Calendar No. 413

115TH CONGRESS
2D SESSION

S. 2315

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

JANUARY 17, 2018

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

MAY 14, 2018

Reported by Mr. ALEXANDER, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

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; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Over-the-Counter Drug Safety, Innovation, and Reform Act".

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

TITLE I—REGULATION OF NONPRESCRIPTION DRUGS

SEC. 101. 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 (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, an active ingredient, or a combination of active ingredients that is not subject to 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) MONOGRAPH DRUGS.—

''(1) IN GENERAL.—With respect to a nonprescription drug that, on or after the date of enactment of the Over-the-Counter Drug Safety, Innovation, and Reform Act, is introduced or delivered for introduction in interstate commerce for which an approved application under section 505 is not required, the following shall apply:

''(A) A nonprescription drug is deemed to be generally recognized as safe and effective within the meaning of section 201(p)(1) and not a new drug under section 201(p) if—

''(i)(I) such drug is—

~~"(aa)(AA) subject to a final monograph issued under part 330 of title 21, Code of Federal Regulations, as of the date of enactment of the Over-the-Counter Drug Safety, Innovation, and Reform Act;~~

~~"(BB) in conformity with the conditions for nonprescription use of such monograph and the general requirements specified for nonprescription drugs, including any modifications to those conditions made under subsections (c), (d), and (j); and~~

~~"(CC) 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~~

"(bb)(AA) 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 Over-the-Counter Drug Safety, Innovation, and Reform Act;

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

"(CC) in conformity with the conditions for nonprescription use of such tentative final monograph, any subsequent determination by the Secretary, and the general conditions for nonprescription drugs, including any modifications of those conditions under subsections (c), (d), and (j); and

"(DD) 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) the active ingredient in such drug is in conformity with—

"(aa) the requirements of a final administrative order issued under subsection (c) determining that such drug under the specific conditions of use is generally recognized as safe and effective within the meaning of section 201(p)(1); and

"(bb) the general requirements for nonprescription drugs, including any modifications of the requirements under subsections (c), (d), and (j); and

"(ii) such drug is—

"(I) not classified in Category II for safety or effectiveness under a tentative final monograph; or

~~"(II) determined by the Secretary to be not 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.~~

~~"(B) A nonprescription drug may be introduced into interstate commerce if such drug is—~~

~~"(i)(I) not classified in Category II for safety or effectiveness under a tentative final monograph; or~~

~~"(II) determined by the Secretary to be not 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; and~~

~~"(ii)(I)(aa) 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;~~

~~"(bb) classified in category III for safety or effectiveness in the preamble of a proposed rule establishing such tentative final monograph;~~

~~"(cc) in conformity with the most recently proposed or final rule establishing or proposing conditions of nonprescription use published in the Federal Register related to such tentative final monograph and the general requirements for nonprescription drugs, including any modifications of those requirements under subsections (c) and (j); and~~

~~"(dd) 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)(aa) 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;~~

~~"(bb) classified in category I for safety and effectiveness under such proposed~~

monograph or advance notice of proposed rulemaking;

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

''(dd) 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).

''(C) A nonprescription drug may be introduced into interstate commerce if—

''(i) such drug is classified in category II for safety or effectiveness under a tentative final monograph, or the Secretary has determined such drug 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; and

"(ii) the Secretary determines within 6 months of the date of enactment of the Over-the-Counter Drug Safety, Innovation, and Reform Act, 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.

"(D) A drug that is subject to the final monograph for sunscreen drug products set forth at part 352 of title 21, Code of Federal Regulations (as published at volume 64 page 27687 of the Federal Register), 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 Over-the-Counter Drug Safety, Innovation, and Reform Act), or such changes to those requirements as may be made under subsections (c), (d), and (j).

"(2) NEW DRUGS.—A nonprescription drug is a new drug within the meaning of section 201(p) and subject to the requirements of section 505 if the drug is—

"(A) not described in subparagraph (A), (B), or (D) of paragraph (1) and not in conformity with subsection (d);

"(B) not subject to an administrative final order pursuant to subsection (e); or

"(C) not a nonprescription sunscreen active ingredient or combination of ingredients subject to a final sunscreen order, as defined in section 586(2).

"(3) MONOGRAPH DRUG.—A nonprescription drug that is in compliance with paragraph (1) shall be referred to in this section as a 'monograph drug'.

"(4) RULES OF CONSTRUCTION.—

"(A) IN GENERAL.—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 Over-the-Counter Drug Safety, Innovation, and Reform Act, is marketed without an application approved under section 505; and

"(ii) to which subparagraphs (A), (B), (C), and (D) of paragraph (1) do not apply.

"(B) APPLICABILITY OF OTHER PROVISIONS.—Nothing in this paragraph shall be construed to preclude or limit the applicability of any other provision of this Act.

"(C) NO EFFECT ON OTHER AUTHORITIES.—Nothing in this subsection shall be construed to prohibit the Secretary from issuing an order under this section finding a drug to be not generally recognized as safe and effective.

"(c) ADMINISTRATIVE ORDERS.—

"(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 requirements under which a specific drug, class of such drugs, or combination of such drugs is determined to be, after substantive review of evidence—

"(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 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 requirements if, after substantive review of evidence, the Secretary determines that—

"(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 section.

‘‘(3) ADMINISTRATIVE ORDERS INITIATED BY THE SECRETARY; CITIZEN PETITIONS.—

‘‘(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) not later than 2 business days before issuance of the proposed order, informally communicate the pending issuance of the order to sponsors of drugs that will be subject to such order;

‘‘(ii) after making any such informal communication—

‘‘(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 calendar 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—

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

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

"(III) afford requestors 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 calendar days of the issuance of the order, and, for subsequent levels of appeal, within 30

calendar 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 CERTAIN MONOGRAPH 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 monograph drug described in subsection (b)(1)(B) 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 effective 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 not 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).

"(C) CITIZEN PETITIONS.—

"(i) IN GENERAL.—The Secretary may issue an administrative order under paragraph (1) in response to a citizen peti-

tion submitted under section 10.30 of title 21, Code of Federal Regulations (or any successor regulation), subject to clause (ii).

"(ii) EFFECT OF PETITION.—Nothing in clause (i) shall be construed to provide an alternative to, or otherwise supplant or supersede—

"(I) the processes through which a requestor may seek an administrative order pursuant to paragraph (6); or

"(II) the fee structure under section 744L–1(a)(2).

"(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 request 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 calendar 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 subclause (I) or (II) of subsection (b)(1)(B)(i); 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 (or, as applicable, since the deeming of such tentative final monograph as a final administrative order under paragraph (7)).

''(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 Secretary 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 a request for such review not later than 60 calendar 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 (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 monograph drug poses an imminent hazard to the public health, the Secretary may, after informally communicating with 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 after issuance of 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, after infor-

mally communicating with 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 in accordance with paragraph (1) to require such change, 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 after issuance of 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, which date, in the case of an order under subparagraph (B) that includes changes to the packaging of the drug, shall not be earlier than the day after the date on which the comment period described in subparagraph (B)(i)(III) ends.

''(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 calendar days of the issuance of the order; and, for subsequent levels of appeal, within 30 calendar days of the prior decision.

''(E) HEARINGS.—

"(i) IN GENERAL.—A sponsor of a drug subject to a final order issued under subparagraph (D) 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 resolution 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) subject to subparagraph (D), 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 subparagraph (D)(v), 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 or a new 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 ap-

proved application under section 505, if such drug is—

"(aa) described in subsection (b)(1)(A); or

"(bb) described in subsection (b)(1)(B), 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, in accordance with subparagraph (D), 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 shall cease proceedings under this subparagraph.

"(C) PRODUCT DIFFERENTIATION.—

"(i) IN GENERAL.—A final administrative order issued in response to a request under this paragraph shall have the effect of providing the order requestor (or the licensees, assignees, or successors in interest of such requestor with respect to the subject of such order and listed under clause (v)) the exclusive right, for a period of 2 years, to market drugs under this section incorporating changes described in clause (ii), subject to the limitations under clause (iv), and beginning on the date the requestor (or any such licensees, assignees, or successors in interest of such requestor) may lawfully market such drugs pursuant to the order.

‘‘(ii) CHANGES DESCRIBED.—A change described in this clause is a change subject to an order specified in clause (i), which—

‘‘(I) permits a drug to contain an active ingredient not previously incorporated in a marketed drug listed in clause (iii); or

‘‘(II) permits a change in the conditions of use of a drug, for which human data studies conducted or sponsored by the requestor (or for which the requestor has an exclusive right of reference) were essential to the issuance of such order.

‘‘(iii) MARKETED DRUGS.—The marketed drugs listed in this clause are drugs—

‘‘(I) marketed in accordance with a final monograph issued under part 330 of title 21, Code of Federal Regulations (including conditions of use thereunder), as in effect on the day before the date of enactment of this section;

"(II) marketed as category I or III in accordance with a tentative final monograph issued under such part 330 (including conditions of use and any applicable subsequent determinations thereunder), as so in effect;

"(III) marketed as category I in accordance with an advance notice of proposed rulemaking issued under such part 330 (including conditions of use and any applicable subsequent determinations thereunder), as so in effect;

"(IV) marketed in accordance with a final order issued under this section; or

"(V) described in subsection (b)(1)(C), other than drugs subject to an active enforcement action under section 303.

"(iv) LIMITATIONS ON PRODUCT DIFFERENTIATION.—

"(I) ONLY ONE PERIOD.—Only one 2-year period may be granted per

drug under clause (i) with respect to any change described in clause (ii).

''(II) EXCLUSIONS.—No period of product differentiation under this subparagraph shall apply to changes to a drug that are—

''(aa) 'Tier 2' changes described in section 744L(14)(A);

''(bb) safety-related changes described in section 744L–1(a)(2)(C), required under paragraph (5), or any other change the Secretary determines necessary to ensure safe use; or

''(cc) changes related to methods of testing safety or efficacy.

''(v) LISTING OF LICENSEES, ASSIGNEES, OR SUCCESSORS IN INTEREST.—The requestors of an order described in clause (i) shall, as applicable, submit to the Secretary, at a time when a finished dosage form subject to such order is introduced or delivered for introduction into interstate commerce, a list of licensees, assignees, or

successors in interest that have the exclusive right described in such clause.

''(vi) HUMAN DATA DEFINED.—For purposes of this subparagraph, the term 'human data' means data from clinical trials of safety or effectiveness, or pharmacokinetics or bioavailability studies.

''(D) INFORMATION REGARDING SAFE NONPRESCRIPTION MARKETING AND USE AS A CONDITION FOR FILING A GRASE REQUEST.—

''(i) IN GENERAL.—In response to a request under this paragraph that a drug described in clause (ii) be generally recognized as safe and effective, the Secretary—

''(I) may file such request, if the request includes information specified under clause (iii) with respect to safe nonprescription marketing and use of such drug; or

''(II) if the request fails to include information specified under clause (iii), shall refuse to file such request and may require that nonprescription marketing of the drug be

pursuant to a new drug application as described in clause (iv).

"(ii) DRUG DESCRIBED.—A drug described in this clause is a monograph drug that contains an active ingredient not previously incorporated in a drug—

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

"(II) marketed as category I in accordance with a tentative final monograph issued under part 330 of title 21, Code of Federal Regulations (including conditions of use and any applicable subsequent determinations under such part), as in effect on the day before the date of enactment of this section; or

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

"(iii) SUFFICIENT INFORMATION FOR A THRESHOLD DEMONSTRATION OF NON-PRESCRIPTION MARKETING AND USE.—Information specified in this subparagraph, with respect to a request described in clause (i)(I), is—

"(I) information sufficient for a threshold demonstration 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;

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

"(aa) for such period of time as needed to provide reasonable assurances concerning the safe

nonprescription use of the drug; and

"(bb) during such period of time, was subject to sufficient monitoring by a regulatory body of any country listed in section 802(b)(1)(A) or any country designated by the Secretary in accordance with section 802(b)(1)(B); or

"(III) if the Secretary determines that information described in subclause (I) or (II) is not needed to provide a threshold demonstration that the drug can be safely marketed and used as a nonprescription drug, other information the Secretary determines sufficient for such purposes.

"(iv) MARKETING PURSUANT TO NEW DRUG APPLICATION.—In the case of a request described in clause (i)(II), the drug subject to such request may be re-submitted for filing only if—

"(I) the drug is marketed as a nonprescription drug, under condi-

tions of use comparable to the requirements 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, or an equivalent quantity of the active ingredient or ingredients of such drug as determined by the Secretary, were distributed for retail sale, as determined in such manner as the Secretary may require.

"(v) RULE OF APPLICATION.—If the Secretary refuses to file a request under this subparagraph, the requestor may not file over protest under subparagraph (A)(iii) unless the request involves a drug described in section 586(9) as in effect on January 1, 2017.

"(7) TREATMENT OF FINAL AND TENTATIVE FINAL MONOGRAPHS.—A final monograph or tentative final monograph establishing requirements of

use for a drug described in subsection (b)(1) 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.

''(8) PACKAGING.—

''(A) IN GENERAL.—An administrative order issued under paragraph (3), (5)(A), or (6) may include requirements for the packaging of a drug, such as to promote use in accordance with labeling, unit dose packaging, or requirements to prevent accidental overdose or ingestion, misuse, or abuse, including by pediatric populations. The Secretary shall consider, as appropriate, any such nonprescription drugs currently available, and the impact of the removal of such drugs without such packaging and the changing of such packaging on patients and manufacturers when establishing such requirements.

''(B) EFFECTIVE DATE.—Requirements for packaging in an administrative order under paragraph (5)(B) shall not take effect earlier than the day after the date on which the com-

ment period under paragraph (5)(B)(i)(III) ends.

''(C) CLARIFICATION.—This paragraph does not authorize the Secretary to require special packaging or child-resistant packaging under the Poison Prevention Packaging Act of 1970.

''(d) PROCEDURE FOR MINOR CHANGES.—

''(1) IN GENERAL.—Minor changes in the dosage form of a drug that is described in clause (i)(I)(aa)(CC) or (ii) of subsection (b)(1)(A) 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;

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

is first introduced into interstate commerce with the change; and

"(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 to the Secretary, under section 704(a)(4), records requested by the Secretary related to a minor change within 15 business days of receiving such request, or such longer period as the Secretary may provide. Such request shall be specific to a company and limited to the product and the minor change that prompted such request. Such request shall be specific to a company and limited to the product and the minor change that prompted such request.

"(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 under subsection (c) specifying requirements for determining whether a minor change made by a re-

questor 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 AND SPECIAL NEEDS OF POPULATIONS.—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 and may take into account special needs of populations, including children.

"(c) 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 (other than information contained in subject-level data sets, such as those derived from individual case report forms) 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, unless such information 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 issued 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 on the initiative of the Secretary 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 other than a change in dosage form, which is in conformity with the requirements under subparagraph (A) or (B) of subsection (b)(1), shall not be subject to the requirements of subsection (c) or (d) with respect to such change, and shall submit updated drug listing information for the drug in accordance with the requirements of section 510(j) within 30 calendar days of the date on which the drug, with the

change, is first introduced or delivered for introduction into interstate commerce.

''(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 section 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 shall 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 requests under this section and other matters relevant to the regulation of monograph drugs and the development of new monograph 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) PRIVATE MEETINGS WITH REQUESTORS.—The procedures established under this subsection shall include appropriate provision for confidential meetings with requestors with respect to discussion of matters involving confidential commercial information or trade secrets.

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

"(1) REGULATIONS OF GENERAL APPLICABILITY TO NONPRESCRIPTION DRUGS.—Except as provided in this subsection, nothing in this section supersedes regulations establishing general requirements for nonprescription drugs, including 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) REGULATIONS ESTABLISHING REQUIREMENTS FOR SPECIFIC NONPRESCRIPTION DRUGS.—

''(A) IN GENERAL.—Section 310.545 of title 21, Code of Federal Regulations, as in effect on the date of enactment of this section, shall be deemed to be final administrative order under subsection (e).

''(B) OTHER REGULATIONS.—Regulations establishing requirements for specific nonprescription drugs marketed pursuant to this section that are in effect on the day before the date of enactment of this section (including such requirements in parts 201, 250, and 330 of title 21, Code of Federal Regulations), shall be deemed to be final administrative orders under subsection (e) only as such requirements apply to monograph drugs.

''(C) EFFECTIVE DATE PERIOD.—Unless withdrawn or revised by the Secretary, the regulations under title 21 of the Code of Federal Regulations that are described in subparagraph (B) shall remain in effect with respect to drugs

not subject to subparagraph (A), (B), (C), or (D) of subsection (b)(1).

"(3) WITHDRAWAL OF 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 day before the date of enactment of this Act), 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 made without public notice and comment and 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 an electronic format specified by the Secretary after providing a period for public comment.

''(m) INAPPLICABILITY OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to collections of information made under this section.''.

SEC. 102. MISBRANDING.

Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by inserting after subsection (dd) 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) If it is a drug for which fees under section 744L–1 have been assessed but have not been paid.''.

SEC. 103. CONFORMING AMENDMENTS TO THE SUNSCREEN INNOVATION ACT.

(a) REVIEW OF NONPRESCRIPTION INGREDIENTS SUBJECT TO SUNSCREEN INNOVATION ACT.—

(1) PENDING SUNSCREEN INGREDIENTS.—Nonprescription sunscreen active ingredients or combinations of sunscreen active ingredients subject, on the date of enactment of this Act, to a proposed sunscreen order, as defined in section 586(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff(7)), shall—

(A) continue to be reviewed in accordance with section 586C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3); or

(B) be reviewed under section 505G of such Act upon notification of the Secretary by the sponsor that such sponsor elects to have such ingredient or combination of ingredients reviewed under such section 505G, and such proposed sunscreen order under such section 586C shall be considered a proposed adminis-

trative order under section 505G(c)(3)(A)(ii) of such Act.

(2) PENDING NONSUNSCREEN INGREDIENTS.—The sponsor of any application described in section 586F of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–6) that was submitted to the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') pursuant to section 330.14 of title 21, Code of Federal Regulations (as in effect on the day before the date of enactment of this Act), shall—

(A) notify the Secretary that the sponsor elects to withdraw such application; or

(B) notify the Secretary that the sponsor elects for such ingredient to be considered under section 505G of the Federal Food, Drug, and Cosmetic Act, and any proposed order under such section 586F shall be considered a proposed administrative order under section 505G(c)(3)(A)(ii) of that Act.

(3) INGREDIENTS SUBMITTED AFTER THE DATE OF ENACTMENT OF SECTION 506G.—Any ingredient that is eligible for review under section 506G of the Federal Food, Drug, and Cosmetic Act

and is submitted after the date of enactment of this Act shall be considered under that section.

(b) MEETINGS REGARDING SUNSCREEN INGREDIENTS.—Section 586C(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3(b)) is amended by adding at the end the following:

"(11) MEETINGS WITH SPONSORS.—A sponsor may request an individual, confidential meeting to discuss the data requirements to support a general recognition of safety and effectiveness with respect to the subject of a pending sunscreen ingredient. The Secretary shall respond within 14 calendar days of the request and schedule such meeting within 45 calendar days, or within such timeline as specified in the letters described in section 201 of the Over-the-Counter Drug Safety, Innovation, and Reform Act. If a sponsor requests more than one confidential meeting for the same request, the Secretary may refuse to grant an additional confidential meeting request if the Secretary determines such additional confidential meeting is not reasonably necessary for the sponsor to advance its request. The Secretary shall publish a post-meeting summary on the internet website of the Food and Drug Administration of any confidential meeting that does not disclose con-

fidential business information. Such meetings shall not be required to comply with guidance issued by the Secretary addressing formal meetings for sponsors of human drug applications, as defined in section 735.''.

(c) PRODUCT DIFFERENTIATION.—Section 586C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3) is amended by adding at the end the following:

''(f) PRODUCT DIFFERENTIATION.—

''(1) IN GENERAL.—A final sunscreen order shall have the effect of providing the order requestor (or the licensees, assignees, or successors in interest of such requestor with respect to the subject of such request and listed under paragraph (5)) the exclusive right, for a period of 2 years, to market a sunscreen ingredient under this section incorporating changes described in paragraph (2) subject to the limitations under paragraph (4), beginning on the date the requestor (or any licensees, assignees, or successors in interest of such requestor with respect to the subject of such request and listed under paragraph (5)) may lawfully market such sunscreen ingredient pursuant to the order.

"(2) CHANGES DESCRIBED.—A change described in this paragraph is a change subject to an order specified in paragraph (1) that—

"(A) permits a sunscreen to contain an active ingredient not previously incorporated in a marketed sunscreen listed in paragraph (3); or

"(B) permits a change in the conditions of use of a sunscreen ingredient, for which human data studies conducted or sponsored by the requestor (or for which the requestor has an exclusive right of reference) were essential to the issuance of such order.

"(3) MARKETED SUNSCREEN.—The marketed sunscreen ingredients described this paragraph are sunscreen ingredients—

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

"(B) marketed as category I or III in accordance with a tentative final monograph issued under such part 330 (including conditions of use and any applicable subsequent determinations thereunder), as so in effect;

"(C) marketed as category I in accordance with an advance notice of proposed rulemaking issued under such part 330 (including conditions of use and any applicable subsequent determinations thereunder), as so in effect; or

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

"(4) LIMITATIONS ON PRODUCT DIFFERENTIATION.—

"(A) ONLY ONE PERIOD.—Only one 2-year period may be granted per ingredient under paragraph (1).

"(B) EXCLUSIONS.—No period of product differentiation under this subparagraph shall apply to changes to a sunscreen that are—

"(i) 'Tier 2' changes described in section 744L(14)(A);

"(ii) safety-related changes described in section 744L–1(a)(2)(C), required under section 505G(c)(5), or any other change the Secretary determines necessary to ensure safe use; or

"(iii) changes related to methods of testing safety or efficacy.

"(5) LISTING OF LICENSEES, ASSIGNEES, OR SUCCESSORS IN INTEREST.—Requestors shall submit to the Secretary at the time when a final dosage form subject to such request is introduced or delivered for introduction into interstate commerce, a list of licensees, assignees, or successors in interest that have the exclusive right described in paragraph (1).

"(6) HUMAN DATA DEFINED.—For purposes of this subsection, the term 'human data' means data from clinical trials of safety or effectiveness (including actual use studies), pharmacokinetics, or bioavailability.".

(d) SUNSCREEN INNOVATION ACT AMENDMENTS.—Section 586C(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3(c)) is amended by striking paragraph (3) and inserting the following:

"(3) RELATIONSHIP TO ORDERS UNDER SECTION 505G.—A final sunscreen order shall be deemed to be a final administrative order under section 505G and subject to the applicable provisions under such section 505G, including with respect to amendment of such order.".

(e) PRECLUSION OF NEW SUNSCREEN SUBMISSIONS; OPTION TO TRANSFER SUBMISSIONS TO OTC MONOGRAPH ORDER PROCESS.—

(1) SUNSET.—Beginning on the date of enactment of this Act, section 586A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–1) shall have no force or effect.

(2) OPTION TO TRANSFER SUBMISSIONS TO OTC MONOGRAPH ORDER PROCESS.—

(A) IN GENERAL.—Any person who submitted a request described in subparagraph (B) may, at any time prior to the sunset of subchapter I of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff et seq.) under section 586H of such Act, withdraw such request from the process under such subchapter and resubmit such request as an order request under section 505G of such Act.

(B) REQUESTS.—A request described in this subparagraph is—

(i) a request under section 586A of the Federal Food, Drug, and Cosmetic Act submitted before the date of enactment of this Act; or

(ii) a pending request described in section 586(6).

(f) TREATMENT OF AUTHORITY REGARDING FINALIZATION OF SUNSCREEN MONOGRAPH.—Section 586E of

the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–5) is amended to read as follows:

"SEC. 586E. SUNSCREEN ORDER.

"(a) IN GENERAL.—

"(1) REVISION OF FINAL SUNSCREEN ORDER.—Not later than November 26, 2019, the Secretary shall amend and revise the final administrative order concerning nonprescription sunscreen (referred to in this section as the 'sunscreen order') for which the substance, prior to the date of enactment of the Over-the-Counter Drug Safety, Innovation, and Reform Act, was represented by stayed regulations under part 352 of title 21, Code of Federal Regulations.

"(2) ISSUANCE OF REVISED SUNSCREEN ORDER; EFFECTIVE DATE.—A revised sunscreen order described in paragraph (1) shall be—

"(A) effective not later than November 26, 2019, and

"(B) issued by the Secretary at least 30 calendar days prior to such date.

"(b) REPORTS.—If a revised sunscreen order issued under subsection (a) does not include provisions related to the effectiveness of various sun protection factor levels, and does not address all dosage forms known to the Sec-

retary to be used in sunscreens marketed in the United States without a new drug application approved under section 505, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the rationale for omission of such provisions from such order, and a plan and timeline to compile any information necessary to address such provisions through such order.''.

(g) SUNSET OF PROCESS UNDER SUNSCREEN INNOVATION ACT.—Subchapter I of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff et seq.), as amended by subsection (f), is further amended by inserting at the end the following new section:

''SEC. 586H. SUNSET.

''This subchapter shall no longer be effective upon the later of—

''(1) a final determination by the Secretary under this subchapter with respect to every request described in section 586A(b)(2) (other than any withdrawn requests and requests resubmitted as order requests under section 505G); or

''(2) the effective date of the revised sunscreen order described in section 586E(a)(2).''.

SEC. 104. DRUGS EXCLUDED FROM OVER-THE-COUNTER REVIEW.

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

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to preclude or limit the applicability of any provision of the Federal Food, Drug, and Cosmetic Act.

SEC. 105. CONFORMING AMENDMENT.

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

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

(A) by striking "final regulation" and inserting "final order"; and

(B) by striking "and not misbranded"; and

(2) in subparagraph (A), by striking "regulation in effect" and inserting "regulation or order in effect".

SEC. 106. ANNUAL UPDATE TO CONGRESS ON APPROPRIATE PEDIATRIC INDICATION FOR CERTAIN COUGH AND COLD MONOGRAPH DRUGS.

(a) IN GENERAL.—Not later than one year after the date of enactment of this Act and annually thereafter, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall 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 letter describing the progress of the Food and Drug Administration—

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

(2) as appropriate, revising such cough and cold monograph to address such children, through the administrative order process under section 505G(b) of the Federal Food, Drug, and Cosmetic Act, as added by section 101.

(b) COUGH AND COLD MONOGRAPH DESCRIBED.—The cough and cold monograph described in this subsection consists of the conditions under which nonprescription drug products containing antitussive, expectorant, nasal decongestant, or antihistamine active ingredients (or combinations thereof) are generally recognized as safe and effective, as specified in part 341 of title 21, Code of Fed-

eral Regulations (as in effect on the day before the date of enactment of this Act), and included in an administrative order deemed established under such section 505G(b) of the Federal Food, Drug, and Cosmetic Act.

(c) DURATION OF AUTHORITY.—Subsection (a) shall have no force or effect beginning on the date on which the Secretary submits a letter under subsection (a) in which the Secretary indicates that the Food and Drug Administration has completed its evaluation and revised, in a final administrative order, as applicable, the cough and cold monograph in accordance with this section.

TITLE II—FEES RELATING TO MONOGRAPH DRUGS

SEC. 201. SHORT TITLE; FINDINGS.

(a) SHORT TITLE.—This title may be cited as the "Over-the-Counter Monograph User Fee Act of 2018".

(b) FINDINGS.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated toward the regulation of monograph drugs under section 505G of the Federal, Food, Drug, and Cosmetic Act, as set forth in the goals identified for purposes of such section, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Com-

merce of the House of Representatives, as set forth in the Congressional Record.

SEC. 202. AUTHORITY TO ACCESS AND USE 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 MONOGRAPH 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 'contract manufacturing organization facility' means a monograph drug facility where neither the owner of such manufacturing facility nor any affiliate of such owner or facility sells such monograph drug produced at such facility directly to wholesalers, retailers, or consumers in the United States.

‘‘(3) The term ‘costs of resources allocated for monograph drug activities’ means the expenses in connection with monograph 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 monograph drug activities.

‘‘(4) 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 'monograph drug' shall have the meaning given the term under section 505G.

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

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

''(i) orders proposing or finalizing applicable requirements of use for monograph drugs products;

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

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

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

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

~~"(vi) meetings regarding monograph drug activities;~~

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

~~"(viii) regulatory science activities related to monograph drugs;~~

~~"(B) inspections related to monograph drugs;~~

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

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

~~"(i) collecting, developing, and reviewing safety information on monograph 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.~~

~~"(7)(A) The term 'monograph drug facility' means a foreign or domestic business or other entity—~~

~~"(i) that is under one management, either direct or indirect;~~

~~"(ii) at one geographic location or address engaged in manufacturing or processing a monograph drug in finished dosage form;~~

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

~~"(II) testing; or~~

“(III) packaging of packaged final dosages in a manner that does not affect the drug.

“(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.

“(8) The term ‘monograph drug meeting’ means any meeting regarding the content of a proposed monograph drug order request.

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

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

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

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

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

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

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

"(ii) the addition of information to the other information section of the drug facts label of a 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 monograph drug order request as a Tier 2 monograph drug order request (including recategorizing a request from Tier 1 to Tier 2) and publish such deter-

mination in a proposed order issued pursuant to section 505G(c).

"SEC. 744L–1. AUTHORITY TO ASSESS AND USE MONOGRAPH 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 monograph 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.—

"(i) IN GENERAL.—A fee shall not be assessed under subparagraph (A) if the identified monograph drug facility has ceased all activities related to monograph 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.

''(ii) FEE AMOUNT.—The amount of the fee for a contract manufacturing organization facility shall be equal to two-thirds the amount of the fee for a monograph drug facility that is not a contract manufacturing organization facility.

''(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 date of enactment of an appropriations Act providing for the collection and obligation of fees under this section for such year.

''(2) MONOGRAPH DRUG ORDER REQUEST FEE.—

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

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

"(ii) for a Tier 2 monograph 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 monograph drug order request fees required under subparagraph (A) shall be due on the date of submission of the monograph drug order request.

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

‘‘(D) REFUND OF FEE IF ORDER REQUEST IS RECATEGORIZED AS A TIER 2 MONOGRAPH DRUG ORDER REQUEST.—If the Secretary determines that a monograph drug request initially characterized as Tier 1 should be re-characterized as a Tier 2 monograph 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 that is refused for filing.

‘‘(F) FEES FOR ORDER REQUESTS PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—A monograph 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 re-

quest justifying such return within 180 calendar days after such fee was paid.

''(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 equiv-

alent 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 monograph 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 monograph 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 monograph 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 monograph 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 op-

erating 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 monograph drug facility fees for fiscal year 2018 under subsection (a)(1), based on the revenue amount for such year under subsection (b) and the ad-

justments 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) monograph drug facility fees under subsection (a)(1);

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

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

"(d) IDENTIFICATION OF FACILITIES.—Each person that owns a monograph 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 monograph drug facility.

''(e) EFFECT OF FAILURE TO PAY FEES.—

''(1) IN GENERAL.—A monograph 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) EFFECT ON ELIGIBILITY FOR MEETINGS.—If a monograph drug requestor fails to pay a fee assessed under subsection (a), the requestor shall be considered ineligible for monograph drug meetings.

''(f) MONOGRAPH DRUG FACILITY FEE.—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 Secretary placing the facility on a publicly available arrears list until such fee has been 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 extent and in the amount provided in advance in ap-

propriations 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 monograph 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 monograph drug activities (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Serv-

ices 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 monograph 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 author-

ized 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 monograph 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 calendar 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 201 of the 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 calendar 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 website 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 monograph 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 calendar 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.".~~

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Over-the-Counter Drug Safety, Innovation, and Reform Act".

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

TITLE I—REGULATION OF NONPRESCRIPTION DRUGS

SEC. 101. 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 (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 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) TREATMENT OF MONOGRAPH DRUGS MARKETED WITHOUT AN APPROVED APPLICATION.—

"(1) IN GENERAL.—A nonprescription drug that is marketed without an approved application under section 505 shall be treated in accordance with this subsection beginning on the date of enactment of the Over-the-Counter Drug Safety, Innovation, and Reform Act:

"(A) A nonprescription drug is deemed to be generally recognized as safe and effective within the meaning of section 201(p)(1) and not a new drug under section 201(p) if such drug is—

"(i)(I)(aa) subject to a final monograph issued under part 330 of title 21, Code of Federal Regulations, as of the date of enactment of the Over-the-Counter Drug Safety, Innovation, and Reform Act;

"(bb) in conformity with the requirements for nonprescription use of such monograph, the general requirements specified for

nonprescription drugs, and the requirements under subsections (c), (d), and (j); and

"(cc) 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, on day before the date of enactment of the Over-the-Counter Drug Safety, Innovation, and Reform Act, has been used to a material extent and for a material time within the meaning of section 201(p)(2);

"(II)(aa) 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, on the day before the date of enactment of the Over-the-Counter Drug Safety, Innovation, and Reform Act;

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

"(cc) in conformity with the requirements for nonprescription use of such tentative final monograph, any subsequent de-

termination by the Secretary, the general requirements for nonprescription drugs, and the requirements under subsections (c), (d), and (j); and

"(dd) 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

"(III) in conformity with—

"(aa) the requirements of a final administrative order issued under subsection (c) determining that such drug is generally recognized as safe and effective within the meaning of section 201(p)(1); and

"(bb) the general requirements for nonprescription drugs and the requirements under subsections (c), (d), and (j);

"(ii) not classified in Category II for safety or effectiveness under a tentative final monograph; and

"(iii) not determined by the Secretary to be not generally recognized as 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.

"(B) A nonprescription drug for which there is not an approved application under section 505 may be introduced into interstate commerce if such drug is—

"(i)(I) not classified in Category II for safety or effectiveness under a tentative final monograph; or

"(II) not determined by the Secretary to be not generally recognized as 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; and

"(ii)(I)(aa) 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;

"(bb) classified in category III for safety or effectiveness in the preamble of a proposed rule establishing such tentative final monograph;

"(cc) in conformity with the most recently proposed or final rule establishing or proposing conditions of nonprescription use published in the Federal Register related to such tentative final monograph, the general requirements for nonprescription drugs, and the requirements under subsections (c) and (j); and

"(dd) in a dosage form that, as of the day before the date of enactment of the Over-the-Counter Drug Safety, Innovation, and Reform Act, has been used to a material extent and for a material time within the meaning of section 201(p)(2); or

"(II)(aa) 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;

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

"(cc) in conformity with the most recently proposed or final rule establishing or proposing conditions of nonprescription use published in the Federal Register related to such proposed monograph or advance notice of proposed rulemaking, the general requirements for nonprescription drugs, and the requirements under subsections (c) and (j); and

"(dd) in a dosage form that, as of the day before the date of enactment of the Over-the-Counter Drug Safety, Innovation, and Reform Act has been used to a material extent and for a material time within the meaning of section 201(p)(2).

"(C)(i) Subject to clause (iii), beginning on the date that is 180 calendar days after the date of enactment of the Over-the-Counter Drug Safety, Innovation, and Reform Act, a nonprescrip-

tion drug is deemed to be not generally recognized as safe and effective within the meaning of section 201(p)(1), a new drug under section 201(p), and misbranded under section 502(ee), if such drug—

"(I) is classified in category II for safety or effectiveness under a tentative final monograph; or

"(II) is subject to a determination to be not generally recognized as safe and effective under a proposed rule that is the most recently applicable proposal issued under part 330 of title 21, Code of Federal Regulations.

"(ii) A nonprescription drug that the Secretary has determined to be not generally recognized as safe and effective under a final determination issued under part 330 of title 21, Code of Federal Regulations is deemed to be not generally recognized as safe and effective within the meaning of section 201(p)(1), a new drug under section 201(p), and misbranded under section 502(ee).

"(iii) A 180-day period described in clause (i) may be extended with respect to a drug by the

Secretary if the Secretary determines that such extension is in the interest of the public health.

"(D) A drug that is subject to the final monograph for sunscreen drug products set forth at part 352 of title 21, Code of Federal Regulations (as published at volume 64 page 27687 of the Federal Register), 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 Over-the-Counter Drug Safety, Innovation, and Reform Act), or such changes to those requirements as may be made under subsections (c), (d), and (j).

"(2) NEW DRUGS.—A nonprescription drug is a new drug within the meaning of section 201(p) and subject to the requirements of section 505 if the drug is—

"(A) not described in subparagraph (A), (B), (C), or (D) of paragraph (1) and not in conformity with subsection (d), as applicable; or

"(B) not a nonprescription sunscreen active ingredient or combination of ingredients subject

to a final sunscreen order, as defined in section 586(2).

"(3) MONOGRAPH DRUG.—In this section, the term 'monograph drug' has the meaning given such term in section 744L.

"(4) RULES OF CONSTRUCTION.—

"(A) IN GENERAL.—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 Over-the-Counter Drug Safety, Innovation, and Reform Act, is marketed without an application approved under section 505; and

"(ii) to which subparagraphs (A), (B), (C), and (D) of paragraph (1) do not apply.

"(B) APPLICABILITY OF OTHER PROVISIONS.—Nothing in this paragraph shall be construed to preclude or limit the applicability of any other provision of this Act.

"(C) NO EFFECT ON OTHER AUTHORITIES.—Nothing in this subsection shall be construed to prohibit the Secretary from issuing an order under this section finding a drug to be not generally recognized as safe and effective.

"(c) ADMINISTRATIVE ORDERS.—

"(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 requirements 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 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 requirements if the Secretary determines that—

"(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) ADMINISTRATIVE ORDERS INITIATED BY THE SECRETARY; CITIZEN PETITIONS.—

"(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) not later than 2 business days before issuance of the proposed order, informally communicate the pending issuance of the order to sponsors of drugs that have a listing in effect under section 510(j) for drugs will be subject to such order;

"(ii) after making any such informal communication—

"(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 calendar 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—

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

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

"(III) afford requestors 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 calendar days of the issuance of the order, and, for subsequent levels of appeal, within 30 calendar days of the prior decision; and

"(IV) except with respect to drugs described in paragraph (3)(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 CERTAIN MONOGRAPH DRUGS.—When issuing an administrative order under paragraph (1) on the initiative of the Secretary (except as provided under paragraph (4)) proposing to determine that a monograph drug described in subsection (b)(1)(B) 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 effective 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 not 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).

"(C) CITIZEN PETITIONS.—

"(i) IN GENERAL.—The Secretary may issue an administrative order under paragraph (1) in response to a citizen petition submitted under section 10.30 of title 21, Code of Federal Regulations (or any successor regulation), subject to clause (ii).

"(ii) EFFECT OF PETITION.—Nothing in clause (i) shall be construed to provide an alternative to, or otherwise supplant or supersede—

"(I) the processes through which a requestor may seek an administrative order pursuant to paragraph (5); or

"(II) the fee structure under section 744L–1(a)(2).

"(3) HEARINGS; JUDICIAL REVIEW.—

"(A) IN GENERAL.—A person who participated in each level of formal dispute resolution under paragraph (2)(A)(iv)(III) of an administrative order with respect to a drug may request a hearing concerning a final administrative order issued under paragraph (2)(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 calendar 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 (2)(A)(iv) if the final administrative order involved relates to a drug—

"(i) that is described in subsection (b)(1)(B)(ii)(I); 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 (or, as applicable, since the deeming of such tentative final monograph as a final administrative order under paragraph (6)).

"(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 (2)(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 Secretary shall designate 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 appli-

cable 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 a request for such review not later than 60 calendar 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 (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.

"(4) 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 monograph drug poses an imminent hazard to the public health, the Secretary, after informally communicating with any sponsor that has a listing in effect under section 510(j) for such drug not later than 48 hours before issuance of an order under this subparagraph, may—

"(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 after issuance of 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) informally communicate, not later than 48 hours before issuance of an interim final order under this sub-

paragraph any sponsors of a drug who has a listing in effect under section 510(j) for such drug or combination of drugs;

"(II) after informally communicating with the sponsors under subclause (I), issue an interim final administrative order under paragraph (1) to require such change, together with a detailed statement of the reasons for such order and, in the case of a required change to the packaging, a brief description of the factors considered in accordance with paragraph (7)(B)(i);

"(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 after issuance of 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 calendar days of the issuance of the order; and, for subsequent levels of appeal, within 30 calendar days of the prior decision.

"(E) HEARINGS.—

"(i) IN GENERAL.—A sponsor of a drug subject to a final order issued under subparagraph (D) 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 (3) 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 (2)(A)(iv), except that, with respect to a final order issued under subparagraph (D), the final decision under paragraph (3)(C)(v) may take effect prior to the expiration of the period under paragraph (3)(D)(ii) for submitting a request for judicial review.

"(ii) REFERENCES.—For purposes of a hearing under this subparagraph, the references in subparagraphs (A), (B), and (C) of paragraph (3)—

"(I) to 'each level of dispute resolution under paragraph (2)(A)(iv)(III)' shall be deemed to

mean 'each level of formal dispute resolution under subparagraph (D)(iii)'; and

"(II) to 'final administrative order issued under paragraph (2)(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 (3)(D).

"(H) CLARIFICATION.—Paragraph (2) shall not apply to the orders issued under this paragraph.

"(5) 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) subject to subparagraph (D), 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 (2) and (3); and

"(iii) except as provided in subparagraph (D)(v), 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 (2)(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 or a new 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) described in subsection (b)(1)(A); or

"(bb) described in subsection (b)(1)(B), 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, in accordance with paragraph (1)(B), 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.—A final administrative order issued in response to a request under this paragraph shall have the effect of authorizing solely the order requestor (or the licensees, assignees, or successors in interest of such requestor with respect to the subject of such order and listed under clause (v)), for a 2-year period beginning on the effective date of such order, to market drugs under this section—

"(I) incorporating changes described in clause (ii); and

"(II) subject to the limitations under clause (iv).

"(ii) CHANGES DESCRIBED.—A change described in this clause is a change subject to an order specified in clause (i), which—

"(I) provides for a drug to contain an active ingredient (including any ester or salt of the active ingredient) not previously incorporated in a drug described in clause (iii); or

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

"(iii) DRUGS DESCRIBED.—The drugs described in this clause are drugs—

"(I) specified in subparagraphs (A), (B), and (D) of subsection (b)(1);

"(II) subject to a final order issued under this section;

"(III) subject to a final sunscreen order (as defined in section 586(2)(A)); or

"(IV) described in subsection (b)(4)(A), other than drugs subject to an active enforcement action under chapter III.

"(iv) LIMITATIONS ON PRODUCT DIFFERENTIATION.—

"(I) ONLY ONE PERIOD.—Only one 2-year period under this subparagraph shall be granted for each order described in clause (i) with respect to changes (to the drug subject to such order) that are—

"(aa) changes described in clause (ii)(I), relating to active ingredients; or

"(bb) changes described in clause (ii)(II), relating to conditions of use.

"(II) EXCLUSIONS.—No 2-year period under this subparagraph shall apply to changes to a drug that are—

"(aa) the subject of a 'Tier 2' monograph drug order requested as described in section 744L(14)(A);

"(bb) safety-related changes described in section 744L–1(a)(2)(C), required under this paragraph, or any other change the Secretary determines necessary to ensure safe use; or

"(cc) changes related to methods of testing safety or efficacy.

"(v) LISTING OF LICENSEES, ASSIGNEES, OR SUCCESSORS IN INTEREST.—The requestors of an order described in clause (i) shall, as applicable, submit to the Secretary, at a time when a drug subject to such order is introduced or delivered for introduction into interstate commerce, a list of licensees, assignees, or successors in interest under such clause.

"(vi) NEW HUMAN DATA STUDIES DEFINED.—For purposes of this subparagraph, the term 'new human data studies' means studies from clinical trials of safety or effectiveness, pharmacokinetics studies, or bioavailability studies, the results of which—

"(I) the Secretary has not relied on to support—

"(aa) a proposed or final determination that a drug described in subclauses (I), (II), or (III) of clause (iii) is generally recognized as safe and effective within the meaning of section 201(p)(1); or

"(bb) approval of a drug under section 505; and

"(II) do not duplicate the results of another study that the Secretary relied on to support—

"(aa) a proposed or final determination that a drug described in subclause (I), (II), or (III) of clause (iii) is generally recognized as safe and effective within the meaning of section 201(p)(1); or

"(bb) approval of a drug that was approved under section 505.

"(D) INFORMATION REGARDING SAFE NONPRESCRIPTION MARKETING AND USE AS A CONDITION FOR FILING A GRASE REQUEST.—

"(i) IN GENERAL.—In response to a request under this paragraph that a drug described in clause (ii) be generally recognized as safe and effective, the Secretary—

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

"(II) if the request fails to include information specified under clause (iii), shall refuse to file such request and may require that nonprescription marketing of the drug be pursuant to a new drug application as described in clause (iv).

"(ii) DRUG DESCRIBED.—A drug described in this clause is a monograph drug that contains an active ingredient not previously incorporated in a drug—

"(I) described in subparagraph (A), (B), or (D) of subsection (b)(1);

"(II) subject to a final order under this section; or

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

"(iii) SUFFICIENT INFORMATION FOR A THRESHOLD DEMONSTRATION OF NON-PRESCRIPTION MARKETING AND USE.—Information specified in this subparagraph, with respect to a request described in clause (i)(I), is—

"(I) information sufficient for a threshold demonstration 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;

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

"(aa) for such period of time as needed to provide reasonable assurances concerning the safe

nonprescription use of the drug; and

"(bb) during such period of time, was subject to sufficient monitoring by a regulatory body of any country listed in section 802(b)(1)(A) or any country designated by the Secretary in accordance with section 802(b)(1)(B); or

"(III) if the Secretary determines that information described in subclause (I) or (II) is not needed to provide a threshold demonstration that the drug can be safely marketed and used as a nonprescription drug, other information the Secretary determines sufficient for such purposes.

"(iv) MARKETING PURSUANT TO NEW DRUG APPLICATION.—In the case of a request described in clause (i)(II), the drug subject to such request may be re-submitted for filing only if—

"(I) the drug is marketed as a nonprescription drug, under conditions

of use comparable to the requirements specified in the request, for such period of 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, or an equivalent quantity of the active ingredient or ingredients of such drug as determined by the Secretary, were distributed for retail sale, as determined in such manner as the Secretary may require.

"(v) RULE OF APPLICATION.—If the Secretary refuses to file a request under this subparagraph, the requestor may not file over protest under subparagraph (A)(iii) unless the request involves a drug described in section 586(9) as in effect on January 1, 2017.

"(6) TREATMENT OF FINAL AND TENTATIVE FINAL MONOGRAPHS.—

"(A) IN GENERAL.—A final monograph or tentative final monograph described in subpara-

graph (B) 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.

"(B) MONOGRAPHS DESCRIBED.—For purposes of subparagraph (A), a final monograph or tentative final monograph, as applicable, is described in this subparagraph if such monograph—

"(i) establishes requirements of use for a drug described in subclause (I) or (II) of subsection (b)(1)(A)(i); and

"(ii) represents the most recently promulgated version of such requirements, including as modified, in whole or in part, by any proposed or final rule.

"(7) PACKAGING.—

"(A) IN GENERAL.—An administrative order issued under paragraph (2), (4), or (5) may include requirements for the packaging of a drug, such as to promote use in accordance with labeling, unit dose packaging, or requirements to prevent overdose or accidental ingestion, including by pediatric populations.

"(B) SAFETY LABELING CHANGES.—An administrative order issued under paragraph (4)(B) that includes requirements for the packaging of a drug may be issued only after—

"(i) consideration of—

"(I) whether labeling changes alone would mitigate a significant or unreasonable risk of a serious adverse event; and

"(II) as appropriate, any of the applicable nonprescription drugs currently available; and

"(ii) consultation with sponsors on the impact of the removal of such drugs without such packaging and the change of such packaging on patients and manufacturers when establishing such requirements.

"(C) CLARIFICATION.—This paragraph does not authorize the Secretary to require standards or testing procedures as described in part 1700 of title 16, Code of Federal Regulations.

"(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 re-

questor 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;

"(B) the requestor submits updated drug listing information for the drug in accordance with the requirements of section 510(j) within 30 calendar days of the date on which the drug is first introduced into interstate commerce with the change; and

"(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.—If the Secretary requests records under section 704(a)(4) with respect to a minor change made to a drug by a requestor under this subsection, any such

records pertinent to such drug, such minor change, and the requestor shall be provided to the Secretary by the requestor 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 under this subsection 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 AND SPECIAL NEEDS OF POPULATIONS.—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 and may take into account special needs of populations, including children.

"(e) INFORMATION SUBMITTED BY REQUESTORS.—

"(1) CONFIDENTIAL INFORMATION.—Subject to paragraph (2), 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 (other than information contained in subject-level data sets, such as those derived from individual case report forms) 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, unless such information 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 requests and obtains the information under subsection (d) and such information is not submitted in relation to an order under subsection (c).

"(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 issued 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 on the initiative of the Secretary 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 subject to this section shall submit updated drug listing information for the drug in accordance with the requirements of section 510(j) not later than the date on which the drug is first introduced or delivered for introduction 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 section 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 shall 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 requests under this section and other matters relevant to the regulation and development of monograph 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) PRIVATE MEETINGS WITH REQUESTORS.—The procedures established under this subsection shall include appropriate provision for confidential meetings with requestors with respect to discussion of matters involving confidential commercial information or trade secrets.

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

"(1) REGULATIONS OF GENERAL APPLICABILITY TO NONPRESCRIPTION DRUGS.—Except as provided in this subsection, nothing in this section supersedes reg-

ulations establishing general requirements for non-prescription drugs, including 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) REGULATIONS ESTABLISHING REQUIREMENTS FOR SPECIFIC NONPRESCRIPTION DRUGS.—

"(A) IN GENERAL.—Section 310.545 of title 21, Code of Federal Regulations, as in effect on the day before the date of enactment of this section, shall be deemed to be final administrative order under subsection (c).

"(B) OTHER REGULATIONS.—Regulations establishing requirements for specific non-prescription drugs marketed pursuant to this section that are in effect on the day before the date of enactment of this section (including such requirements in parts 201, 250, and 330 of title 21, Code of Federal Regulations), shall be deemed to be final administrative orders under subsection (c) only as such requirements apply to monograph drugs subject to this section.

"(C) EFFECTIVE DATE PERIOD.—Unless withdrawn or revised by the Secretary, the regulations under title 21 of the Code of Federal Regulations that are described in subparagraph (B) shall remain in effect with respect to drugs not subject to subparagraph (A), (B), (C), or (D) of subsection (b)(1).

"(3) WITHDRAWAL OF 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 day before the date of enactment of the Over-the-Counter Drug Safety, Innovation, and Reform Act), 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 made without public notice and comment and 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 (d)(3)(A).

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

"(m) INAPPLICABILITY OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to collections of information made under this section.

"(n) 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 section.

"(o) INVESTIGATIONAL NEW DRUGS.—A drug for which an exemption under section 505(i) is in effect is not subject to this section.".

SEC. 102. MISBRANDING.

Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by inserting after subsection (dd) 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) If it is a drug for which fees under section 744L–1 have been assessed but have not been paid.".

SEC. 103. CONFORMING AMENDMENTS TO THE SUNSCREEN INNOVATION ACT.

(a) REVIEW OF NONPRESCRIPTION INGREDIENTS SUBJECT TO SUNSCREEN INNOVATION ACT.—

(1) PENDING SUNSCREEN INGREDIENTS.—Nonprescription sunscreen active ingredients or combinations of sunscreen active ingredients for use under specified conditions subject, on the date of enactment of this Act, to a proposed sunscreen order, as defined in section 586(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff(7)), shall—

(A) continue to be reviewed in accordance with section 586C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3); or

(B) be reviewed under section 505G of such Act upon written notification of the Secretary by the sponsor within 180 calendar days after the date of enactment of the Over-the-Counter Drug Safety, Innovation, and Reform Act that such sponsor elects to have such ingredient or combination of ingredients reviewed under such section 505G, and, upon notification, such proposed sunscreen order under such section 586C shall be considered to be a request for an administrative order that has been accepted for filing under section 505G(c)(6)(A)(ii) of such Act.

(2) PENDING NONSUNSCREEN INGREDIENTS.—

(A) IN GENERAL.—Any application described in section 586F of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–6) that was submitted to the Secretary of Health and Human Services pursuant to section 330.14 of title 21, Code of Federal Regulations (as such provisions were in effect on the day before the date of enactment of this Act), shall be voided as

of such date of enactment, subject to subparagraph (B).

(B) ORDER REQUEST.—Nothing in subparagraph (A) precludes the submission of an order request under section 505G(b) of the Federal Food, Drug, and Cosmetic Act, as added by section 101 of this Act, with respect to a drug that was the subject of an application voided under subparagraph (A).

(C) INGREDIENTS SUBMITTED AFTER THE DATE OF ENACTMENT OF SECTION 506G.—Any ingredient that is eligible for review under section 505G of the Federal Food, Drug, and Cosmetic Act and is submitted after the date of enactment of this Act shall be considered under that section.

(b) MEETINGS REGARDING SUNSCREEN INGREDIENTS.—Section 586C(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3(b)) is amended by adding at the end the following:

"(11) MEETINGS WITH SPONSORS.—A sponsor may request an individual, confidential meeting to discuss the data requirements to support a general recognition of safety and effectiveness with respect to the subject of a pending sunscreen ingredient. The

Secretary shall respond within 14 calendar days of the request and schedule such meeting within 45 calendar days, or within such timeline as specified in the letters described in section 201 of the Over-the-Counter Drug Safety, Innovation, and Reform Act. If a sponsor requests more than one confidential meeting for the same proposed sunscreen order, the Secretary may refuse to grant an additional confidential meeting request if the Secretary determines such additional confidential meeting is not reasonably necessary for the sponsor to advance the proposed sunscreen order, or if the sponsor does not provide sufficient information upon which to base a substantive discussion. The Secretary shall publish a post-meeting summary on the internet website of the Food and Drug Administration of any confidential meeting that does not disclose confidential business information.".

(c) PRODUCT DIFFERENTIATION.—Section 586C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3) is amended by adding at the end the following:

"(f) PRODUCT DIFFERENTIATION.—

"(1) IN GENERAL.—A final sunscreen order shall have the effect of authorizing solely the order requestor (or the licensees, assignees, or successors in interest of

such requestor with respect to the subject of such request and listed under paragraph (5)) for a period of 2 years, to market a sunscreen ingredient under this section incorporating changes described in paragraph (2) subject to the limitations under paragraph (4), beginning on the date the requestor (or any licensees, assignees, or successors in interest of such requestor with respect to the subject of such request and listed under paragraph (5)) may lawfully market such sunscreen ingredient pursuant to the order.

"(2) CHANGES DESCRIBED.—A change described in this paragraph is a change subject to an order specified in paragraph (1) that permits a sunscreen to contain an active sunscreen ingredient not previously incorporated in a marketed sunscreen listed in paragraph (3).

"(3) MARKETED SUNSCREEN.—The marketed sunscreen ingredients described this paragraph are sunscreen ingredients—

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

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

"(4) LIMITATIONS ON PRODUCT DIFFERENTIATION.—Only one 2-year period may be granted per ingredient under paragraph (1).

"(5) LISTING OF LICENSEES, ASSIGNEES, OR SUCCESSORS IN INTEREST.—Requestors shall submit to the Secretary at the time when a drug subject to such request is introduced or delivered for introduction into interstate commerce, a list of licensees, assignees, or successors in interest under paragraph (1).".

(d) SUNSCREEN INNOVATION ACT AMENDMENTS.—Section 586C(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3(e)) is amended by striking paragraph (3) and inserting the following:

"(3) RELATIONSHIP TO ORDERS UNDER SECTION 505G.—A final sunscreen order shall be deemed to be a final administrative order under section 505G and subject to the applicable provisions under such section 505G, including with respect to amendment of such order.".

(e) PRECLUSION OF NEW SUNSCREEN SUBMISSIONS; OPTION TO TRANSFER SUBMISSIONS TO OTC MONOGRAPH ORDER PROCESS.—

(1) SUNSET.—Beginning on the date of enactment of this Act, section 586A of the Federal Food,

Drug, and Cosmetic Act (21 U.S.C. 360fff–1) shall have no force or effect.

(2) OPTION TO TRANSFER SUBMISSIONS TO OTC MONOGRAPH ORDER PROCESS.—

(A) IN GENERAL.—Any person who submitted a request described in subparagraph (B) may, at any time prior to the sunset of subchapter I of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff et seq.) under section 586H of such Act, withdraw such request from the process under such subchapter and resubmit such request as an order request under section 505G of such Act.

(B) REQUESTS.—A request described in this subparagraph is—

(i) a request under section 586A of the Federal Food, Drug, and Cosmetic Act submitted before the date of enactment of this Act; or

(ii) a pending request described in section 586(6).

(f) TREATMENT OF AUTHORITY REGARDING FINALIZATION OF SUNSCREEN MONOGRAPH.—Section 586E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–5) is amended to read as follows:

"SEC. 586E. SUNSCREEN ORDER.

"(a) IN GENERAL.—

"(1) REVISION OF FINAL SUNSCREEN ORDER.—Not later than November 26, 2019, the Secretary shall amend and revise the final administrative order concerning nonprescription sunscreen (referred to in this section as the 'sunscreen order') for which the substance, prior to the date of enactment of the Over-the-Counter Drug Safety, Innovation, and Reform Act, was marketed in accordance with a final monograph for sunscreen drug products set forth in part 352 of title 21, Code of Federal Regulations (as published at 64 Fed. Reg. 27687)

"(2) ISSUANCE OF REVISED SUNSCREEN ORDER; EFFECTIVE DATE.—A revised sunscreen order described in paragraph (1) shall be—

"(A) issued in accordance with the procedures described in section 505G(c)(2);

"(B) issued in proposed form not later than May 28, 2019;

"(C) effective not later than November 26, 2020; and

"(D) issued by the Secretary at least 1 year prior to such effective date.

"(b) REPORTS.—If a revised sunscreen order issued under subsection (a) does not include provisions related to

the effectiveness of various sun protection factor levels, and does not address all dosage forms known to the Secretary to be used in sunscreens marketed in the United States without a new drug application approved under section 505, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the rationale for omission of such provisions from such order, and a plan and timeline to compile any information necessary to address such provisions through such order.".

(g) SUNSET OF PROCESS UNDER SUNSCREEN INNOVATION ACT.—Subchapter I of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff et seq.), as amended by subsection (f), is further amended by inserting at the end the following new section:

"SEC. 586H. SUNSET.

"This subchapter shall no longer be effective upon the later of—

"(1) a final determination by the Secretary under this subchapter with respect to every request described in section 586A(b)(2) (other than any withdrawn requests and requests resubmitted as order requests under section 505G); or

"(2) the effective date of the revised sunscreen order described in section 586E(a)(2).".

SEC. 104. DRUGS EXCLUDED FROM OVER-THE-COUNTER REVIEW.

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

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to preclude or limit the applicability of any provision of the Federal Food, Drug, and Cosmetic Act.

SEC. 105. CONFORMING AMENDMENT.

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

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

(A) by striking "final regulation promulgated" and inserting "final order issued under section 505G"; and

(B) by striking "and not misbranded"; and

(2) in subparagraph (A), by striking "regulation in effect" and inserting "regulation or order in effect".

SEC. 106. ANNUAL UPDATE TO CONGRESS ON APPROPRIATE PEDIATRIC INDICATION FOR CERTAIN COUGH AND COLD MONOGRAPH DRUGS.

(a) IN GENERAL.—Not later than one year after the date of enactment of this Act and annually thereafter, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall 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 letter describing the progress of the Food and Drug Administration—

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

(2) as appropriate, revising such cough and cold monograph to address such children, through the administrative order process under section 505G(c) of the Federal Food, Drug, and Cosmetic Act, as added by section 101.

(b) COUGH AND COLD MONOGRAPH DESCRIBED.—The cough and cold monograph described in this subsection consists of the conditions under which nonprescription drug products containing antitussive, expectorant, nasal decongestant, or antihistamine active ingredients (or combinations thereof) are generally recognized as safe and effective, as specified in part 341 of title 21, Code of Federal Regula-

tions (as in effect on the day before the date of enactment of this Act), and included in an administrative order deemed established under such section 505G(c) of the Federal Food, Drug, and Cosmetic Act.

(c) DURATION OF AUTHORITY.—Subsection (a) shall have no force or effect beginning on the date on which the Secretary submits a letter under subsection (a) in which the Secretary indicates that the Food and Drug Administration has completed its evaluation and revised, in a final administrative order, as applicable, the cough and cold monograph in accordance with this section.

TITLE II—FEES RELATING TO MONOGRAPH DRUGS

SEC. 201. SHORT TITLE; FINDINGS.

(a) SHORT TITLE.—This title may be cited as the "Over-the-Counter Monograph User Fee Act of 2018".

(b) FINDINGS.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated toward the regulation of monograph drugs under section 505G of the Federal, Food, Drug, and Cosmetic Act, as set forth in the goals identified for purposes of such section, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the

House of Representatives, as set forth in the Congressional Record.

SEC. 202. AUTHORITY TO ASSESS AND USE 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 MONOGRAPH 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 'contract manufacturing organization facility' means a monograph drug facility where neither the owner of such manufacturing facility nor any affiliate of such owner or facility sells such monograph drug produced at such facility directly to wholesalers, retailers, or consumers in the United States.

"(3) The term 'costs of resources allocated for monograph drug activities' means the expenses in connection with monograph 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 monograph drug activities.

"(4) 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 'monograph drug' means a drug subject to section 505G.

"(6) The term 'monograph drug activities' means activities of the Secretary associated with monograph drugs and inspection of facilities associated with such drugs, including—

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

"(i) orders proposing or finalizing applicable requirements for monograph drugs;

"(ii) orders affecting status regarding general recognition of safety and effectiveness of a monograph drug ingredient or combination of ingredients under specified requirements;

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

"(iv) regulation and policy development activities related to monograph drugs;

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

"(vi) meetings regarding monograph drug activities;

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

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

"(B) inspections related to monograph drugs;

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

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

"(i) collecting, developing, and reviewing safety information on monograph 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.

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

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

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

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

"(II) testing; or

"(III) placement of outer overpackaging on packages containing multiple products, for such purposes as creating multipacks, when each monograph drug product contained within the overpackaging

is already in a final packaged form prior to placement in the outer overpackaging.

"(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.

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

"(9) The term 'monograph drug product' means a monograph drug product that is marketed without

an approved new drug application in accordance with section 505G.

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

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

"(12) The term 'person' includes an affiliate thereof.

"(13) The term 'Tier 1 monograph drug order request' means any monograph drug order request not determined to be a Tier 2 monograph drug order request.

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

"(i) the reordering of existing information in the drug facts label of a monograph drug product;

"(ii) the addition of information to the other information section of the drug facts label

of a 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 (or any successor regulation).

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

"SEC. 744L–1. AUTHORITY TO ASSESS AND USE MONOGRAPH DRUG FEES.

"(a) TYPES OF FEES.—Beginning with fiscal year 2019, 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 monograph 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.—

"(i) IN GENERAL.—A fee shall not be assessed under subparagraph (A) if the identified monograph drug facility has ceased all activities related to monograph drugs 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.

"(ii) FEE AMOUNT.—The amount of the fee for a contract manufacturing organization facility shall be equal to two-thirds

the amount of the fee for a monograph drug facility that is not a contract manufacturing organization facility.

"(C) DUE DATE.—

"(i) FOR FIRST PROGRAM YEAR.—For fiscal year 2019, the facility fees required under subparagraph (A) shall be due 45 calendar days after publication of the Federal Register notice provided for under subsection (c)(4)(A).

"(ii) SUBSEQUENT FISCAL YEARS.—For each fiscal year after fiscal year 2019, the facility fees required under subparagraph (A) shall be due on the later of—

"(I) the first business day of June of such year; or

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

"(2) MONOGRAPH DRUG ORDER REQUEST FEE.—

"(A) IN GENERAL.—Each person that submits a monograph drug order request shall be subject to a fee for a monograph drug order re-

quest. The monograph drug order request fee under paragraph (2) shall be—

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

"(ii) for a Tier 2 monograph 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 monograph drug order request fees required under subparagraph (A) shall be due on the date of submission of the monograph drug order request.

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

"(D) REFUND OF FEE IF ORDER REQUEST IS RECATEGORIZED AS A TIER 2 MONOGRAPH DRUG ORDER REQUEST.—If the Secretary determines that a monograph drug request initially characterized as Tier 1 should be re-characterized as a Tier 2 monograph 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 that is refused for filing.

"(F) FEES FOR ORDER REQUESTS PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—A monograph drug order request that was submitted but was refused for fil-

ing, 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 re-

quest justifying such return within 180 calendar days after such fee was paid.

"(b) FEE REVENUE AMOUNTS.—

"(1) FISCAL YEAR 2019.—For fiscal year 2019, 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 2019 (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 2020 through 2023, 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 2020.

"(ii) $6,000,000 for fiscal year 2021.

"(iii) $7,000,000 for fiscal year 2022.

"(iv) $3,000,000 for fiscal year 2023.

"(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 2019, $8,000,000; and

"(B) for fiscal years 2020 through 2023, 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 infla-

tion adjustment to the annual base revenue for fiscal year 2020 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 2020 through 2021, 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 2022 and 2023, 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 com-

pensation 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 monograph 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 monograph drug activities for the first 3 years of the preceding 4 fiscal years.

"(2) OPERATING RESERVE ADJUSTMENT.—

"(A) For fiscal year 2019 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 monograph 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 2019;

"(ii) 7 weeks for fiscal year 2020;

"(iii) 10 weeks for fiscal year 2021;

"(iv) 10 weeks for fiscal year 2022; and

"(v) 10 weeks for fiscal year 2023.

"(C) If, for fiscal years 2020 through 2023, the Secretary has carryover balances for monograph 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 2019;

"(B) 7,000,000 for fiscal year 2020;

"(C) 4,000,000 for fiscal year 2021;

"(D) 3,000,000 for fiscal year 2022; and

"(E) 3,000,000 for fiscal year 2023.

"(4) ANNUAL FEE SETTING.—

"(A) FISCAL YEAR 2019.—The Secretary shall, not later than January 31, 2019—

"(i) establish monograph drug facility fees for fiscal year 2019 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, 2019, establish for each such fiscal year, based on the revenue amounts under subsection (b) and the adjustments provided under this subsection—

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

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

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

"(d) IDENTIFICATION OF FACILITIES.—Each person that owns a monograph 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 monograph drug facility.

"(e) EFFECT OF FAILURE TO PAY FEES.—

"(1) IN GENERAL.—A monograph 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) EFFECT ON ELIGIBILITY FOR MEETINGS.—If a monograph drug requestor fails to pay a fee assessed under subsection (a), the requestor shall be considered ineligible for monograph drug meetings.

"(f) MONOGRAPH DRUG FACILITY FEE.—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 Secretary placing the facility on a publicly available arrears list until such fee has been paid.

"(g) CREDITING AND AVAILABILITY OF FEES.—

"(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent 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 monograph drug activities.

"(2) COLLECTIONS AND APPROPRIATION ACTS.—

"(A) IN GENERAL.—Subject to subparagraph (C), 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 monograph drug activities (including increases in such costs for an additional number of full-time equivalent positions 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 monograph drug activities are not more than 15 percent below the level specified in such subparagraph.

"(D) PROVISION FOR EARLY PAYMENTS IN SUBSEQUENT YEARS.—Payment of fees authorized under this section for a fiscal year (after fiscal year 2019), 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 2019 through 2023, 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 monograph 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 2019, and not later than 120 calendar 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 201 of the Over-the-Counter Drug Safety, Innovation, and Reform Act 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 calendar days after the end of fiscal year 2019 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 website 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 monograph drug activities for the first 5 fiscal years after fiscal year 2023, 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 calendar 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, 2023, 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.".

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S. 2315

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.

MAY 14, 2018

Reported with an amendment