIN SAFETY  
4 CHANGES.—A person who is named as the re-  
5 questor in a nonprescription drug order shall  
6 not be subject to a fee under subparagraph (A)  
7 if the Secretary finds that the nonprescription  
8 drug order request seeks to change the Drug  
9 Facts labeling of a nonprescription drug prod-  
10 uct in a way that would add to or strengthen—

11 “(i) a contraindication, warning, or  
12 precaution;

13 “(ii) a statement about risk associated  
14 with misuse or abuse; or

15 “(iii) an instruction about dosage and  
16 administration that is intended to increase  
17 the safe use of the nonprescription drug  
18 product.

19 “(D) REFUND OF FEE IF ORDER REQUEST  
20 IS RECATEGORIZED AS A TIER 2 NONPRESCRIP-  
21 TION DRUG ORDER REQUEST.—If the Secretary  
22 determines that a nonprescription drug request  
23 initially characterized as Tier 1 should be re-  
24 characterized as a Tier 2 nonprescription drug  
25 order request, and the requestor has paid a

1 Tier 1 fee in accordance with subparagraph  
2 (A)(i), the Secretary shall refund the requestor  
3 the difference between the Tier 1 and Tier 2  
4 fees determined under subparagraphs (A)(i)  
5 and (A)(ii), respectively.

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

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

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

1 fee or a portion of the fee under this subpara-  
2 graph. A determination by the Secretary con-  
3 cerning a refund under this paragraph shall not  
4 be reviewable.

5 “(3) REFUNDS.—

6 “(A) IN GENERAL.—Other than refunds  
7 under subparagraphs (D) through (G) of para-  
8 graph (2), the Secretary shall not refund any  
9 fee paid under this subsection, except as pro-  
10 vided in subparagraph (B).

11 “(B) DISPUTES CONCERNING FEES.—To  
12 qualify for the return of a fee claimed to have  
13 been paid in error under this paragraph, a per-  
14 son shall submit to the Secretary a written re-  
15 quest justifying such return within 180 cal-  
16 endar days after such fee was paid.

17 “(4) NOTICE.—Within the timeframe specified  
18 in subsection (c), the Secretary shall publish in the  
19 Federal Register the amount of the fees under this  
20 subsection for such fiscal year.

21 “(b) FEE REVENUE AMOUNTS.—

22 “(1) FISCAL YEAR 2018.—For fiscal year 2018,  
23 fees under subsection (a)(1) shall be established to  
24 generate a total facility fee revenue amount equal to  
25 the sum of—

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

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

8           “(C) additional direct cost adjustments (as  
9           determined under subsection (c)(3)).

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

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

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

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

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

1           “(E) additional dollar amounts for each  
2           fiscal year as follows:

3                   “(i) \$7,000,000 for fiscal year 2019.

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

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

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

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

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

12                   “(B) for fiscal years 2019 through 2022,  
13           the dollar amount of the total revenue amount  
14           established under this subsection for the pre-  
15           vious fiscal year, not including any adjustments  
16           made under subsection (c)(2) or (c)(3).

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

18                   “(1) INFLATION ADJUSTMENT.—

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

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



1 “(ii) the inflation adjustment percent-  
2 age under subparagraph (B).

3 “(B) INFLATION ADJUSTMENT PERCENT-  
4 AGE.—The inflation adjustment percentage  
5 under this subparagraph for a fiscal year is  
6 equal to—

7 “(i) for each of fiscal years 2019  
8 through 2020, the average annual percent  
9 change that occurred in the Consumer  
10 Price Index for urban consumers (Wash-  
11 ington-Baltimore, DC–MD–VA–WV; Not  
12 Seasonally Adjusted; All items; Annual  
13 Index) for the first 3 years of the pre-  
14 ceding 4 years of available data; and

15 “(ii) for each of fiscal years 2021 and  
16 2022, the sum of—

17 “(I) the average annual percent  
18 change in the cost, per full-time equiv-  
19 alent position of the Food and Drug  
20 Administration, of all personnel com-  
21 pensation and benefits paid with re-  
22 spect to such positions for the first 3  
23 years of the preceding 4 fiscal years,  
24 multiplied by the proportion of per-  
25 sonnel compensation and benefits

1 costs to total costs of nonprescription  
2 drug activities (as defined in sub-  
3 section (a)) for the first 3 years of the  
4 preceding 4 fiscal years; and

5 “(II) the average annual percent  
6 change that occurred in the Consumer  
7 Price Index for urban consumers  
8 (Washington-Baltimore, DC–MD–VA–  
9 WV; Not Seasonally Adjusted; All  
10 items; Annual Index) for the first 3  
11 years of the preceding 4 years of  
12 available data multiplied by the pro-  
13 portion of all costs other than per-  
14 sonnel compensation and benefits  
15 costs to total costs of nonprescription  
16 drug activities for the first 3 years of  
17 the preceding 4 fiscal years.

18 “(2) OPERATING RESERVE ADJUSTMENT.—

19 “(A) For fiscal year 2018 and subsequent  
20 fiscal years, the Secretary may, in addition to  
21 adjustments under paragraphs (1) and (2), fur-  
22 ther increase the fee revenue and fees if such  
23 an adjustment is necessary to provide operating  
24 reserves of carryover user fees for nonprescrip-

1           tion drug activities for the number of weeks  
2           specified in subparagraph (B).

3           “(B) For each fiscal year the number of  
4           weeks of operating reserves shall be no more  
5           than—

6                       “(i) 3 weeks for fiscal year 2018;

7                       “(ii) 7 weeks for fiscal year 2019;

8                       “(iii) 10 weeks for fiscal year 2020;

9                       “(iv) 10 weeks for fiscal year 2021;

10                      and

11                      “(v) 10 weeks for fiscal year 2022.

12           “(C) If, for fiscal years 2019 through  
13           2022, the Secretary has carryover balances for  
14           nonprescription drug activities in excess of the  
15           number of weeks of such operating reserves  
16           specified in subparagraph B, the Secretary shall  
17           reduce such fee revenue and fees to provide for  
18           not more than the number of weeks of such op-  
19           erating reserves specified in subparagraph  
20           (B)(v).

21           “(D) If an adjustment under this para-  
22           graph is made, the rationale for the amount of  
23           the increase or decrease (as applicable) in fee  
24           revenue and fees shall be contained in the an-  
25           nual Federal Register notice under paragraph

1 (5) establishing fee revenue and fees for the fis-  
2 cal year involved.

3 “(3) ADDITIONAL DIRECT COST ADJUST-  
4 MENT.—The Secretary shall, in addition to adjust-  
5 ments under paragraphs (1) and (2), further in-  
6 crease the fee revenue by an amount equal to—

7 “(A) 14,000,000 for fiscal year 2018;

8 “(B) 7,000,000 for fiscal year 2019;

9 “(C) 4,000,000 for fiscal year 2020;

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

11 “(E) 3,000,000 for fiscal year 2022.

12 “(4) ANNUAL FEE SETTING.—

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

15 “(i) establish nonprescription drug fa-  
16 cility fees for fiscal year 2018 under sub-  
17 section (a)(1), based on the revenue  
18 amount for such year under subsection (b)  
19 and the adjustments provided under this  
20 subsection; and

21 “(ii) publish such fee revenue and fa-  
22 cility fees in the Federal Register.

23 “(B) SUBSEQUENT FISCAL YEARS.—The  
24 Secretary shall, not later than January 31 of  
25 each fiscal year that begins after September 30,

1           2018, establish for each such fiscal year, based  
2           on the revenue amounts under subsection (b)  
3           and the adjustments provided under this sub-  
4           section—

5                   “(i) nonprescription drug facility fees  
6                   under subsection (a)(1);

7                   “(ii) nonprescription drug order re-  
8                   quest fees under subsection (a)(2); and,

9                   “(iii) publish such fee revenue, facility  
10                  fees, and nonprescription drug order re-  
11                  quest fees in the Federal Register.

12          “(d) IDENTIFICATION OF FACILITIES.—Each person  
13          that owns a nonprescription drug facility shall submit to  
14          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 a nonprescription drug facility.

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

24                  “(1) A nonprescription drug order request sub-  
25                  mitted by a person subject to fees under subsection

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

4 “(2) A nonprescription drug requestor shall be  
5 considered ineligible for nonprescription drug meet-  
6 ings.

7 **【“(f) NONPRESCRIPTION DRUG FACILITY FEE.—】**

8 **【“(1) IN GENERAL.—**Failure to pay the fee  
9 under subsection (a)(1) within 20 calendar days of  
10 the due date as specified in subparagraph (D) of  
11 such subsection shall result in the following:**】**

12 **【“(A) The Secretary shall place the facility**  
13 **on a publicly available arrears list.】**

14 **【“(B) All nonprescription drug products**  
15 **manufactured in such a facility or containing**  
16 **an ingredient manufactured in such a facility**  
17 **shall be deemed misbranded under section**  
18 **502(a).】**

19 **【“(2) APPLICATION OF PENALTIES.—**The pen-  
20 alties under this paragraph shall apply until the fee  
21 established by subsection (a)(1) is paid.**】**

22 **“(g) CREDITING AND AVAILABILITY OF FEES.—**

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

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

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

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

20                   “(B) USE OF FEES AND LIMITATION.—  
21                   The fees authorized by this section shall be  
22                   available to defray increases in the costs of the  
23                   resources allocated for nonprescription drug ac-  
24                   tivities (including increases in such costs for an  
25                   additional number of full-time equivalent posi-

1 tions in the Department of Health and Human  
2 Services to be engaged in such activities), only  
3 if the Secretary allocates for such purpose an  
4 amount for such fiscal year (excluding amounts  
5 from fees collecting under this section) no less  
6 than \$12,000,000, multiplied by the adjustment  
7 factor applicable to the fiscal year involved.

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

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



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

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

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

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

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

3           “(a) PERFORMANCE REPORT.—Beginning with fiscal  
4 year 2018, and not later than 120 days after the end of  
5 each fiscal year thereafter for which fees are collected  
6 under this part, the Secretary shall prepare and submit  
7 to the Committee on the Health, Education, Labor, and  
8 Pensions of the Senate and the Committee on Energy and  
9 Commerce of the House of Representatives a report con-  
10 cerning the progress of the Food and Drug Administration  
11 in achieving the goals identified in the letters described  
12 in [section X of Policy Reform Statute] during such fiscal  
13 year and the future plans of the Food and Drug Adminis-  
14 tration for meeting such goals.

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

25           “(c) PUBLIC AVAILABILITY.—The Secretary shall  
26 make the reports required under subsections (a) and (b)

1 available to the public on the Internet Web site of the  
2 Food and Drug Administration.

3 “(d) REAUTHORIZATION.—

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

11 “(A) the Committee on Health, Education,  
12 Labor, and Pensions of the Senate;

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

15 “(C) scientific and academic experts;

16 “(D) health care professionals;

17 “(E) representatives of patient and con-  
18 sumer advocacy groups; and

19 “(F) the regulated industry.

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

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

1 “(B) publish such recommendations in the  
2 Federal Register;

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

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

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

12 “(3) TRANSMITTAL OF RECOMMENDATIONS.—  
13 Not later than January 15, 2022, the Secretary  
14 shall transmit to Congress the revised recommenda-  
15 tions under paragraph (2), a summary of the views  
16 and comments received under such paragraph, and  
17 any changes made to the recommendations in re-  
18 sponse to such views and comments.”.

19 **SEC. 4. MISBRANDING.**

20 Section 502 of the Federal Food, Drug and Cosmetic  
21 Act (21 U.S.C. 352) is amended by inserting after sub-  
22 section (cc) the following:

23 “(ee) If it is a nonprescription drug that is not the  
24 subject of an application approved under section 505, and

1 does not comply with the requirements under section  
2 505G.

3       【“(ff) Fee misbranding placeholder.”.】

4 **【SEC. 5. CONFORMING AMENDMENTS TO SUNSCREEN IN-**  
5 **NOVATION ACT.**

6       (a) REQUIREMENTS GOVERNING EFFECTIVENESS  
7 AND LABELING.—With respect to sunscreen drug prod-  
8 ucts subject to section 505G of the Federal Food, Drug,  
9 and Cosmetic Act, as added by section 2, the applicable  
10 requirements shall be those set out at part 352 of title  
11 21, Code of Federal Regulations, except that the applica-  
12 ble requirements governing effectiveness and labeling shall  
13 be those specified in section 201.327 of title 21, Code of  
14 Federal Regulations, subject to any changes to such re-  
15 quirements under 【subsections (b) or (k)(2) of section  
16 【101.】 of such title 21】.

17       (b) PROPOSED SUNSCREEN ORDERS ISSUED UNDER  
18 SUNSCREEN INNOVATION ACT.—In accordance with sub-  
19 section (a) , any proposed sunscreen orders issued under  
20 section 586C of the Federal Food, Drug, and Cosmetic  
21 Act (21 U.S.C. 360fff–3), prior to the date of enactment  
22 of this Act are deemed to be proposed administrative or-  
23 ders under section 505G(c) of the Federal Food, Drug,  
24 and Cosmetic Act and subject to the applicable provisions  
25 thereunder.