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.

IN THE SENATE OF THE UNITED STATES

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

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "_____ Act of _____".

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

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

"SEC. 505G. REGULATION OF CERTAIN NONPRESCRIPTION DRUGS THAT ARE MARKETED WITHOUT AN APPROVED NEW DRUG APPLICATION.

''(a) DEFINITIONS.—In this section:

''(1) NONPRESCRIPTION DRUG.—The term 'nonprescription drug' means a drug that is not subject to the requirements of section 503(b)(1).

''(2) REQUESTOR.—The term 'requestor' means a person or group of persons marketing, manufacturing, processing, or developing a drug.

''(3) SPONSOR.—The term 'sponsor' means a person or group of persons marketing, manufacturing, or processing a drug and who has a listing in effect under section 510(j) for such drug.

''(b) CERTAIN NONPRESCRIPTION DRUGS.—With respect to a drug that, on or after the date of enactment of the _____ Act of _____, is offered in interstate commerce as a nonprescription drug, the following 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

"(ii)(I) the subject of a tentative final monograph that is the most recently applicable proposal or determination issued under part 330 of title 21, Code of Federal Regulations, as of the date of enactment of the _____ Act of _____;

"(II) classified in category I for safety and effectiveness under such tentative final monograph;

"(III) in conformity with the conditions for nonprescription use of such tentative final monograph, any applicable final order under subsection (c)(5)(D), and the general conditions for nonprescription drugs, including any modifications of those conditions under subsections (c), (d), and **[**(l)**]** **[**(g)?**]**; and

"(IV) 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

"(B) the drug is in conformity with—

"(i) the conditions of a final administrative order issued under subsection (c) determining that the active ingredients in such drug are generally recognized as safe and effective within the meaning of section 201(p)(1); and

"(ii) the general conditions for nonprescription drugs, including any modifications of the requirements and conditions under subsections (c), (d), and **[**(l)**]**/**[**(g)?**]**.

"(2) A drug that is not a Category I drug may be lawfully marketed without an approved new drug application under section 505, is not subject to section 503(b)(1), and is referred to in this section as a 'lawfully marketed drug' if the drug is—

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

"(ii) classified in category III for safety or effectiveness under such tentative final monograph;

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

nonprescription use published in the Federal Register related to such tentative final monograph and the general conditions for nonprescription drugs, including any modifications of those requirements and conditions under subsections (c) and **[**(l)**]**/**[**(g)?**]**; and

''(iv) 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

''(B)(i) the subject of a proposed monograph or advance notice of proposed rulemaking that is the most recently applicable proposal or determination issued under part 330 of title 21, Code of Federal Regulations;

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

''(iii) in conformity with the most recently proposed or final rule establishing conditions of nonprescription use published in the Federal Register related to such proposed monograph or advance notice of proposed rulemaking and the general conditions for nonprescription drugs, including any modifications of those requirements

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

"(iv) 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).

"(3) A drug that is classified in category II for safety or effectiveness under a tentative final monograph or that the Secretary has determined not to be safe and effective in a final monograph or preamble to a rule that is the most recently applicable proposal or determination issued under part 330 of title 21, Code of Federal Regulations shall be deemed to be a new drug within the meaning of section 201(p), misbranded under section 502(ee), and subject to the requirement for an approved new drug application under section 505 beginning 180 days after the date of enactment of the _____ Act of _____, unless, before such day, the Secretary determines that it is in the interest of public health to extend the period during which the drug may be marketed without an approved new drug application under section 505. Such drug shall be referred to in this section as a 'Category II drug'.

''(4)(A) This section shall not affect the treatment or status of a nonprescription drug subject to section 505—

''(i) that, on the date of enactment of the _____ Act of _____, is marketed without an application approved under section 505; and

''(ii) to which paragraphs (1), (2), and (3) do not apply.

''(B) Nothing in this paragraph shall be construed to preclude or limit the applicability of any other provision of this Act.

''(5) A drug that is subject to the final monograph for sunscreen drug products set forth at part 352 of title 2, Code of Federal Regulations (as in effect on the date of enactment of the _____ Act of _____), shall comply with the requirements of that monograph, except that the testing requirements for effectiveness and the provisions governing labeling shall be in accordance with section 201.327 of title 21, Code of Federal Regulations (as in effect on the date of enactment of the _____ Act of _____), or such changes to those requirements as may be made under subsection **[**(c) or (d)**]** **[***should this be (j)?***]**.

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

"(c) ADMINISTRATIVE ORDERS.—[*Note: I think this subsection should be restructured to separate out the processes for hearing and judicial review, which are currently drafted in reference to paragraph (3), but have broader applicability. I would propose creating a new subsection for hearings and review, to separate that concept from the issuance of orders. This would be a large structural change, so please advise on whether you would want that in the next draft.*]

"(1) IN GENERAL.—

"(A) GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE.—The Secretary may, on the initiative of the Secretary or at the request of one or more requestors, issue an administrative order determining whether there are conditions under which a specific drug, class of such drugs, or combination of such drugs is determined to be—

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

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

"(iii) not required to be approved under section 505.

"(B) NOT GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE.—The Secretary shall **[**find**]**/**[**issue an order determining**]** that a drug is not generally recognized as safe and effective within the meaning of section 201(p)(1) for the specified conditions if—

"(i) the evidence shows that the drug is not generally recognized as safe and effective within the meaning of section 201(p)(1); or

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

"(2) NONAPPLICATION OF CERTAIN REQUIREMENTS.—The requirements of subchapter II of chapter 5 of title 5, United States Code shall not apply with respect to administrative orders issued under this subsection.

"(3) ADMINISTRATIVE ORDERS INITIATED BY THE SECRETARY.—

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

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

"(ii) after any such posting—

"(I) issue such a proposed administrative order by publishing it on the Internet website of the Food and Drug Administration and include in such order the reasons for the issuance of such order; and

"(II) publish notice of availability of such proposed order in the Federal Register;

"(iii) except as provided in subparagraph (B), provide for a public comment

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

''(iv) if, after satisfying the requirements of clauses (i) through (iii), the Secretary determines that it is appropriate to issue a final administrative order, the Secretary shall—

''(I) issue the final administrative order, together with a detailed statement of reasons, which order shall not take effect until the time for requesting judicial review under clause (ii) of paragraph (4)(D) has expired;

''(II) publish a notice of availability of such final administrative order in the Federal Register;

''(III) afford sponsors of products that will be subject to such order the opportunity for formal dispute resolution up to the level of the Director of the Center for Drug Evaluation and Research, which initially shall be requested within 45 days of the issuance of the order, and, for subse-

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

''(IV) except with respect to drugs described in paragraph (4)(B), upon completion of the formal dispute resolution procedure, inform the person or persons which sought such dispute resolution of their right to request a hearing.

''(B) SPECIAL REQUIREMENTS WITH RESPECT TO LAWFULLY MARKETED DRUGS.—When issuing an administrative order under paragraph (1) on the initiative of the Secretary (except as provided under paragraph (5)) proposing to determine that a lawfully marketed drug is not generally recognized as safe and effective within the meaning of section 201(p)(1), the Secretary shall follow the procedures in subparagraph (A) except that—

''(i) the proposed order shall include notice of—

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

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

"(II) the format for submissions by interested persons;

"(ii) the Secretary shall provide for a public comment period of no less than 180 calendar days with respect to such proposed order, except when the Secretary determines, for good cause, that a shorter period is in the interest of public health; and

"(iii) any person who submits data in such comment period shall include a certification that the person has submitted all evidence created, obtained, or received by that person that is both within the categories of data identified in the proposed order and relevant to a determination as to whether the drug is generally recognized as safe and effective within the meaning of section 201(p)(1).

"(4) HEARINGS; JUDICIAL REVIEW.—

"(A) IN GENERAL.—A person who participated in each level of formal dispute resolution under paragraph (3)(A)(iv)(III) of an administrative order with respect to a drug may re-

quest a hearing concerning a final administrative order issued under paragraph (3)(A)(iv) with respect to such drug. Such person may submit a request for a hearing, which shall be based solely on the information in the administrative record, to the Secretary not later than 30 days after receiving notice of the final decision of the formal dispute resolution procedure.

"(B) NO HEARING REQUIRED WITH RESPECT TO ORDERS RELATING TO CERTAIN DRUGS.—The Secretary is not required to provide notice and an opportunity for a hearing pursuant to paragraph (3)(A)(iv) if the final administrative order involved relates to a drug—

"(i) that is described in subsection (b)(2)(A); and

"(ii) with respect to which no data relevant to the safety or effectiveness of such drug have been submitted to the administrative record since the issuance of the most recent tentative final monograph relating to such drug.

"(C) HEARING PROCEDURES.—

"(i) DENIAL OF REQUEST FOR HEARING.—If the Secretary determines that a request for a hearing under subparagraph (A) with respect to a final administrative order issued under paragraph (3)(A)(iv), does not establish the existence of a genuine and substantial question of material fact, the Secretary may deny such request. In making such a determination, the Secretary may consider only information and data that are based on relevant and reliable scientific principles and methodologies.

"(ii) SINGLE HEARING FOR MULTIPLE RELATED REQUESTS.—If more than one request for a hearing is submitted with respect to the same administrative order under subparagraph (A), the Secretary may direct that a single hearing be conducted in which all persons whose hearing requests were granted may participate.

"(iii) PRESIDING OFFICER.—The Commissioner of Food and Drugs shall appoint a presiding officer of a hearing requested under subparagraph (A) who—

"(I) is not an employee of the Center for Drug Evaluation and Research; and

"(II) has not previously been involved in the development of the applicable administrative order or in the proceedings relating to that administrative order.

"(iv) RIGHTS OF PARTIES TO HEARING.—The parties to a hearing requested under subparagraph (A) shall have the right to present testimony, including testimony of expert witnesses, and to cross-examine witnesses presented by other parties. Where appropriate, the presiding officer may require that cross-examination by parties representing substantially the same interests be consolidated to promote efficiency and avoid duplication.

"(v) FINAL DECISION.—At the conclusion of a hearing requested under subparagraph (A), the presiding officer of the hearing shall issue a decision containing findings of fact and conclusions of law. The decision of the presiding officer shall

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

"(D) JUDICIAL REVIEW OF FINAL ADMINISTRATIVE ORDER.—

"(i) IN GENERAL.—The procedures described in section 505(h) shall apply with respect to judicial review of final administrative orders issued under this subsection in the same manner and to the same extent as such section applies to an order described in such section except that the judicial review shall be taken by filing in an appropriate district court of the United States in lieu of the appellate courts specified in such section.

"(ii) TIME TO SUBMIT A REQUEST FOR JUDICIAL REVIEW.—A person eligible to request a hearing under this paragraph and seeking judicial review of a final administrative order issued under this subsection shall file such appeal not later than 60 days after the latest of—

"(I) the date on which notice of such order is published;

"(II) the date on which any hearing with respect to such order is denied under subparagraph [(B)] [*This does not allow for a denial, but only explains when a hearing is not available--strike?*] or (C)(i);

"(III) the date on which a final decision is made following any hearing with respect to such order under subparagraph (C)(v); or

"(IV) if no hearing is requested, the date on which the time for requesting a hearing expires.

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

"(A) IMMINENT HAZARD TO THE PUBLIC HEALTH.—

"(i) IN GENERAL.—In the case of a determination by the Secretary that a drug, class of drugs, or combination of drugs subject to this section poses an imminent hazard to the public health, the

Secretary may, after notifying any sponsor that will be the subject of such determination, not later than 48 hours before issuance of an order under this subparagraph—

"(I) issue an interim final administrative order for such drug or combination of drugs under paragraph (1), together with a detailed statement of the reasons for such order;

"(II) publish in the Federal Register a notice of availability of such order; and

"(III) provide for a public comment period of at least 45 calendar days with respect to such interim final order.

"(ii) NONDELEGATION.—The Secretary may not delegate the authority to issue an interim final administrative order under this subparagraph.

"(B) SAFETY LABELING CHANGES.—

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

drugs, or combination of drugs subject to this section is reasonably expected to mitigate a significant or unreasonable risk of a serious adverse event associated with use of the drug, the Secretary may—

''(I) notify, not later than 48 hours before the issuance of the interim final order, the sponsor or group of sponsors of any drug that will be the subject of such determination;

''(II) after notification, issue an interim final administrative order in accordance with paragraph (1) to require such change, together with a detailed statement of the reasons for such order;

''(III) publish in the Federal Register a notice of availability of such order; and

''(IV) provide for a public comment period of at least 45 calendar days with respect to such interim final order.

"(ii) CONTENT OF ORDER.—An interim final order issued under this subparagraph with respect to the labeling of a drug may provide for new warnings and other information required for safe use of the drug.

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

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

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

"(ii) publish a notice of availability of such final administrative order in the Federal Register; and

"(iii) afford sponsors of drugs that will be subject to such an order the opportunity for formal dispute resolution up to the level of the Director of the Center for Drug Evaluation and Research, which initially shall be within 45 days of the issuance of the order; and, for subsequent

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

''(E) HEARINGS.—

''(i) IN GENERAL.—A sponsor of a drug subject to a final order issued under subparagraph (A) or (B) who participated in each level of formal dispute resolution under subparagraph (D)(iii) may request a hearing on such order. The provisions of subparagraphs (A), (B), and (C) of paragraph (4) shall apply with respect to a hearing on such order in the same manner and to the same extent as such provisions apply with respect to a hearing on an administrative order issued under paragraph (3)(A)(iv).

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

''(I) to 'each level of dispute resolution under paragraph (3)(A)(iv)(III)' shall be deemed to mean 'each level of formal dispute res-

olution under subparagraph (D)(iii)'; and

"'(II) to 'final administrative order issued under paragraph (3)(A)(iv)' shall be deemed to mean 'final order under subparagraph (D)(i)'.

"'(F) FINAL ORDER.—Not later than 1 year after the date on which an interim final order is issued under subparagraph (A) or (B), the Secretary shall issue a final order in accordance with paragraph (1) and complete any required hearing.

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

"'(H) CLARIFICATION.—Paragraph (3) shall not apply to the orders issued under this paragraph.

"'(6) ADMINISTRATIVE ORDER INITIATED BY REQUEST.—

"'(A) IN GENERAL.—In issuing an administrative order under paragraph (1) at the request of a requestor or a group of requestors

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

"(i) the Secretary shall, after receiving a request under this subparagraph, determine whether the request is sufficiently complete and formatted to permit a substantive review;

"(ii) if the Secretary determines that the request is sufficiently complete and formatted to permit a substantive review, the Secretary shall—

"(I) file the request; and

"(II) initiate proceedings with respect to issuing an administrative order in accordance with paragraphs (3) and (4); and

"(iii) except as provided in paragraph (7), if the Secretary determines that a request does not meet the requirements for filing or is not sufficiently complete or formatted to permit a substantive review, the requestor may elect that the Secretary file the request over protest, and the Secretary shall initiate proceedings to review the request in accordance with paragraph (3)(A).

"(B) REQUEST TO INITIATE PROCEEDINGS.—

"(i) IN GENERAL.—A requestor seeking an administrative order with respect to certain drugs, classes of drugs, or combinations of drugs, shall submit to the Secretary a request to initiate proceedings for such order in the form and manner as specified by the Secretary. Such requestor may submit a request under this subparagraph for the issuance of an administrative order—

"(I) determining whether a drug is generally recognized as safe and effective within the meaning of section 201(p)(1), exempt from section 503(b)(1), and not required to be the subject of an approved application under section 505; or

"(II) determining whether a change to a condition of use of a drug is generally recognized as safe and effective within the meaning of section 201(p)(1), exempt from section 503(b)(1), and not required to be the

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

"(aa) a Category I drug; or

"(bb) a lawfully marketed drug, but only if such requestor initiates such request in conjunction with a request for the Secretary to determine whether such drug is generally recognized as safe and effective within the meaning of section 201(p)(1), which is filed by the Secretary under subparagraph (A)(ii)(I).

The Secretary is not required to complete review of the request for a change described in subclause (II) if the Secretary determines that there is an inadequate basis to find the drug is generally recognized as safe and effective under paragraph (1) and issues a final order announcing that determination.

"(ii) WITHDRAWAL OF REQUEST.—The requestor may withdraw a request under this paragraph, according to the procedures established by the Secretary.

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

''(C) PRODUCT DIFFERENTIATION.—

''(i) IN GENERAL.—In the case of a final order issued under this paragraph providing for a change in the conditions of use of a drug with respect to which original human data submitted by the requestor of the drug were essential to the issuance of such order, the administrative order shall, for a period of **[**2 years**]** after the date on which the order is issued, be effective only with respect to drugs marketed by the requestor that submitted the request under subparagraph (A) (or the licensees, assignees, or successors in interest of such requestor) with respect to such drug. Only one **[**2-year**]** period shall be provided for the same change in the formulation or conditions of use of the same drug.

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

'human data' means data from any testing with human subjects, including clinical trials of safety or effectiveness (including actual use studies), pharmacokinetics, or bioavailability.

"(7) INFORMATION REGARDING SAFE NONPRESCRIPTION MARKETING AND USE AS A CONDITION FOR FILING A GRASE REQUEST.—[*Should this be under paragraph (6)?*]

"(A) IN GENERAL.—In response to a request under paragraph (6) that a drug described in subparagraph (B) be generally recognized as safe and effective, the Secretary—

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

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

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

"(i) marketed in accordance with a final monograph issued under section 330 of title 21, Code of Federal Regulations (including conditions of use under such section), as in effect on the date of enactment of this section;

"(ii) marketed as category I in accordance with a tentative final monograph issued under [section 330 of title 21, Code of Federal Regulations] [*Check citation--this appears to be incorrect*] (including conditions of use and any applicable subsequent determinations under such section), as in effect on the date of enactment of this section; or

"(iii) marketed in accordance with a final order issued under this section.

"(C) INFORMATION DEMONSTRATING PRIMA FACIE SAFE NONPRESCRIPTION MARKETING AND USE.—Information specified in

this subparagraph, with respect to a request described in subparagraph (A)(i), is—

"(i) information sufficient to demonstrate that the drug subject to such request has a verifiable history of being marketed and safely used by consumers in the United States as a nonprescription drug under comparable conditions of use; or

"(ii) if the drug has not been previously marketed in the United States as a nonprescription drug, information sufficient to demonstrate that the drug was marketed and safely used in a foreign country under comparable conditions of marketing and use—

"(I) for such period of time as needed to provide reasonable assurances concerning the safe nonprescription use of the drug; and

"(II) during such period of time, was subject to sufficient monitoring by a regulatory body considered acceptable by the Secretary for such monitoring purposes, including for ad-

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

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

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

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

''(E) RULE OF APPLICATION.—If the Secretary refuses to file a request under this paragraph, the requestor may not file over protest under paragraph (6)(A)(iii).

''(8) FINAL AND TENTATIVE FINAL MONOGRAPHS FOR CATEGORY I DRUGS.—A final mono-

graph or tentative final monograph establishing conditions of use for a Category I drug shall be deemed to be a final administrative order under this subsection and may be amended, revoked, or otherwise modified in accordance with the procedures of this subsection.

''(d) PROCEDURE FOR MINOR CHANGES.—

''(1) IN GENERAL.—Minor changes in the dosage form of a drug that is described in subparagraph (A) or (B) of subsection (b)(1) may be made by a requestor without the issuance of an administrative order under subsection (c) if—

''(A) the requestor maintains information necessary to demonstrate that the change—

''(i) will not affect the safety or effectiveness of the drug; and

''(ii) will not materially affect the extent of absorption or other exposure to the active ingredient in comparison to a suitable reference product; and

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

introduced into interstate commerce with the change;

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

''(2) ADDITIONAL INFORMATION.—

''(A) ACCESS TO RECORDS.—The requestor shall submit records requested related to a minor change under section 704 to the Secretary within 15 business days of receiving such request, or such longer period as the Secretary may provide.

''(B) INSUFFICIENT INFORMATION.—If the Secretary determines that the information contained in such records is not sufficient to demonstrate that the change does not affect the safety or effectiveness of the drug or materially affect the extent of absorption or other exposure to the active ingredient, the Secretary—

''(i) may so inform the requestor of the drug in writing; and

''(ii) provide the requestor of the drug with a reasonable opportunity to provide additional information.

"(C) FAILURE TO SUBMIT SUFFICIENT INFORMATION.—If the requestor fails to provide such additional information within the prescribed time, or if the Secretary determines that such additional information does not demonstrate that the change does not affect the safety or effectiveness of the drug or materially affect the extent of absorption or other exposure to the active ingredient, the drug as modified is a new drug within the meaning of section 201(p) and shall be deemed to be misbranded under section 502(ee).

"(3) DETERMINING WHETHER CHANGE WILL AFFECT SAFETY OR EFFECTIVENESS.—

"(A) IN GENERAL.—The Secretary shall issue one or more administrative orders specifying requirements for determining whether a minor change made by a requestor pursuant to this subsection will affect the safety or effectiveness of a drug or materially affect the extent of absorption or other exposure to an active ingredient in the drug in comparison to a suitable reference product, together with guidance for applying those orders to specific dosage forms.

"(B) STANDARD PRACTICES.—The orders and guidance issued by the Secretary under subparagraph (A) shall take into account relevant public standards and standard practices for evaluating the quality of drug products.

"(e) INFORMATION SUBMITTED BY REQUESTORS.—

"(1) CONFIDENTIAL INFORMATION.—Any information, including reports of testing conducted on the drug or drugs involved, that is submitted by a requestor in connection with proceedings on an administrative order under this section (or any minor change under subsection (d)) and is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code, shall not be disclosed to the public unless the requestor consents to that disclosure.

"(2) PUBLIC AVAILABILITY LIMITATIONS.—The Secretary shall make available to the public any information submitted by a requestor in support of a request under subsection (c)(6)(A) as of the date on which the proposed order is issued unless—

"(A) the information pertains to pharmaceutical quality information which is necessary to establish standards under which a drug is

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

"(B) the information is submitted in a requestor-initiated request, but the requestor withdraws such request before the Secretary issues the proposed order in accordance with withdrawal procedures established by the Secretary; or

"(C) the Secretary otherwise obtains the information under subsection (d).

"(f) PUBLIC AVAILABILITY OF ADMINISTRATIVE ORDERS.—The Secretary shall establish, maintain, update (as the Secretary determines necessary, but not less frequently than annually), and make available on the Internet website of the Food and Drug Administration—

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

"(2) a listing of all administrative orders proposed and under development under this section, including—

"(A) a brief description of the administrative order; and

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

"(g) UPDATES TO DRUG LISTING INFORMATION.—A sponsor who makes a change to a drug described in paragraph (1) or (2) of subsection (b) shall submit updated drug listing information for the drug in accordance with the requirements of section 510(j) within 30 days of the date on which the drug is first introduced into interstate commerce with the change.

"(h) APPROVALS UNDER SECTION 505.—This section shall not be construed to preclude a sponsor of a drug or requestor from seeking or maintaining the approval of an application for such drug under subsection (b)(1), (b)(2), or (j) of section 505. A determination under this section that a drug is not subject to section 503(b)(1), is generally recognized as safe and effective within the meaning of 201(p)(1), and is not a new drug under section 201(p) shall constitute a finding of safety and effectiveness for purposes of section 505(b)(2), so that the applicant shall be required to submit only that information needed to support the modification of the drug that is subject to the determination under this section.

"(i) DEVELOPMENT ADVICE TO REQUESTORS OR SPONSORS.—

''(1) IN GENERAL.—The Secretary may establish procedures under which requestors may meet with appropriate officials of the Food and Drug Administration to obtain advice on the studies and other information necessary to support submissions under this section and other matters relevant to the regulation of nonprescription drugs and the development of new nonprescription drugs under this section.

''(2) PARTICIPATION OF MULTIPLE SPONSORS.—The Secretary shall establish procedures to facilitate efficient participation by multiple requestors in proceedings under this section, including provision for joint meetings with multiple requestors or with organizations nominated by requestors to represent their interests in a proceeding.

''(3) PUBLICATION OF MEETING SUMMARIES.—The Secretary shall publish a summary of any meeting held under this subsection, in a manner consistent with subsection (e).

''(j) EFFECT ON EXISTING REGULATIONS GOVERNING NONPRESCRIPTION DRUGS.—

''(1) EXISTING REGULATIONS.—Except as provided in this subsection, nothing in this section supersedes regulations establishing requirements for

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

''(2) SPECIAL LABELING REQUIREMENTS.—

''(A) IN GENERAL.—The Secretary shall establish or modify regulations in effect on the day before the date of enactment of this section establishing general requirements for nonprescription drugs and regulations of general applicability contained in parts 201, 250, and 330 of title 21, Code of Federal Regulations (or any successor regulations).

''(B) EFFECTIVE DATE PERIOD.—Unless withdrawn or revised by the Secretary, the regulations described in subparagraph (A) shall remain in effect in title 21 of the Code of Federal Regulations as they apply to drugs not subject to paragraphs (1) through (4) of subsection (b).

''(3) PROCEDURAL REGULATIONS.—The Secretary shall withdraw regulations establishing final monographs and the procedures governing the over-

the-counter drug review under part 330 and other relevant parts of title 21, Code of Federal Regulations (as in effect on the date immediately before this section takes effect), or make technical changes to such regulations to ensure conformity with appropriate terminology and cross references, to the extent needed to effectuate or harmonize the provisions of this section. Notwithstanding subchapter II of chapter 5 of title 5, United States Code, any such withdrawal or technical amendments shall be effective upon publication through notice in the Federal Register (or upon such date as specified in such notice).

''(k) GUIDANCE.—

''(1) ISSUANCE.—The Secretary shall issue guidance that provides—

''(A) the procedures and principles for formal meetings between the Secretary and sponsors or requestors for drugs subject to this section;

''(B) the format and content of data submissions to the Secretary under this section;

''(C) the format of electronic submissions to the Secretary under this section;

''(D) consolidated proceedings and the procedures for such proceedings where appropriate; and

''(E) for minor changes in drugs, recommendations on how to comply with the requirements in administrative orders issued under subsection (c)(3).

''(l) ELECTRONIC FORMAT.—All submissions under this section shall be in a format specified by the Secretary after providing a period for public comment.''.

SEC. 3. AUTHORIZATION OF USER FEES.

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

''PART 10—FEES RELATING TO NONPRESCRIPTION DRUGS

''SEC. 744L. DEFINITIONS.

''For purposes of this part:

''(1) The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

''(A) one business entity controls, or has the power to control, the other business entity; or

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

"(2) The term 'costs of resources allocated for nonprescription drug activities' means the expenses in connection with nonprescription drug activities for—

"(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees and to contracts with such contractors;

"(B) management of information, and the acquisition, maintenance, and repair of computer resources;

"(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

"(D) collecting fees under [section 744L–1] and accounting for resources allocated for nonprescription drug activities.

"(3) The term 'firm establishment identifier' is the unique number automatically generated by the

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

''(5) The term 'nonprescription drug activities' means activities of the Secretary associated with nonprescription drug products and inspection of facilities associated with such products, including—

''(A) the activities necessary for review and evaluation of nonprescription drugs and nonprescription drug order requests, including—

''(i) orders proposing or finalizing applicable conditions of use for nonprescription drugs products;

''(ii) orders affecting status regarding general recognition of safety and effectiveness of a nonprescription drug ingredient or combination of ingredients under specified conditions of use;

''(iii) all nonprescription drug development and review activities, including intra-agency collaboration;

''(iv) regulation and policy development activities related to nonprescription drugs;

"(v) development of product standards for products subject to review and evaluation;

"(vi) meetings regarding nonprescription drug activities;

"(vii) review of labeling prior to issuance of orders related to nonprescription drugs or conditions of use; and

"(viii) regulatory science activities related to nonprescription drugs;

"(B) inspections related to nonprescription drugs;

"(C) monitoring of clinical and other research conducted in connection with nonprescription drugs;

"(D) safety activities with respect to nonprescription drugs, including—

"(i) collecting, developing, and reviewing safety information on nonprescription drugs, including adverse event reports;

"(ii) developing and using improved adverse event data-collection systems, including information technology systems; and

"(iii) developing and using improved analytical tools to assess potential safety risks, including access to external databases; and

"(E) other activities necessary for implementation of section 505G.

"(6)(A) The term 'nonprescription drug facility' means a foreign or domestic business or other entity—

"(i) that is under 1 management, either direct or indirect; and

"(ii) at 1 geographic location or address engaged in manufacturing or processing a nonprescription drug finished dosage form;

"(iii) includes a finished dosage form manufacturer facility or an affiliate thereof in a contractual relationship with a nonprescription drug requestor or requestors to manufacture or process nonprescription drugs; and

"(iv) does not include a business or other entity whose only manufacturing or processing activities relate to—

"(I) production of clinical research supplies; or

"(II) testing.

"(B) For purposes of subparagraph (A), separate buildings or locations within close proximity are considered to be at 1 geographic location or address if the activities conducted in them are—

"(i) closely related to the same business enterprise;

"(ii) under the supervision of the same local management; and

"(iii) under a single firm establishment identifier and capable of being inspected by the Food and Drug Administration during a single inspection.

"(C) If a business or other entity would meet the definition of a facility under this paragraph but for being under multiple management, the business or other entity is deemed to constitute multiple facilities, one per management entity, for purposes of this paragraph.

"(7) The term 'nonprescription drug meeting' means any meeting regarding the content of a proposed nonprescription drug order request.

"(8) The term 'nonprescription drug product' means a nonprescription drug product that is marketed without an approved new drug application in accordance with section 505G(b).

''(9) The term 'nonprescription drug order request' means a request for an order under section 505G for the issuance of an administrative order for a change to the nonprescription drug product.

''(10) The term 'nonprescription drug requestor' means an entity submitting a nonprescription drug order request or a nonprescription drug meeting request or any other inquiry relating to a request for an order or development of a nonprescription drug order request.

''(11) The term 'person' includes an affiliate thereof.

''(12) The term 'Tier 1 nonprescription drug order request' means any nonprescription drug order request not determined to be a Tier 2 nonprescription drug order request.

''(13)(A) The term 'Tier 2 nonprescription drug order request' means subject to subparagraph (B), a nonprescription drug monograph order request for—

''(i) the reordering of existing information in the drug facts label of a nonprescription drug product;

''(ii) the addition of information to the other information section of the drug facts label of an nonprescription drug product, as limited

by part 201.66(c)(7) of title 21, Code of Federal Regulations;

"(iii) modification to the directions for use section of the drug facts label of a nonprescription drug product, if such changes conform to changes made pursuant to section 505G(d);

"(iv) the standardization of the concentration or dose of a specific finalized ingredient within a particular finalized monograph;

"(v) a change to ingredient nomenclature to align with nomenclature of a standards-setting organization; or

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

"(B) The Secretary may, based on program implementation experience or other factors found appropriate by the Secretary, characterize any nonprescription drug order request as a Tier 2 nonprescription drug order request (including recharacterizing a request from Tier 1 to Tier 2) and publish such determination in a proposed order issued pursuant to section **[**505G(c)(6)(A)**]**.

"SEC. 744L–1. AUTHORITY TO ASSESS AND USE NON-PRESCRIPTION DRUG FEES.

"(a) TYPES OF FEES.—Beginning with fiscal year 2018, the Secretary shall assess and collect fees in accordance with this section as follows:

"(1) FACILITY FEE.—

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

"(B) EXCEPTION.—A fee shall not be assessed under subparagraph (A) if the identified nonprescription drug facility has ceased all activities related to nonprescription drug products prior to the publication of the Notice under subparagraph C and has updated its registration to reflect such change under the requirements for drug establishment registration set forth in section 510.

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

"(i) the first business day of April of such year; and

"(ii) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees under this section for such year.

"(2) NONPRESCRIPTION DRUG ORDER REQUEST FEE.—

"(A) IN GENERAL.—Each person that submits a nonprescription drug order request shall be subject to a fee for a nonprescription drug order request. The nonprescription drug order request fee under paragraph (2) shall be—

"(i) for a tier 1 nonprescription drug order request, $500,000, adjusted for inflation for the fiscal year (as determined under subsection (c)(1)); and

"(ii) for a tier 2 nonprescription drug order request other than a tier 1 request, $100,000 adjusted for inflation for the fiscal year (as determined under subsection (c)(1)).

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

graph (A) shall be due on the date of submission of the nonprescription drug order request.

''(C) EXCEPTION FOR CERTAIN SAFETY CHANGES.—A person who is named as the requestor in a nonprescription drug order shall not be subject to a fee under subparagraph (A) if the Secretary finds that the nonprescription drug order request seeks to change the Drug Facts labeling of a nonprescription drug product in a way that would add to or strengthen—

''(i) a contraindication, warning, or precaution;

''(ii) a statement about risk associated with misuse or abuse; or

''(iii) an instruction about dosage and administration that is intended to increase the safe use of the nonprescription drug product.

''(D) REFUND OF FEE IF ORDER REQUEST IS RECATEGORIZED AS A TIER 2 NONPRESCRIPTION DRUG ORDER REQUEST.—If the Secretary determines that a nonprescription drug request initially characterized as Tier 1 should be recharacterized as a Tier 2 nonprescription drug order request, and the requestor has paid a

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

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

"(F) FEES FOR ORDER REQUESTS PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—A nonprescription drug order request that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest.

"(G) REFUND OF FEE IF ORDER REQUEST WITHDRAWN.—If an order request is withdrawn after the order request was filed, the Secretary may refund the fee or a portion of the fee if no substantial work was performed on the order request after the application was filed. The Secretary shall have the sole discretion to refund a

fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.

''(3) REFUNDS.—

''(A) IN GENERAL.—Other than refunds under subparagraphs (D) through (G) of paragraph (2), the Secretary shall not refund any fee paid under this subsection, except as provided in subparagraph (B).

''(B) DISPUTES CONCERNING FEES.—To qualify for the return of a fee claimed to have been paid in error under this paragraph, a person shall submit to the Secretary a written request justifying such return within 180 calendar days after such fee was paid.

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

''(b) FEE REVENUE AMOUNTS.—

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

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

"(B) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(2)); and

"(C) additional direct cost adjustments (as determined under subsection (c)(3)).

"(2) SUBSEQUENT FISCAL YEARS.—For each of the fiscal years 2019 through 2022, fees under subsection (a)(1) shall be established to generate a total facility fee revenue amount equal to the sum of—

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

"(B) the dollar amount equal to the inflation adjustment for the fiscal year (as determined under subsection (c)(1));

"(C) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(2));

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

"(E) additional dollar amounts for each fiscal year as follows:

"(i) $7,000,000 for fiscal year 2019.

"(ii) $6,000,000 for fiscal year 2020.

"(iii) $7,000,000 for fiscal year 2021.

"(iv) $3,000,000 for fiscal year 2022.

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

"(A) for fiscal year 2018, $8,000,000; and

"(B) for fiscal years 2019 through 2022, the dollar amount of the total revenue amount established under this subsection for the previous fiscal year, not including any adjustments made under subsection (c)(2) or (c)(3).

"(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

"(1) INFLATION ADJUSTMENT.—

"(A) IN GENERAL.—For purposes of subsection (b)(2)(B), the dollar amount of the inflation adjustment to the annual base revenue for fiscal year 2019 and each subsequent fiscal year shall be equal to the product of—

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

"(ii) the inflation adjustment percentage under subparagraph (B).

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

"(i) for each of fiscal years 2019 through 2020, the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data; and

"(ii) for each of fiscal years 2021 and 2022, the sum of—

"(I) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits

costs to total costs of nonprescription drug activities (as defined in subsection (a)) for the first 3 years of the preceding 4 fiscal years; and

"(II) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of nonprescription drug activities for the first 3 years of the preceding 4 fiscal years.

"(2) OPERATING RESERVE ADJUSTMENT.—

"(A) For fiscal year 2018 and subsequent fiscal years, the Secretary may, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenue and fees if such an adjustment is necessary to provide operating reserves of carryover user fees for nonprescrip-

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

''(B) For each fiscal year the number of weeks of operating reserves shall be no more than—

''(i) 3 weeks for fiscal year 2018;

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

''(iii) 10 weeks for fiscal year 2020;

''(iv) 10 weeks for fiscal year 2021; and

''(v) 10 weeks for fiscal year 2022.

''(C) If, for fiscal years 2019 through 2022, the Secretary has carryover balances for nonprescription drug activities in excess of the number of weeks of such operating reserves specified in subparagraph B, the Secretary shall reduce such fee revenue and fees to provide for not more than the number of weeks of such operating reserves specified in subparagraph (B)(v).

''(D) If an adjustment under this paragraph is made, the rationale for the amount of the increase or decrease (as applicable) in fee revenue and fees shall be contained in the annual Federal Register notice under paragraph

(5) establishing fee revenue and fees for the fiscal year involved.

''(3) ADDITIONAL DIRECT COST ADJUSTMENT.—The Secretary shall, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenue by an amount equal to—

''(A) 14,000,000 for fiscal year 2018;

''(B) 7,000,000 for fiscal year 2019;

''(C) 4,000,000 for fiscal year 2020;

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

''(E) 3,000,000 for fiscal year 2022.

''(4) ANNUAL FEE SETTING.—

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

''(i) establish nonprescription drug facility fees for fiscal year 2018 under subsection (a)(1), based on the revenue amount for such year under subsection (b) and the adjustments provided under this subsection; and

''(ii) publish such fee revenue and facility fees in the Federal Register.

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

2018, establish for each such fiscal year, based on the revenue amounts under subsection (b) and the adjustments provided under this subsection—

"(i) nonprescription drug facility fees under subsection (a)(1);

"(ii) nonprescription drug order request fees under subsection (a)(2); and,

"(iii) publish such fee revenue, facility fees, and nonprescription drug order request fees in the Federal Register.

"(d) IDENTIFICATION OF FACILITIES.—Each person that owns a nonprescription drug facility shall submit to the Secretary the information required under this subsection each year. Such information shall, for each fiscal year—

"(1) be submitted as part of the requirements for drug establishment registration set forth in section 510; and

"(2) include for each such facility, at a minimum, identification of the facility's business operation as that of a nonprescription drug facility.

"(e) EFFECT OF FAILURE TO PAY FEES.—

"(1) A nonprescription drug order request submitted by a person subject to fees under subsection

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

''(2) A nonprescription drug requestor shall be considered ineligible for nonprescription drug meetings.

[''(f) NONPRESCRIPTION DRUG FACILITY FEE.—]

[''(1) IN GENERAL.—Failure to pay the fee under subsection (a)(1) within 20 calendar days of the due date as specified in subparagraph (D) of such subsection shall result in the following:]

[''(A) The Secretary shall place the facility on a publicly available arrears list.]

[''(B) All nonprescription drug products manufactured in such a facility or containing an ingredient manufactured in such a facility shall be deemed misbranded under section 502(a).]

[''(2) APPLICATION OF PENALTIES.—The penalties under this paragraph shall apply until the fee established by subsection (a)(1) is paid.]

''(g) CREDITING AND AVAILABILITY OF FEES.—

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

tent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for nonprescription drug activities.

''(2) COLLECTIONS AND APPROPRIATION ACTS.—

''(A) IN GENERAL.—Subject to subparagraphs (C) and (D), the fees authorized by this section shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year.

''(B) USE OF FEES AND LIMITATION.—The fees authorized by this section shall be available to defray increases in the costs of the resources allocated for nonprescription drug activities (including increases in such costs for an additional number of full-time equivalent posi-

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

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

''(D) FEE COLLECTION DURING FIRST PROGRAM YEAR.—Until the date of enactment of an Act making appropriations and providing for the collection and obligation of fees under this section through September 30, 2018, for the salaries and expenses account of the Food and Drug Administration, fees authorized by this section for fiscal year 2018 may be collected and shall be credited to such account and remain available until expended.

"(E) PROVISION FOR EARLY PAYMENTS IN SUBSEQUENT YEARS.—Payment of fees authorized under this section for a fiscal year (after fiscal year 2018), prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

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

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

"(i) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in nonprescription drug activities, be reduced to offset the number of officers, employees, and advisory committees so engaged.

"SEC. 744L–2. REAUTHORIZATION; REPORTING REQUIREMENTS.

"(a) PERFORMANCE REPORT.—Beginning with fiscal year 2018, and not later than 120 days after the end of each fiscal year thereafter for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on the Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in [section X of Policy Reform Statute] during such fiscal year and the future plans of the Food and Drug Administration for meeting such goals.

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

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

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

''(d) REAUTHORIZATION.—

''(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals described in subsection (a), and plans for meeting the goals, for nonprescription drug activities for the first 5 fiscal years after fiscal year 2022, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

''(A) the Committee on Health, Education, Labor, and Pensions of the Senate;

''(B) the Committee on Energy and Commerce of the House of Representatives;

''(C) scientific and academic experts;

''(D) health care professionals;

''(E) representatives of patient and consumer advocacy groups; and

''(F) the regulated industry.

''(2) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

''(A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;

"(B) publish such recommendations in the Federal Register;

"(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

"(D) hold a meeting at which the public may present its views on such recommendations; and

"(E) after consideration of such public views and comments, revise such recommendations as necessary.

"(3) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2022, the Secretary shall transmit to Congress the revised recommendations under paragraph (2), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.".

SEC. 4. MISBRANDING.

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

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

does not comply with the requirements under section 505G.

[''(ff) Fee misbranding placeholder.''.]

[SEC. 5. CONFORMING AMENDMENTS TO SUNSCREEN INNOVATION ACT.

(a) REQUIREMENTS GOVERNING EFFECTIVENESS AND LABELING.—With respect to sunscreen drug products subject to section 505G of the Federal Food, Drug, and Cosmetic Act, as added by section 2, the applicable requirements shall be those set out at part 352 of title 21, Code of Federal Regulations, except that the applicable requirements governing effectiveness and labeling shall be those specified in section 201.327 of title 21, Code of Federal Regulations, subject to any changes to such requirements under [subsections (b) or (k)(2) of section [101.] of such title 21].

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