115TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPORT
115–827

OVER-THE-COUNTER MONOGRAPH SAFETY, INNOVATION, AND REFORM ACT OF 2018

JULY 16, 2018.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. WALDEN, from the Committee on Energy and Commerce, submitted the following

R E P O R T

together with

ADDITIONAL VIEWS

[To accompany H.R. 5333]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 5333) 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, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

79–006

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018".

TITLE I—OTC DRUG REVIEW

SEC. 101. REGULATION OF CERTAIN NONPRESCRIPTION DRUGS THAT ARE MARKETED WITHOUT AN APPROVED NEW DRUG APPLICATION.

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

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

"(a) NONPRESCRIPTION DRUGS MARKETED WITHOUT AN APPROVED APPLICATION.—Nonprescription drugs marketed without an approved new drug application under section 505, as of the date of the enactment of the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018, shall be treated in accordance with this subsection.

"(1) DRUGS SUBJECT TO A FINAL MONOGRAPH; CATEGORY I DRUGS SUBJECT TO A TENTATIVE FINAL MONOGRAPH.—A drug is deemed to be generally recognized as safe and effective within the meaning of section 201(p)(1), not a new drug under section 201(p), and not subject to section 503(b)(1), if—

"(A) the drug is—

"(i) in conformity with the requirements for nonprescription use of a final monograph issued under part 330 of title 21, Code of Federal Regulations (except as provided in paragraph (2)), the general requirements for nonprescription drugs, and requirements under subsections (b), (c), and (k); and

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

"(B) the drug is—

"(i) classified in category I for safety and effectiveness under a tentative final monograph that is the most recently applicable proposal or determination issued under part 330 of title 21, Code of Federal Regulations;

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

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

"(2) TREATMENT OF SUNSCREEN DRUGS.—With respect to sunscreen drugs subject to this section, the applicable requirements shall be the requirements specified in part 352 of title 21, Code of Federal Regulations, as published on May 21, 1999, beginning on page 27687 of volume 64 of the Federal Register, except that the applicable requirements governing effectiveness and labeling shall be those specified in section 201.327 of title 21, Code of Federal Regulations, subject to the requirements of subsections (b), (c), and (k).

"(3) CATEGORY III DRUGS SUBJECT TO A TENTATIVE FINAL MONOGRAPH; CATEGORY I DRUGS SUBJECT TO PROPOSED MONOGRAPH OR ADVANCE NOTICE OF PROPOSED RULEMAKING.—A drug that is not described in paragraphs (1), (2), or (4) is not required to be the subject of an application approved under section 505, and is not subject to section 503(b)(1), if—

"(A) the drug is—

"(i) classified in category III for safety or effectiveness in the preamble of a proposed rule establishing a tentative final monograph that is the most recently applicable proposal or determination for such drug issued under part 330 of title 21, Code of Federal Regulations;

"(ii) in conformity with—

"(I) the conditions of use, including indication and dosage strength, if any, described for such category III drug in such preamble or in an applicable subsequent proposed rule;

"(II) the proposed requirements for drugs classified in such tentative final monograph in category I in the most recently proposed rule establishing requirements related to such tentative final monograph and in any final rule establishing requirements that are applicable to the drug; and

"(III) the general requirements for nonprescription drugs and requirements under subsections (b) or (k); and

"(iii) in a dosage form that, immediately prior to the date of the enactment of this section, was not required to have satisfied the requirements of section 330.14 of title 21, Code of Federal Regulations (as in effect at that time), in order for such drug to be lawfully marketed without an application approved under section 505; or

"(B) the drug is—

"(i) classified in category I for safety and effectiveness under a proposed monograph or advance notice of proposed rulemaking that is the most recently applicable proposal or determination for such drug issued under part 330 of title 21, Code of Federal Regulations;

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

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

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

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

"(6) OTHER DRUGS DEEMED NEW DRUGS.—Except as provided in subsection (m), a drug is deemed to be a new drug within the meaning of section 201(p) and misbranded under section 502(ee) if the drug—

"(A) is not subject to section 503(b)(1); and

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

"(b) ADMINISTRATIVE ORDERS.—

"(1) IN GENERAL.—

"(A) DETERMINATION.—The Secretary may, on the initiative of the Secretary or at the request of one or more requestors, issue administrative orders determining whether there are conditions under which specific drugs, classes of such drugs, or combinations of such drugs are determined to be—

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

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

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

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

"(ii) is marketed in conformity with an administrative order under this subsection;

"(iii) meets the general requirements for nonprescription drugs; and

"(iv) meets the requirements under subsections (c) and (k).

"(C) STANDARD.—The Secretary shall find that a drug is not generally recognized as safe and effective within the meaning of section 201(p)(1) if—

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

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

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

"(A) IN GENERAL.—In issuing an administrative order under paragraph (1) upon the Secretary's initiative, the Secretary shall—

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

"(ii) after any such reasonable efforts of notification—

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

"(II) publish a 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 completion of the proceedings specified in 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, which order shall not take effect until the time for requesting judicial review under paragraph (3)(D)(ii) has expired;

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

"(III) afford requestors of drugs 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 must 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 persons which sought such dispute resolution of their right to request a hearing.

"(B) EXCEPTIONS.—When issuing an administrative order under paragraph (1) on the Secretary's initiative proposing to determine that a drug described in subsection (a)(3) 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 no less than 180 calendar days with respect to such proposed order, except when the Secretary determines, for good cause, that a shorter period is in the interests 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).

"(3) HEARINGS; JUDICIAL REVIEW.—

"(A) IN GENERAL.—Only a person who participated in each stage of formal dispute resolution under subclause (III) of paragraph (2)(A)(iv) of an administrative order with respect to a drug may request a hearing concerning a final administrative order issued under such paragraph with respect to such drug. Such person must submit a request for a hearing, which shall be based solely on 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.—

"(i) IN GENERAL.—The Secretary shall not be 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 (a)(3)(A); and

"(II) with respect to which no human or non-human data studies 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.

"(ii) HUMAN DATA STUDIES AND NON-HUMAN DATA DEFINED.—In this subparagraph:

"(I) The term 'human data studies' means clinical trials of safety or effectiveness (including actual use studies), pharmacokinetics studies, or bioavailability studies.

"(II) The term 'non-human data' means data from testing other than with human subjects which provides information concerning safety or effectiveness.

"(C) HEARING PROCEDURES.—

"(i) DENIAL OF REQUEST FOR HEARING.—If the Secretary determines that information submitted in a request for a hearing under subparagraph (A) with respect to a final administrative order issued under paragraph (2)(A)(iv), does not identify 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 presiding officer of a hearing requested under subparagraph (A) shall—

"(I) be designated by the Secretary;

"(II) not be an employee of the Center for Drug Evaluation and Research; and

"(III) not have been previously involved in the development of the administrative order involved or 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.—

"(I) 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.

"(II) 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 dis-

trict court of the United States in lieu of the appellate courts specified in such section.

"(ii) PERIOD TO SUBMIT A REQUEST FOR JUDICIAL REVIEW.—A person eligible to request a hearing under this paragraph and seeking judicial review of a final administrative order issued under this subsection shall file such request for judicial 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 a hearing with respect to such order is denied under subparagraph (B) or (C)(i);

"(III) the date on which a final decision is made following a hearing 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 drug, class of drugs, or combination of drugs subject to this section poses an imminent hazard to the public health, the Secretary, after first making reasonable efforts to notify, not later than 48 hours before issuance of such order under this subparagraph, sponsors who have a listing in effect under section 510(j) for such drug or combination of drugs—

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

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

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

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

"(B) SAFETY LABELING CHANGES.—

"(i) IN GENERAL.—In the case of a determination by the Secretary that a change in the labeling of a drug, class of drugs, or combination of drugs subject to this section is reasonably expected to mitigate a significant or unreasonable risk of a serious adverse event associated with use of the drug, the Secretary may—

"(I) make reasonable efforts to notify informally, not later than 48 hours before the issuance of the interim final order, the sponsors of drugs who have a listing in effect under section 510(j) for such drug or combination of drugs;

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

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

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

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

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

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

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

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

"(iii) afford sponsors of such 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 must initially 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.—A sponsor of a drug subject to a final order issued under subparagraph (D) and that participated in each stage of formal dispute res-

olution under clause (iii) of such subparagraph may request a hearing on such order. The provisions of subparagraphs (A), (B), and (C) of paragraph (3), other than paragraph (3)(C)(v)(II), 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).

"(F) TIMING.—

"(i) FINAL ORDER AND HEARING.—The Secretary shall—

"(I) not later than 6 months after the date on which the comment period closes under subparagraph (A) or (B), issue a final order in accordance with paragraph (1); and

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

"(ii) DISPUTE RESOLUTION REQUEST.—The Secretary shall specify in an interim final order issued under subparagraph (A) or (B) such shorter periods for requesting dispute resolution under subparagraph (D)(iii) as are necessary to meet the requirements of this subparagraph.

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

"(5) ADMINISTRATIVE ORDER INITIATED AT THE REQUEST OF A REQUESTOR.—

"(A) IN GENERAL.—In issuing an administrative order under paragraph (1) at the request of a requestor with respect to certain drugs, classes of drugs, or combinations of drugs—

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

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

"(I) file the request; and

"(II) initiate proceedings with respect to issuing an administrative order in accordance with paragraphs (2) and (3); and

"(iii) except as provided in paragraph (6), if the Secretary determines that a request does not meet the requirements for filing or is not sufficiently complete and formatted to permit a substantive review, the requestor may demand that the request be filed 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 under paragraph (1) with respect to certain drugs, classes of drugs, or combinations of drugs, shall submit to the Secretary a request to initiate proceedings for such order in the form and manner as specified by the Secretary. Such requestor may submit a request under this subparagraph for the issuance of an administrative order—

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

"(II) determining whether a change to a condition of use of a drug is generally recognized as safe and effective within the meaning of section 201(p)(1), exempt from section 503(b)(1), and not required to be the subject of an approved application under section 505, if, absent such a changed condition of use, such drug is—

"(aa) generally recognized as safe and effective within the meaning of section 201(p)(1) in accordance with subsection (a)(1), (a)(2), or an order under this subsection; or

"(bb) subject to subsection (a)(3), 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).

"(ii) EXCEPTION.—The Secretary is not required to complete review of a request for a change described in clause (i)(II) if the Secretary determines that there is an inadequate basis to find the drug is generally recognized as safe and effective within the meaning of section 201(p)(1) under paragraph (1) and issues a final order announcing that determination.

"(iii) WITHDRAWAL.—The requestor may withdraw a request under this paragraph, according to the procedures set forth pursuant to subsection (d)(2)(B). Notwithstanding any other provision of this section, if such request is withdrawn, the Secretary may cease proceedings under this subparagraph.

"(C) EXCLUSIVITY.—

"(i) IN GENERAL.—A final administrative order issued in response to a request under this section 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), for a period of 18 months following the effective date of such final order, to market drugs—

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

"(II) beginning on the date the requestor (or any such licensees, assignees, or successors in interest) may lawfully market such drugs pursuant to the order; and

"(III) 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 subsection (a)(1), (a)(2), or (a)(3);

"(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 (m)(1), other than drugs subject to an active enforcement action under chapter III of this Act.

"(iv) LIMITATIONS ON EXCLUSIVITY.—

"(I) IN GENERAL.—Only one period of exclusivity shall be granted, under each order described in clause (i), with respect to changes (to the drug subject to such order) which are either—

"(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) NO EXCLUSIVITY ALLOWED.—No exclusivity shall apply to changes to a drug which are—

"(aa) the subject of a Tier 2 OTC monograph order request (as defined in section 744N);

"(bb) safety-related changes, as defined by the Secretary, or any other changes the Secretary considers necessary to assure safe use; or

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

"(v) NEW HUMAN DATA STUDIES DEFINED.—In this subparagraph, the term 'new human data studies' means clinical trials of safety or effectiveness (including actual use studies), pharmacokinetics studies, or bioavailability studies, the results of which—

"(I) have not been relied on by the Secretary 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 that was approved under section 505; and

"(II) do not duplicate the results of another study that was relied on by the Secretary 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 that was approved under section 505.

"(vi) EFFECTIVE DATE.—A final order subject to clause (i) shall take effect on the date when the order requestor (or the licensees, assignees, or successors in interest of such requestor with respect to such order) submits updated drug listing information under subsection (e) with respect to the change which is permitted under such order.

"(vii) GAO STUDY.—Not later than 4 years after the date of enactment of the Over-the-Counter Monograph, Safety, Innovation, and Reform Act of 2018, the Comptroller General of the United States shall submit a study to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate addressing the effectiveness and overall impact of exclusivity under this section, including its impact on consumer access. Such study shall include—

"(I) the number of nonprescription drug products that were granted exclusivity and the indication for which the nonprescription drug products were determined to be generally recognized as safe and effective;

"(II) whether the exclusivity for such drug products was granted for—

"(aa) a new active ingredient (including any ester or salt of the active ingredient); or

"(bb) changes in the conditions of use of a drug, for which new human data studies conducted or sponsored by the requestor were essential;

"(III) whether, and to what extent, the exclusivity impacted the requestor's or sponsor's decision to develop the drug product;

"(IV) an analysis of the implementation of the exclusivity provision in this subparagraph, including—

"(aa) the resources used by the Food and Drug Administration;

"(bb) the impact of such provision on innovation, as well as research and development in the nonprescription drug market;

"(cc) the impact of such provision on competition in the nonprescription drug market;

"(dd) the impact of such provision on consumer access to nonprescription drug products;

"(ee) the impact of such provision on the prices of nonprescription drug products; and

"(ff) whether the administrative orders initiated by requestors under this section have been sufficient to encourage the development of nonprescription drug products that would likely not be otherwise developed, or developed in as timely a manner; and

"(V) whether the administrative orders initiated by requestors under this section have been sufficient incentive to encourage innovation in the nonprescription drug market.

"(6) INFORMATION REGARDING SAFE NONPRESCRIPTION MARKETING AND USE AS CONDITION FOR FILING A GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE REQUEST.—

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

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

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

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

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

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

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

"(C) INFORMATION DEMONSTRATING PRIMA FACIE SAFE NONPRESCRIPTION MARKETING AND USE.—Information specified in this subparagraph, with respect to a request described in subparagraph (A)(i), is—

"(i) information sufficient for a prima facie 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 prima facie demonstration that the drug was marketed and safely used under comparable conditions of marketing and use in a country listed in section 802(b)(1)(A) or designated by the Secretary in accordance with section 802(b)(1)(B)—

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

"(II) during such time was subject to sufficient monitoring by a regulatory body considered acceptable by the Secretary for such monitoring purposes, including for adverse events associated with nonprescription use of the drug; or

"(iii) if the Secretary determines that information described in clauses (i) or (ii) is not needed to provide a prima facie demonstration that the drug can be safely marketed and used as a nonprescription drug, such other information the Secretary determines is sufficient for such purposes.

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

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

"(ii) during such time period, one million retail packages of the drug, or an equivalent quantity as determined by the Secretary, were distributed for retail sale, as determined in such manner as the Secretary finds appropriate.

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

"(7) PACKAGING.—An administrative order issued under paragraph (2), (4)(A), or (5) may include requirements for the packaging of a drug to encourage use in accordance with labeling. Such requirements may include unit dose packaging, requirements for products intended for use by children, requirements to reduce risk of harm from unsupervised ingestion, and other appropriate requirements. This paragraph does not authorize the Food and Drug Administration to require standards or testing procedures as described in part 1700 of title 16, Code of Federal Regulations.

"(8) FINAL AND TENTATIVE FINAL MONOGRAPHS FOR CATEGORY I DRUGS DEEMED FINAL ADMINISTRATIVE ORDERS.—

"(A) IN GENERAL.—A final monograph or tentative final monograph described in subparagraph (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 is described in this subparagraph if it—

"(i) establishes conditions of use for a drug described in paragraph (1) or (2) of subsection (a); and

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

"(C) DEEMED ORDERS INCLUDE HARMONIZING TECHNICAL AMENDMENTS.—The deemed establishment of a final administrative order under subparagraph (A) shall be construed to include any technical amendments to such order as the Secretary determines necessary to ensure that such order is appropriately harmonized, in terms of terminology or cross-references, with the applicable provisions of this Act (and regulations thereunder) and any other orders issued under this section.

"(c) PROCEDURE FOR MINOR CHANGES.—

"(1) IN GENERAL.—Minor changes in the dosage form of a drug that is described in paragraph (1) or (2) of subsection (a) or the subject of an order issued

under subsection (b) may be made by a requestor without the issuance of an order under subsection (b) if—

"(A) the requestor maintains such information as is necessary to demonstrate that the change—

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

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

"(B) the 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.—A sponsor shall submit records requested by the Secretary relating to such a minor change under section 704(a)(4), within 15 business days of receiving such a 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 sponsor of the drug in writing; and

"(ii) provide the sponsor of the drug with a reasonable opportunity to provide additional information.

"(C) FAILURE TO SUBMIT SUFFICIENT INFORMATION.—If the sponsor 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 A CHANGE WILL AFFECT SAFETY OR EFFECTIVENESS.—

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

"(B) STANDARD PRACTICES.—The orders and guidance issued by the Secretary under subparagraph (A) shall take into account relevant public standards and standard practices for evaluating the quality of drugs, and may take into account the special needs of populations, including children.

"(d) CONFIDENTIALITY OF INFORMATION SUBMITTED TO THE SECRETARY.—

"(1) IN GENERAL.—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 order under this section (including any minor change under subsection (c)) 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.—

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

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

"(ii) make any information submitted by any other person with respect to an order requested (or initiated by the Secretary) under subsection (b), available to the public upon such submission.

"(B) LIMITATIONS ON PUBLIC AVAILABILITY.—Information described in subparagraph (A) shall not be made public if—

"(i) the information pertains to pharmaceutical quality information, 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);

"(ii) the information is submitted in a requestor-initiated request, but the requestor withdraws such request, in accordance with withdrawal

procedures established by the Secretary, before the Secretary issues the proposed order;

"(iii) the Secretary requests and obtains the information under subsection (c) and such information is not submitted in relation to an order under subsection (b); or

"(iv) the information is of the type contained in raw datasets.

"(e) 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 section 510(j) within 30 calendar days of the date when the drug is first commercially marketed, except that a sponsor who was the order requestor with respect to an order subject to subsection (b)(5)(C) (or a licensee, assignee, or successor in interest of such requestor) shall submit updated drug listing information on or before the date when the drug is first commercially marketed.

"(f) APPROVALS UNDER SECTION 505.—The provisions of this section shall not be construed to preclude a person from seeking or maintaining the approval of a drug under sections 505(b)(1), 505(b)(2), and 505(j). 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 that the drug is safe and effective that may be relied upon for purposes of an application under section 505(b)(2), so that the applicant shall be required to submit for purposes of such application only information needed to support any modification of the drug that is not covered by such determination under this section.

"(g) PUBLIC AVAILABILITY OF ADMINISTRATIVE ORDERS.—The Secretary shall establish, maintain, update (as determined necessary by the Secretary but no less frequently than annually), and make publicly available, with respect to orders issued under this section—

"(1) a repository of each final order and interim final order in effect, including the complete text of the order; and

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

"(A) a brief description of each such order; and

"(B) the Secretary's expectations, if resources permit, for issuance of proposed orders over a three-year period.

"(h) DEVELOPMENT ADVICE TO SPONSORS OR REQUESTORS.—The Secretary shall establish procedures under which sponsors or requestors may meet with appropriate officials of the Food and Drug Administration to obtain advice on the studies and other information necessary to support submissions under this section and other matters relevant to the regulation of nonprescription drugs and the development of new nonprescription drugs under this section.

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

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

"(k) 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) The provisions of section 310.545 of title 21, Code of Federal Regulations, as in effect on the day before the date of the enactment of this section, shall be deemed to be a final order under subsection (b).

"(B) Regulations in effect on the day before the date of the enactment of this section, establishing requirements for specific nonprescription drugs marketed pursuant to this section (including such requirements in parts 201 and 250 of title 21, Code of Federal Regulations), shall be deemed to be final orders under subsection (b), only as they apply to drugs—

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

"(ii) otherwise subject to an order under this section.

"(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 the enactment of this section), or make technical changes to such regulations to ensure conformity with appropriate terminology and cross references. Notwithstanding subchapter II of chapter 5 of title 5, United States Code, any such withdrawal or technical changes shall be made without public notice and comment and shall be effective upon publication through notice in the Federal Register (or upon such date as specified in such notice).

"(l) GUIDANCE.—The Secretary shall issue guidance that specifies—

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

"(2) the format and content of data submissions to the Secretary under this section;

"(3) the format of electronic submissions to the Secretary under this section;

"(4) consolidated proceedings and the procedures for such proceedings where appropriate; and

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

"(m) RULE OF CONSTRUCTION.—

"(1) IN GENERAL.—This section shall not affect the treatment or status of a nonprescription drug—

"(A) that is marketed without an application approved under section 505 as of the date of the enactment of this section;

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

"(C) to which paragraphs (1), (2), (3), (4), or (5) of subsection (a) do not apply.

"(2) TREATMENT OF PRODUCTS PREVIOUSLY FOUND TO BE SUBJECT TO TIME AND EXTENT REQUIREMENTS.—

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

"(B) A drug described in this subparagraph is a drug which, prior to the date of the enactment of this section, the Secretary had determined in a proposed or final rule to be ineligible for review under the OTC drug review (as such phrase 'OTC drug review' was used in section 330.14 of title 21, Code of Federal Regulations, as in effect on the day before the date of the enactment of this section).

"(3) PRESERVATION OF AUTHORITY.—

"(A) Nothing in paragraph (1) shall be construed to preclude or limit the applicability of any other provision of this Act.

"(B) Nothing in subsection (a) 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 within the meaning of section 201(p)(1), as the Secretary determines appropriate.

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

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

"(p) INAPPLICABILITY OF NOTICE AND COMMENT RULEMAKING AND OTHER REQUIREMENTS.—The requirements of subsection (b) shall apply with respect to orders issued under this section instead of the requirements of subchapter II of chapter 5 of title 5, United States Code.

"(q) DEFINITIONS.—In this section:

"(1) The term 'nonprescription drug' refers to a drug not subject to the requirements of section 503(b)(1).

"(2) The term 'sponsor' refers to any person marketing, manufacturing, or processing a drug that—

"(A) is listed pursuant to section 510(j); and

"(B) is or will be subject to an administrative order of the Food and Drug Administration.

"(3) The term 'requestor' refers to any person or group of persons marketing, manufacturing, processing, or developing a drug.".

SEC. 102. MISBRANDING.

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

"(ee) If it is a nonprescription drug that is subject to section 505G, 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 and it was manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid as required by section 744O.".

SEC. 103. DRUGS EXCLUDED FROM THE OVER-THE-COUNTER DRUG 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 other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

SEC. 104. TREATMENT OF SUNSCREEN INNOVATION ACT.

(a) REVIEW OF NONPRESCRIPTION SUNSCREEN ACTIVE INGREDIENTS.—

(1) APPLICABILITY OF SECTION 505G FOR PENDING SUBMISSIONS.—

(A) IN GENERAL.—A sponsor of a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that, as of the date of enactment of this Act, is subject to a proposed sunscreen order under section 586C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3) may elect, by means of giving written notification to the Secretary of Health and Human Services within 180 calendar days of the enactment of this Act, to transition into the review of such ingredient or combination of ingredients pursuant to the process set out in section 505G of the Federal Food, Drug, and Cosmetic Act, as added by section 101 of this Act.

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

(i) the proposed sunscreen order involved is deemed to be a request for an order under subsection (b) of section 505G of the Federal Food, Drug, and Cosmetic Act, as added by section 101 of this Act; and

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

(C) ELECTION NOT EXERCISED.—A sponsor of a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients described in subparagraph (A) that does not elect for such ingredient or combination of ingredients to be reviewed under section 505G of the Federal Food, Drug, and Cosmetic Act, as added by section 101 of this Act, shall continue to have such ingredient or combination of ingredients reviewed in accordance with section 586C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3) and may not subsequently elect to transition into the review of such ingredient or combination of ingredients pursuant to the process set out in section 505G of such Act, as added by section 101 of this Act.

(2) DEFINITIONS.—In this subsection, the terms "sponsor", "nonprescription", "sunscreen active ingredient", and "proposed sunscreen order" have the meanings given to those terms in section 586 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff).

(b) AMENDMENTS TO SUNSCREEN PROVISIONS.—

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

"(3) RELATIONSHIP TO ORDERS UNDER SECTION 505G.—A final sunscreen order shall be deemed to be a final order under section 505G.".

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

(A) by striking "A sponsor may request" and inserting the following:

"(A) IN GENERAL.—A sponsor may request"; and

(B) by adding at the end the following:

"(B) CONFIDENTIAL MEETINGS.—A sponsor may request one or more confidential meetings with respect to a proposed sunscreen order, including a letter deemed to be a proposed sunscreen order under paragraph (3), to discuss matters involving confidential commercial information or trade secrets. The Secretary shall convene a confidential meeting with such sponsor in a reasonable time period. 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 that such additional confidential meeting is not reasonably necessary for the sponsor to advance its proposed sunscreen order, or if the request for a confidential meeting fails to include sufficient information upon which to base a substantive discussion. The Secretary shall publish a post-meeting summary of each confidential meeting under this subparagraph that does not disclose confidential commercial information or trade secrets.".

(3) SUNSET PROVISION.—Subchapter I of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff et seq.) is amended by adding at the end the following:

"SEC. 586H. SUNSET.

"This subchapter shall cease to be effective at the end of fiscal year 2022.".

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

(c) TREATMENT OF NON-SUNSCREEN TIME AND EXTENT APPLICATIONS.—

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

(2) ORDER REQUEST.—Nothing in paragraph (1) 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 extinguished under paragraph (1).

SEC. 105. ANNUAL UPDATE TO CONGRESS ON APPROPRIATE PEDIATRIC INDICATION FOR CERTAIN OTC COUGH AND COLD DRUGS.

(a) IN GENERAL.—Subject to subsection (c), the Secretary of Health and Human Services shall, beginning not later than one year after the date of enactment of this Act, annually submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate 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 order process under section 505G(b) of the Federal Food, Drug, and Cosmetic Act, as added by section 101 of this Act.

(b) COUGH AND COLD MONOGRAPH DESCRIBED.—The cough and cold monograph described in this subsection consists of the conditions under which nonprescription drugs 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 Regulations (as in effect immediately prior to the date of enactment of this Act), and included in an order deemed to be established under section 505G(b) of the Federal Food, Drug, and Cosmetic Act, as added by section 101 of this Act.

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

TITLE II—USER FEES

SEC. 201. SHORT TITLE; FINDING.

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

(b) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated to OTC monograph drug activities, as set forth in the goals identified for purposes of part 10 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, 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. FEES RELATING TO OVER-THE-COUNTER DRUGS.

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

"PART 10—FEES RELATING TO OVER-THE-COUNTER DRUGS

"SEC. 744N. DEFINITIONS.

"In 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 an OTC monograph drug facility where neither the owner of such manufacturing facility nor any affiliate of such owner or facility sells the OTC monograph drug produced at such facility directly to wholesalers, retailers, or consumers in the United States.

"(3) The term 'costs of resources allocated for OTC monograph drug activities' means the expenses in connection with OTC 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 costs related 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 744O and accounting for resources allocated for OTC monograph drug activities.

"(4) The term 'FDA establishment identifier' is the unique number automatically generated by Food and Drug Administration's Field Accomplishments and Compliance Tracking System (FACTS) (or any successor system).

"(5) The term 'OTC monograph drug' means a nonprescription drug without an approved new drug application which is governed by the provisions of section 505G.

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

"(A) The activities necessary for review and evaluation of OTC monographs and OTC monograph order requests, including—

"(i) orders proposing or finalizing applicable conditions of use for OTC monograph drugs;

"(ii) orders affecting status regarding general recognition of safety and effectiveness of an OTC monograph ingredient or combination of ingredients under specified conditions of use;

"(iii) all OTC monograph drug development and review activities, including intraagency collaboration;

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

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

"(vi) meetings referred to in section 505G(i);

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

"(viii) regulatory science activities related to OTC monograph drugs.

"(B) Inspections related to OTC monograph drugs.

"(C) Monitoring of clinical and other research conducted in connection with OTC monograph drugs.

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

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

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

"(7) The term 'OTC monograph order request' means a request for an order submitted under section 505G(b)(5).

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

"(9)(A) The term 'Tier 2 OTC monograph order request' means, subject to subparagraph (B), an OTC monograph order request for—

"(i) the reordering of existing information in the drug facts label of an OTC monograph drug;

"(ii) the addition of information to the other information section of the drug facts label of an OTC monograph drug, as limited by section 201.66(c)(7) of title 21, Code of Federal Regulations (or any successor regulations);

"(iii) modification to the directions for use section of the drug facts label of an OTC monograph drug, if such changes conform to changes made pursuant to section 505G(c)(3)(A);

"(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 section 330.1 of title 21, Code of Federal Regulations (or any successor regulations).

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

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

"(i) is—

"(I) under one management, either direct or indirect; and

"(II) at one geographic location or address engaged in manufacturing or processing the finished dosage form of an OTC monograph drug;

"(ii) includes a finished dosage form manufacturer facility in a contractual relationship with the sponsor of one or more OTC monograph drugs to manufacture or process such drugs; and

"(iii) does not include a business or other entity whose only manufacturing or processing activities are one or more of the following: production of clinical research supplies, or testing.

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

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

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

"(iii) under a single FDA 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 criteria specified in subparagraph (A), 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.

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

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

"(13) The terms 'requestor' and 'sponsor' have the meanings given such terms in section 505G.

"SEC. 744O. AUTHORITY TO ASSESS AND USE OTC MONOGRAPH 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.—Each person that owns a facility identified as an OTC 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) EXCEPTIONS.—

"(i) A fee shall not be assessed under subparagraph (A) if the identified OTC monograph drug facility has ceased all activities related to OTC monograph drugs prior to the date specified in subparagraph (D)(ii) and has updated its registration to reflect such change under the requirements for drug establishment registration set forth in section 510.

"(ii) The amount of the fee for a contract manufacturing organization facility shall be equal to ⅔ the amount of the fee for an OTC monograph drug facility that is not a contract manufacturing organization facility.

"(C) AMOUNT.—The amount of fees established under subparagraph (A) shall be established under subsection (c).

"(D) 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 enactment of an appropriations Act providing for the collection and obligation of fees under this section for such year.

"(2) OTC MONOGRAPH ORDER REQUEST FEE.—

"(A) IN GENERAL.—Each person that submits an OTC monograph order request shall be subject to a fee for an OTC monograph order request. The amount of such fee shall be—

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

"(ii) for a Tier 2 OTC monograph order request, $100,000 adjusted for inflation for the fiscal year (as determined under subsection (c)(1)(B)).

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

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

"(D) REFUND OF FEE IF ORDER REQUEST IS RECATEGORIZED AS A TIER 2 OTC MONOGRAPH ORDER REQUEST.—If the Secretary determines that an OTC monograph request initially characterized as Tier 1 shall be re-characterized as a Tier 2 OTC monograph order request, and the requestor has paid a Tier 1 fee in accordance with subparagraph (A)(i), the Secretary shall refund the requestor the difference between the Tier 1 and Tier 2 fees determined under subparagraphs (A)(i) and (A)(ii), respectively.

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

"(F) FEES FOR ORDER REQUESTS PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—An OTC monograph 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 subparagraph shall not be reviewable.

"(3) REFUNDS.—

"(A) IN GENERAL.—Other than refunds provided in subparagraphs (D) through (G) of paragraph (2), the Secretary shall not refund any fee paid under paragraph (1) 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 paragraph (1) or (2), a person shall submit to the Secretary a written request justifying such return within 180 calendar days after such fee was paid.

"(4) NOTICE.—Within the timeframe specified in subsection (c), the Secretary shall publish in the Federal Register the amount of the fees under paragraph (1) for such fiscal year.

"(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 inflation 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 (C).

"(B) OTC MONOGRAPH ORDER REQUEST FEES.—For purposes of subsection (a)(2), the dollar amount of the inflation adjustment to the fee for OTC monograph order requests for fiscal year 2020 and each subsequent fiscal year shall be equal to the product of—

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

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

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

"(i) for each of fiscal years 2020 and 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 compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multi-

plied by the proportion of personnel compensation and benefits costs to total costs of OTC monograph drug activities 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 OTC monograph drug activities for the first 3 years of the preceding 4 fiscal years.

"(2) OPERATING RESERVE ADJUSTMENT.—

"(A) IN GENERAL.—For fiscal year 2019 and subsequent fiscal years, for purposes of subsections (b)(1)(B) and (b)(2)(C), the Secretary may, in addition to adjustments under paragraph (1), further increase the fee revenue and fees if such an adjustment is necessary to provide operating reserves of carryover user fees for OTC monograph drug activities for not more than the number of weeks specified in subparagraph (B).

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

"(i) 3 weeks for fiscal year 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) DECREASE.—If the Secretary has carryover balances for such process in excess of 10 weeks of the operating reserves referred to in subparagraph (A), the Secretary shall decrease the fee revenue and fees referred to in such subparagraph to provide for not more than 10 weeks of such operating reserves.

"(D) RATIONALE FOR ADJUSTMENT.—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 (4) 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 and fees for purposes of subsection (b)(2)(D) 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 OTC monograph drug facility fees for fiscal year 2019 under subsection (a), based on the revenue amount for such year under subsection (b) and the adjustments provided under this subsection; and

"(ii) publish fee revenue, facility fees, and OTC monograph order requests 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) OTC monograph drug facility fees under subsection (a)(1);

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

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

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

"(e) EFFECT OF FAILURE TO PAY FEES.—

"(1) OTC MONOGRAPH DRUG FACILITY FEE.—

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

"(i) The Secretary shall place the facility on a publicly available arrears list.

"(ii) All OTC monograph drugs manufactured in such a facility or containing an ingredient manufactured in such a facility shall be deemed misbranded under section 502(a).

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

"(2) ORDER REQUESTS.—An OTC monograph 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 under this section have been paid.

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

"(f) 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 OTC 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 OTC 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 collected under this section) no less than $12,000,000, multiplied by the adjustment factor applicable to the fiscal year involved under subsection (c)(1).

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

"(D) PROVISION FOR EARLY PAYMENTS IN SUBSEQUENT YEARS.—Payment of fees authorized under this section for a fiscal year (after fiscal year 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.

"(g) 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, United States Code.

"(h) 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 OTC monograph drug activities, be reduced to offset the number of officers, employees, and advisory committees so engaged.

"SEC. 744P. 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 Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the

progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(b) of the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018 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 Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate 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 the Congress with respect to the goals described in subsection (a), and plans for meeting the goals, for OTC 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 Energy and Commerce of the House of Representatives;

"(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

"(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 the 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.".

PURPOSE AND SUMMARY

The legislation would amend the Federal Food, Drug, and Cosmetic Act to reform the over-the-counter (OTC) monograph regulatory framework. To streamline the current regulatory process, the legislation would create a system for future changes to OTC monographs to be done through an administrative order procedure with the opportunity for development meetings or other consultations, submission of comments on proposed orders, and dispute resolution procedures. To transition the OTC monograph framework to an administrative order process, the legislation includes, by reference, the OTC Drug Review Final Monographs and Tentative Final Monographs in the statute. The legislation would also create a mechanism for faster safety label changes and establish a pathway for innovations under the monographs. To support these reforms, the legislation would authorize a new user fee program subject to agreement between the Food and Drug Administration (FDA) and manufacturers on performance goals, reporting milestones, and financial specifications.

BACKGROUND AND NEED FOR LEGISLATION

An OTC drug can be marketed if FDA approves a new drug application or if the drug conforms to a monograph, which is a set of standard specifications established by FDA for each therapeutic category of product. If a product conforms to these specifications, FDA considers it to be generally recognized as safe and effective and it can be marketed without a product-specific application being approved by the agency. FDA began evaluating twenty-six therapeutic categories of OTC drug products in 1972 and has yet to finalize monographs for each of them. Due in large part to the multiphase public rulemaking process required even for changes to the monograph, such as label warnings or new dosage forms, the current process is inefficient and does not enable product advancements to reach consumers quickly.

COMMITTEE ACTION

On September 13, 2017, the Subcommittee on Health held a hearing on a discussion draft entitled "Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018." The Subcommittee received testimony from:

- Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, Food and Drug Administration;
- Scott Melville, President and CEO, Consumer Health Products Association;
- Kirsten Moore, Project Director, Health Care Products, The Pew Charitable Trusts;
- Michael Werner, Partner, Holland and Knight, on behalf of the Public Access to SunScreens (PASS) Coalition;
- Bridgette Jones, M.D., Chair, American Academy of Pediatrics; and
- Gil Roth, President, Pharma and Biopharma Outsourcing Association.

On January 17, 2018, the Subcommittee on Health met in open markup session and forwarded the discussion draft, without amendment, to the full Committee by a voice vote. On May 9, 2018, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 5333, as amended, favorably reported to the House by a voice vote. H.R. 5333 was similar to the discussion draft forwarded to the full Committee.

COMMITTEE VOTES

Clause 3(b) of rule XIII requires the Committee to list the record votes on the motion to report legislation and amendments thereto. The following reflects the record votes taken during the Committee consideration:

COMMITTEE ON ENERGY AND COMMERCE -- 115TH CONGRESS
ROLL CALL VOTE # 65

BILL: H.R. 5333, Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018

AMENDMENT: An amendment in the nature of a substitute, offered by Mr. Pallone, No. 2, to provide that a final administrative order issued in response to a request under section 505G 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), for a period of 12 months, instead of months, following the effective date of such final order, to market drugs.

DISPOSITION: NOT AGREED TO, by a roll call vote of 24 yeas and 30 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Walden		X		Mr. Pallone	X		
Mr. Barton		X		Mr. Rush	X		
Mr. Upton		X		Ms. Eshoo	X		
Mr. Shimkus		X		Mr. Engel	X		
Mr. Burgess		X		Mr. Green	X		
Mrs. Blackburn		X		Ms. DeGette	X		
Mr. Scalise				Mr. Doyle	X		
Mr. Latta		X		Ms. Schakowsky	X		
Mrs. McMorris Rodgers		X		Mr. Butterfield	X		
Mr. Harper		X		Ms. Matsui	X		
Mr. Lance		X		Ms. Castor	X		
Mr. Guthrie		X		Mr. Sarbanes	X		
Mr. Olson		X		Mr. McNerney	X		
Mr. McKinley		X		Mr. Welch	X		
Mr. Kinzinger		X		Mr. Lujan	X		
Mr. Griffith		X		Mr. Tonko	X		
Mr. Bilirakis		X		Ms. Clarke	X		
Mr. Johnson		X		Mr. Loebsack	X		
Mr. Long		X		Mr. Schrader	X		
Mr. Bucshon		X		Mr. Kennedy	X		
Mr. Flores		X		Mr. Cardenas	X		
Mrs. Brooks		X		Mr. Ruiz	X		
Mr. Mullin		X		Mr. Peters	X		
Mr. Hudson		X		Ms. Dingell	X		
Mr. Collins		X					
Mr. Cramer		X					
Mr. Walberg		X					
Mrs. Walters		X					
Mr. Costello		X					
Mr. Carter		X					
Mr. Duncan		X					

5/09/2018

OVERSIGHT FINDINGS AND RECOMMENDATIONS

Pursuant to clause 2(b)(1) of rule X and clause 3(c)(1) of rule XIII, the Committee held a hearing and made findings that are reflected in this report.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to clause 3(c)(2) of rule XIII, the Committee finds that H.R. 5333 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

Opioid Legislation

Summary: On May 9 and May 17, 2018, the House Committee on Energy and Commerce ordered 59 bills to be reported related to the nation's response to the opioid epidemic. Generally, the bills would:

- Provide grants to facilities and providers that treat people with substance use disorders,
- Direct various agencies within the Department of Health and Human Services (HHS) to explore nonopioid approaches to treating pain and to educate providers about those alternatives,
- Modify requirements under Medicaid and Medicare for prescribing controlled substances,
- Expand Medicaid coverage for substance abuse treatment, and
- Direct the Food and Drug Administration (FDA) to modify its oversight of opioid drugs and other medications that are used to manage pain.

Because of the large number of related bills ordered reported by the Committee, CBO is publishing a single comprehensive document that includes estimates for each piece of legislation.

CBO estimates that enacting 20 of the bills would affect direct spending, and 2 of the bills would affect revenues; therefore, pay-as-you-go procedures apply for those bills.

CBO estimates that enacting H.R. 4998, the Health Insurance for Former Foster Youth Act, would increase net direct spending by more than $2.5 billion and on-budget deficits by more than $5 billion in at least one of the four consecutive 10-year periods beginning in 2029. None of the remaining 58 bills included in this estimate would increase net direct spending by more than $2.5 billion or on-budget deficits by more than $5 billion in any of the four consecutive 10-year periods beginning in 2029.

One of the bills reviewed for this document, H.R. 5795, would impose both intergovernmental and private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA). CBO estimates that the costs of those mandates on public and private entities would fall below the thresholds in UMRA ($80 million and $160 million, respectively, in 2018, adjusted annually for inflation).

Five bills, H.R. 5228, H.R. 5333, H.R. 5554, H.R. 5687, and H.R. 5811, would impose private-sector mandates as defined in UMRA. CBO estimates that the costs of the mandates in three of the bills (H.R. 5333, H.R. 5554, and H.R. 5811) would not exceed the UMRA threshold for private entities. Because CBO is uncertain how federal agencies would implement new authority granted in the other two bills, H.R. 5228 and H.R. 5687, CBO cannot determine whether the costs of those mandates would exceed the UMRA threshold.

Estimated cost to the Federal Government: The estimates in this document do not include the effects of interactions among the bills. If all 59 bills were combined and enacted as one piece of legislation, the budgetary effects would be different from the sum of the estimates in this document, although CBO expects that any such differences would be small. The costs of this legislation fall within budget functions 550 (health), 570 (Medicare), 750 (administration of justice), and 800 (general government).

Basis of estimate: For this estimate, CBO assumes that all of the legislation will be enacted late in 2018 and that authorized and estimated amounts will be appropriated each year. Outlays for discretionary programs are estimated based on historical spending patterns for similar programs.

Uncertainty

CBO aims to produce estimates that generally reflect the middle of a range of the most likely budgetary outcomes that would result if the legislation was enacted. Because data on the utilization of mental health and substance abuse treatment under Medicaid and Medicare is scarce, CBO cannot precisely predict how patients or providers would respond to some policy changes or what budgetary effects would result. In addition, several of the bills would give the Department of Health and Human Services (HHS) considerable latitude in designing and implementing policies. Budgetary effects could differ from those provided in CBO's analyses depending on those decisions.

Direct Spending and Revenues

Table 1 lists the 22 bills of the 59 ordered to be reported that would affect direct spending or revenues.

TABLE 1.—ESTIMATED CHANGES IN MANDATORY SPENDING AND REVENUES

	By fiscal year, in millions of dollars—												
	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2019–2023	2019–2028
INCREASES OR DECREASES (−) IN DIRECT SPENDING													
Legislation Primarily Affecting Medicaid:													
H.R. 1925, At-Risk Youth Medicaid Protection Act of 2017	0	*	5	5	5	10	10	10	10	10	10	25	75
H.R. 4998, Health Insurance for Former Foster Youth Act	0	0	0	0	0	*	10	21	33	46	61	*	171
H.R. 5477, Rural Development of Opioid Capacity Services Act	0	13	35	58	68	83	27	9	3	3	3	256	301
H.R. 5583, a bill to amend title XI of the Social Security Act to require States to annually report on certain adult health quality measures, and for other purposes	0	*	*	*	*	*	*	*	*	*	*	*	*
H.R. 5797, IMD CARE Act	0	38	158	251	265	279	0	0	0	0	0	991	991
H.R. 5799, Medicaid DRUG Improvement Act [a]	0	*	*	1	1	1	1	1	1	1	1	2	5
H.R. 5801, Medicaid Providers Are Required To Note Experiences in Record Systems to Help In-Need Patients (PARTNERSHIP) Act [a]	0	*	*	*	*	*	*	*	*	*	*	*	*
H.R. 5808, Medicaid Pharmaceutical Home Act of 2018 [a]	0	*	−1	−1	−1	−1	−2	−2	−2	−2	−2	−4	−13
H.R. 5810, Medicaid Health HOME Act	0	94	58	62	56	52	48	43	38	32	25	323	509
Legislation Primarily Affecting Medicare:													
H.R. 3528, Every Prescription Conveyed Securely Act	0	0	0	−24	−35	−33	−30	−33	−32	−31	−32	−92	−250
H.R. 4841, Standardizing Electronic Prior Authorization for Safe Prescribing Act of 2018	0	0	0	*	*	*	*	*	*	*	*	*	*
H.R. 5603, Access to Telehealth Services for Opioid Use Disorders Act	0	2	*	*	*	1	1	1	2	2	2	3	11
H.R. 5605, Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act	0	0	0	15	26	24	23	23	10	1	*	65	122
H.R. 5675, a bill to amend title XVIII of the Social Security Act to require prescription drug plan sponsors under the Medicare program to establish drug management programs for at-risk beneficiaries	0	0	0	−6	−7	−7	−7	−8	−9	−9	−11	−20	−64
H.R. 5684, Protecting Seniors From Opioid Abuse Act	0	0	0	*	*	*	*	*	*	*	*	*	*
H.R. 5796, Responsible Education Achieves Care and Healthy Outcomes for Users' Treatment Act of 2018	0	10	25	50	10	5	0	0	0	0	0	100	100
H.R. 5798, Opioid Screening and Chronic Pain Management Alternatives for Seniors Act	0	0	*	1	1	1	1	1	1	1	1	2	5
H.R. 5804, Post-Surgical Injections as an Opioid Alternative Act [a]	0	0	25	30	25	20	10	5	0	0	0	100	115
H.R. 5809, Postoperative Opioid Prevention Act of 2018	0	0	0	0	10	15	20	25	30	35	45	25	180
Legislation Primarily Affecting the Food and Drug Administration:													

TABLE 1.—ESTIMATED CHANGES IN MANDATORY SPENDING AND REVENUES—Continued

	By fiscal year, in millions of dollars—												
	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2019–2023	2019–2028
H.R. 5333, Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018 [a]	0	0	*	*	*	*	*	*	*	*	*	*	*
INCREASES OR DECREASES (−) IN REVENUES [b]													
H.R. 5752, Stop Illicit Drug Importation Act of 2018	0	*	*	*	*	*	*	*	*	*	*	*	*

Annual amounts may not sum to totals because of rounding * = between −$500,000 and $500,000. Budget authority is equivalent to outlays.
[a] This bill also would affect spending subject to appropriation.
[b] One additional bill, H.R. 5228, the Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act, would have a negligible effect on revenues.

Legislation Primarily Affecting Medicaid. The following nine bills would affect direct spending for the Medicaid program.

H.R. 1925, the At-Risk Youth Medicaid Protection Act of 2017, would require states to suspend, rather than terminate, Medicaid eligibility for juvenile enrollees (generally under 21 years of age) who become inmates of public correctional institutions. States also would have to redetermine those enrollees' Medicaid eligibility before their release and restore their coverage upon release if they qualify for the program. States would be required to process Medicaid applications submitted by or on behalf of juveniles in public correctional institutions who were not enrolled in Medicaid before becoming inmates and ensure that Medicaid coverage is provided when they are released if they are found to be eligible. On the basis of an analysis of juvenile incarceration trends and of the per enrollee spending for Medicaid foster care children, who have a similar health profile to incarcerated juveniles, CBO estimates that implementing the bill would cost $75 million over the 2019–2028 period.

H.R. 4998, the Health Insurance for Former Foster Youth Act, would require states to provide Medicaid coverage to adults up to age 25 who had aged out of foster care in any state. Under current law, such coverage is mandatory only if the former foster care youth has aged out in the state in which the individual applies for coverage. The policy also would apply to former foster children who had been in foster care upon turning 14 years of age but subsequently left foster care to enter into a legal guardianship with a kinship caregiver. The provisions would take effect respect for foster youth who turn 18 on or after January 1, 2023. On the basis of spending for Medicaid foster care children and data from the Census Bureau regarding annual migration rates between states, CBO estimates that implementing the bill would cost $171 million over the 2019–2028 period.

H.R. 5477, the Rural Development of Opioid Capacity Services Act, would direct the Secretary of HHS to conduct a five-year demonstration to increase the number and ability of providers participating in Medicaid to provide treatment for substance use disorders. On the basis of an analysis of federal and state spending for treatment of substance use disorders and the prevalence of such disorders, CBO estimates that enacting the bill would increase direct spending by $301 million over the 2019–2028 period.

H.R. 5583, a bill to amend title XI of the Social Security Act to require States to annually report on certain adult health quality measures, and for other purposes, would require states to include behavioral health indicators in their annual reports on the quality of care under Medicaid. Although the bill would add a requirement for states, CBO estimates that its enactment would not have a significant budgetary effect because most states have systems in place for reporting such measures to the federal government.

H.R. 5797, the IMD CARE Act, would expand Medicaid coverage for people with opioid use disorder who are in institutions for mental disease (IMDs) for up to 30 days per year. Under a current-law policy known as the IMD exclusion, the federal government generally does not make matching payments to state Medicaid programs for most services provided by IMDs to adults between the ages of 21 and 64. Recent administrative changes have made fed-

eral financing for IMDs available in limited circumstances, but the statutory prohibition remains in place. CBO analyzed several data sets, primarily those collected by the Substance Abuse and Mental Health Services Administration (SAMHSA), to estimate current federal spending under Medicaid for IMD services and to estimate spending under H.R. 5797. Using that analysis, CBO estimates that enacting H.R. 5797 would increase direct spending by $991 million over the 2019–2028 period.

H.R. 5799, the Medicaid DRUG Improvement Act, would require state Medicaid programs to implement additional reviews of opioid prescriptions, monitor concurrent prescribing of opioids and certain other drugs, and monitor use of antipsychotic drugs by children. CBO estimates that the bill would increase direct spending by $5 million over the 2019–2028 period to cover the administrative costs of complying with those requirements. On the basis of stakeholder feedback, CBO expects that the bill would not have a significant effect on Medicaid spending for prescription drugs because many of the bill's requirements would duplicate current efforts to curb opioid and antipsychotic drug use. (If enacted, H.R. 5799 also would affect spending subject to appropriation; CBO has not completed an estimate of that amount.)

H.R. 5801, the Medicaid Providers Are Required To Note Experiences in Record Systems to Help In-Need Patients (PARTNERSHIP) Act, would require providers who are permitted to prescribe controlled substances and who participate in Medicaid to query prescription drug monitoring programs (PDMPs) before prescribing controlled substances to Medicaid patients. PDMPs are statewide electronic databases that collect data on controlled substances dispensed in the state. The bill also would require PDMPs to comply with certain data and system criteria, and it would provide additional federal matching funds to certain states to help cover administrative costs. On the basis of a literature review and stakeholder feedback, CBO estimates that the net budgetary effect of enacting H.R. 5801 would be insignificant. Costs for states to come into compliance with the systems and administrative requirements would be roughly offset by savings from small reductions in the number of controlled substances paid for by Medicaid under the proposal. (If enacted, H.R. 5801 also would affect spending subject to appropriation; CBO has not completed an estimate of that amount.)

H.R. 5808, the Medicaid Pharmaceutical Home Act of 2018, would require state Medicaid programs to operate pharmacy programs that would identify people at high risk of abusing controlled substances and require those patients to use a limited number of providers and pharmacies. Although nearly all state Medicaid programs currently meet such a requirement, a small number of high-risk Medicaid beneficiaries are not now monitored. Based on an analysis of information about similar state and federal programs, CBO estimates that net Medicaid spending under the bill would decrease by $13 million over the 2019–2028 period. That amount represents a small increase in administrative costs and a small reduction in the number of controlled substances paid for by Medicaid under the proposal. (If enacted, H.R. 5808 also would affect spending subject to appropriation; CBO has not completed an estimate of that amount.)

H.R. 5810, the Medicaid Health HOME Act, would allow states to receive six months of enhanced federal Medicaid funding for programs that coordinate care for people with substance use disorders. Based on enrollment and spending data from states that currently participate in Medicaid's Health Homes program, CBO estimates that the expansion would cost approximately $469 million over the 2019–2028 period. The bill also would require states to cover all FDA-approved drugs used in medication-assisted treatment for five years, although states could seek a waiver from that requirement. (Medication-assisted treatment combines behavioral therapy and pharmaceutical treatment for substance use disorders.) Under current law, states already cover most FDA-approved drugs used in such programs in some capacity, although a few exclude methadone dispensed by opioid treatment programs. CBO estimates that a small share of those states would begin to cover methadone if this bill was enacted at a federal cost of about $39 million over the 2019–2028 period. In sum, CBO estimates that enacting H.R. 5810 would increase direct spending by $509 million over the 2019–2028 period.

Legislation Primarily Affecting Medicare. The following ten bills would affect direct spending for the Medicare program.

H.R. 3528, the Every Prescription Conveyed Securely Act, would require prescriptions for controlled substances covered under Medicare Part D to be transmitted electronically, starting on January 1, 2021. Based on CBO's analysis of prescription drug spending, spending for controlled substances is a small share of total drug spending. CBO also assumes a small share of those prescriptions would not be filled because they are not converted to an electronic format. Therefore, CBO expects that enacting H.R. 3528 would reduce the number of prescriptions filled and estimates that Medicare spending would be reduced by $250 million over the 2019–2028 period.

H.R. 4841, the Standardizing Electronic Prior Authorization for Safe Prescribing Act of 2018, would require health care professionals to submit prior authorization requests electronically, starting on January 1, 2021, for drugs covered under Medicare Part D. Taking into account that many prescribers already use electronic methods to submit such requests, CBO estimates that enacting H.R. 4841 would not significantly affect direct spending for Part D.

H.R. 5603, the Access to Telehealth Services for Opioid Use Disorders Act, would permit the Secretary of HHS to lift current geographic and other restrictions on coverage of telehealth services under Medicare for treatment of substance use disorders or co-occurring mental health disorders. Under the bill, the Secretary of HHS would be directed to encourage other payers to coordinate payments for opioid use disorder treatments and to evaluate the extent to which the demonstration reduces hospitalizations, increases the use of medication-assisted treatments, and improves the health outcomes of individuals with opioid use disorders during and after the demonstration. Based on current use of Medicare telehealth services for treatment of substance use disorders, CBO estimates that expanding that coverage would increase direct spending by $11 million over the 2019–2028 period.

H.R. 5605, the Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act, would establish a five-year demonstra-

tion program to increase access to treatment for opioid use disorder. The demonstration would provide incentive payments and funding for care management services based on criteria such as patient engagement, use of evidence-based treatments, and treatment length and intensity. Under the bill, the Secretary of HHS would be directed to encourage other payers to coordinate payments for opioid use disorder treatments and to evaluate the extent to which the demonstration reduces hospitalizations, increases the use of medication-assisted treatments, and improves the health outcomes of individuals with opioid use disorders during and after the demonstration. Based on historical utilization of opioid use disorder treatments and projected spending on incentive payments and care management fees, CBO estimates that increased use of treatment services and the demonstration's incentive payments would increase direct spending by $122 million over the 2019–2028 period.

H.R. 5675, a bill to amend title XVIII of the Social Security Act to require prescription drug plan sponsors under the Medicare program to establish drug management programs for at-risk beneficiaries, would require Part D prescription drug plans to provide drug management programs for Medicare beneficiaries who are at risk for prescription drug abuse. (Under current law, Part D plans are permitted but not required to establish such programs as of 2019.) Based on an analysis of the number of plans currently providing those programs, CBO estimates that enacting H.R. 5675 would lower federal spending by $64 million over the 2019–2028 period by reducing the number of prescriptions filled and Medicare's payments for controlled substances.

H.R. 5684, the Protecting Seniors From Opioid Abuse Act, would expand medication therapy management programs under Medicare Part D to include beneficiaries who are at risk for prescription drug abuse. Because relatively few beneficiaries would be affected by this bill, CBO estimates that its enactment would not significantly affect direct spending for Part D.

H.R. 5796, the Responsible Education Achieves Care and Healthy Outcomes for Users' Treatment Act of 2018, would allow the Secretary of HHS to award grants to certain organizations that provide technical assistance and education to high-volume prescribers of opioids. The bill would appropriate $100 million for fiscal year 2019. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5796 would cost $100 million over the 2019–2028 period.

H.R. 5798, the Opioid Screening and Chronic Pain Management Alternatives for Seniors Act, would add an assessment of current opioid prescriptions and screening for opioid use disorder to the Welcome to Medicare Initial Preventive Physical Examination. Based on historical use of the examinations and pain management alternatives, CBO expects that enacting the bill would increase use of pain management services and estimates that direct spending would increase by $5 million over the 2019–2028 period.

H.R. 5804, the Post-Surgical Injections as an Opioid Alternative Act, would freeze the Medicare payment rate for certain analgesic injections provided in ambulatory surgical centers (ASCs). (For injections identified by specific billing codes, Medicare would pay the 2016 rate, which is higher than the current rate, during the 2020–2024 period.) Based on current utilization in the ASC setting, CBO

estimates that enacting the legislation would increase direct spending by about $115 million over the 2019–2028 period. (If enacted, H.R. 5804 also would affect spending subject to appropriation; see Table 3.)

H.R. 5809, the Postoperative Opioid Prevention Act of 2018, would create an additional payment under Medicare for nonopioid analgesics. Under current law, certain new drugs and devices may receive an additional payment—separate from the bundled payment for a surgical procedure—in outpatient hospital departments and ambulatory surgical centers. The bill would allow nonopioid analgesics to qualify for a five-year period of additional payments. Based on its assessment of current spending for analgesics and on the probability of new nonopioid analgesics coming to market, CBO estimates that H.R. 5809 would increase direct spending by about $180 million over the 2019–2028 period.

Legislation Primarily Affecting the Food and Drug Administration. One bill related to the FDA would affect direct spending.

H.R. 5333, the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018, would change the way that the FDA regulates the marketing of over-the-counter (OTC) medicines, and it would authorize that agency to grant 18 months of exclusive market protection for certain qualifying OTC drugs, thus delaying the entry of other versions of the same qualifying OTC product. Medicaid currently provides some coverage for OTC medicines, but only if a medicine is the least costly alternative in its drug class. On the basis of stakeholder feedback, CBO expects that delaying the availability of additional OTC versions of a drug would not significantly affect the average net price paid by Medicaid. As a result, CBO estimates that enacting H.R. 5333 would have a negligible effect on the federal budget. (If enacted, H.R. 5333 also would affect spending subject to appropriation; see Table 3.)

Legislation with Revenue Effects. Two bills would affect revenues. However, CBO estimates that one bill, H.R. 5228, the Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act, would have only a negligible effect.

H.R. 5752, the Stop Illicit Drug Importation Act of 2018, would amend the Federal, Food, Drug, and Cosmetic Act (FDCA) to strengthen the FDA's seizure powers and enhance its authority to detain, refuse, seize, or destroy illegal products offered for import. The legislation would subject more people to debarment under the FDCA and thus increase the potential for violations, and subsequently, the assessment of civil penalties, which are recorded in the budget as revenues. CBO estimates that those collections would result in an insignificant increase in revenues. Because H.R. 5752 would prohibit the importation of drugs that are in the process of being scheduled, it also could reduce amounts collected in customs duties. CBO anticipates that the result would be a negligible decrease in revenues. With those results taken together, CBO estimates, enacting H.R. 5752 would generate an insignificant net increase in revenues over the 2019–2028 period.

Spending Subject to Appropriation

For this document, CBO has grouped bills with spending that would be subject to appropriation into four general categories:

- Bills that would have no budgetary effect,

- Bills with provisions that would authorize specified amounts to be appropriated (see Table 2),
- Bills with provisions for which CBO has estimated an authorization of appropriations (see Table 3), and
- Bills with provisions that would affect spending subject to appropriation for which CBO has not yet completed an estimate.

No Budgetary Effect. CBO estimates that 6 of the 59 bills would have no effect on direct spending, revenues, or spending subject to appropriation.

H.R. 3192, the CHIP Mental Health Parity Act, would require all Children's Health Insurance Program (CHIP) plans to cover mental health and substance abuse treatment. In addition, states would not be allowed to impose financial or utilization limits on mental health treatment that are lower than limits placed on physical health treatment. Based on information from the Centers for Medicare and Medicaid Services, CBO estimates that enacting the bill would have no budgetary effect because all CHIP enrollees are already in plans that meet those requirements.

H.R. 3331, a bill to amend title XI of the Social Security Act to promote testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology, would give the Center for Medicare and Medicaid Innovation (CMMI) explicit authorization to test a program offering incentive payments to behavioral health providers that adopt and use certified electronic health record technology. Because it is already clear to CMMI that it has that authority, CBO estimates that enacting the legislation would not affect federal spending.

H.R. 5202, the Ensuring Patient Access to Substance Use Disorder Treatments Act of 2018, would clarify permission for pharmacists to deliver controlled substances to providers under certain circumstances. Because this provision would codify current practice, CBO estimates that H.R. 5202 would not affect direct spending or revenues during the 2019–2028 period.

H.R. 5685, the Medicare Opioid Safety Education Act of 2018, would require the Secretary of HHS to include information on opioid use, pain management, and nonopioid pain management treatments in future editions of *Medicare & You*, the program's handbook for beneficiaries, starting on January 1, 2019. Because H.R. 5685 would add information to an existing administrative document, CBO estimates that enacting the bill would have no budgetary effect.

H.R. 5686, the Medicare Clear Health Options in Care for Enrollees Act of 2018, would require prescription drug plans that provide coverage under Medicare Part D to furnish information to beneficiaries about the risks of opioid use and the availability of alternative treatments for pain. CBO estimates that enacting the bill would not affect direct spending because the required activities would not impose significant administrative costs.

H.R. 5716, the Commit to Opioid Medical Prescriber Accountability and Safety for Seniors Act, would require the Secretary of HHS on an annual basis to identify high prescribers of opioids and furnish them with information about proper prescribing methods. Because HHS already has the capacity to meet those requirements,

CBO estimates that enacting that provision would not impose additional administrative costs on the agency.

Specified Authorizations. Table 2 lists the ten bills that would authorize specified amounts to be appropriated over the 2019–2023 period. Spending from those authorized amounts would be subject to appropriation.

TABLE 2.—ESTIMATED SPENDING SUBJECT TO APPROPRIATION FOR BILLS WITH SPECIFIED AUTHORIZATIONS

	By fiscal year, in millions of dollars—						
	2018	2019	2020	2021	2022	2023	2019–2023
INCREASES IN SPENDING SUBJECT TO APPROPRIATION							
H.R. 4684, Ensuring Access to Quality Sober Living Act:							
Authorization Level	0	3	0	0	0	0	3
Estimated Outlays	0	1	2	*	*	*	3
H.R. 5102, Substance Use Disorder Workforce Loan Repayment Act of 2018:							
Authorization Level	0	25	25	25	25	25	125
Estimated Outlays	0	9	19	23	25	25	100
H.R. 5176, Preventing Overdoses While in Emergency Rooms Act of 2018:							
Authorization Level	0	50	0	0	0	0	50
Estimated Outlays	0	16	26	6	2	1	50
H.R. 5197, Alternatives to Opioids (ALTO) in the Emergency Department Act:							
Authorization Level	0	10	10	10	0	0	30
Estimated Outlays	0	3	8	10	7	2	30
H.R. 5261, Treatment, Education, and Community Help to Combat Addiction Act of 2018:							
Authorization Level	0	4	4	4	4	4	20
Estimated Outlays	0	1	3	4	4	4	16
H.R. 5327, Comprehensive Opioid Recovery Centers Act of 2018:							
Authorization Level	0	10	10	10	10	10	50
Estimated Outlays	0	3	8	10	10	10	41
H.R. 5329, Poison Center Network Enhancement Act of 2018:							
Authorization Level	0	30	30	30	30	30	151
Estimated Outlays	0	12	25	29	29	29	125
H.R. 5353, Eliminating Opioid-Related Infectious Diseases Act of 2018:							
Authorization Level	0	40	40	40	40	40	200
Estimated Outlays	0	15	34	38	39	40	166
H.R. 5580, Surveillance and Testing of Opioids to Prevent Fentanyl Deaths Act of 2018:							
Authorization Level	30	30	30	30	30	0	120
Estimated Outlays	0	11	25	29	29	19	113
H.R. 5587, Peer Support Communities of Recovery Act:							
Authorization Level	0	15	15	15	15	15	75
Estimated Outlays	0	5	13	14	15	15	62

Annual amounts may not sum to totals because of rounding. * = between zero and $500,000.

H.R. 4684, the Ensuring Access to Quality Sober Living Act, would direct the Secretary of HHS to develop and disseminate best practices for organizations that operate housing designed for people recovering from substance use disorders. The bill would authorize a total of $3 million over the 2019–2021 period for that purpose. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 4684 would cost $3 million over the 2019–2023 period.

H.R. 5102, the Substance Use Disorder Workforce Loan Repayment Act of 2018, would establish a loan repayment program for mental health professionals who practice in areas with few mental

health providers or with high rates of death from overdose and would authorize $25 million per year over the 2019–2028 period for that purpose. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5102 would cost $100 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

H.R. 5176, the Preventing Overdoses While in Emergency Rooms Act of 2018, would require the Secretary of HHS to develop protocols and a grant program for health care providers to address the needs of people who survive a drug overdose, and it would authorize $50 million in 2019 for that purpose. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5176 would cost $50 million over the 2019–2023 period.

H.R. 5197, the Alternatives to Opioids (ALTO) in the Emergency Department Act, would direct the Secretary of HHS to carry out a demonstration program for hospitals and emergency departments to develop alternative protocols for pain management that limit the use of opioids and would authorize $10 million annually in grants for fiscal years 2019 through 2021. Based on historical spending patterns for similar programs, CBO estimates that implementing H.R. 5197 would cost $30 million over the 2019–2023 period.

H.R. 5261, the Treatment, Education, and Community Help to Combat Addiction Act of 2018, would direct the Secretary of HHS to designate regional centers of excellence to improve the training of health professionals who treat substance use disorders. The bill would authorize $4 million annually for grants to those programs over the 2019–2023 period. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5261 would cost $16 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

H.R. 5327, the Comprehensive Opioid Recovery Centers Act of 2018, would direct the Secretary of HHS to award grants to at least 10 providers that offer treatment services for people with opioid use disorder, and it would authorize $10 million per year over the 2019–2023 period for that purpose. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5327 would cost $41 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

H.R. 5329, the Poison Center Network Enhancement Act of 2018, would reauthorize the poison control center toll-free number, national media campaign, and grant program under the Public Health Service Act. Among other actions, H.R. 5329 would increase the share of poison control center funding that could be provided by federal grants. The bill would authorize a total of about $30 million per year over the 2019–2023 period. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5329 would cost $125 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

H.R. 5353, the Eliminating Opioid Related Infectious Diseases Act of 2018, would amend the Public Health Service Act by broadening the focus of surveillance and education programs from preventing and treating hepatitis C virus to preventing and treating infections associated with injection drug use. It would authorize $40 million per year over the 2019–2023 period for that purpose.

Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5353 would cost $166 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

H.R. 5580, the Surveillance and Testing of Opioids to Prevent Fentanyl Deaths Act of 2018, would establish a grant program for public health laboratories that conduct testing for fentanyl and other synthetic opioids. It also would direct the Centers for Disease Control and Prevention to expand its drug surveillance program, with a particular focus on collecting data on fentanyl. The bill would authorize a total of $30 million per year over the 2018–2022 period for those activities. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5580 would cost $113 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

H.R. 5587, Peer Support Communities of Recovery Act, would direct the Secretary of HHS to award grants to nonprofit organizations that support community-based, peer-delivered support, including technical support for the establishment of recovery community organizations, independent, nonprofit groups led by people in recovery and their families. The bill would authorize $15 million per year for the 2019–2023 period. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5587 would cost $62 million over the 2019–2023 period; the remaining amounts would be spent in years after 2023.

Estimated Authorizations. Table 3 shows CBO's estimates of the appropriations that would be necessary to implement 19 of the bills. Spending would be subject to appropriation of those amounts.

H.R. 449, the Synthetic Drug Awareness Act of 2018, would require the Surgeon General to report to the Congress on the health effects of synthetic psychoactive drugs on children between the ages of 12 and 18. Based on spending patterns for similar activities, CBO estimates that implementing H.R. 449 would cost approximately $1 million over the 2019–2023 period.

H.R. 4005, the Medicaid Reentry Act, would direct the Secretary of HHS to convene a group of stakeholders to develop and report to the Congress on best practices for addressing issues related to health care faced by those returning from incarceration to their communities. The bill also would require the Secretary to issue a letter to state Medicaid directors about relevant demonstration projects. Based on an analysis of anticipated workload, CBO estimates that implementing H.R. 4005 would cost less than $500,000 over the 2018–2023 period.

H.R. 4275, the Empowering Pharmacists in the Fight Against Opioid Abuse Act, would require the Secretary of HHS to develop and disseminate materials for training pharmacists, health care practitioners, and the public about the circumstances under which a pharmacist may decline to fill a prescription. Based on historical spending patterns for similar activities, CBO estimates that costs to the federal government for the development and distribution of those materials would not be significant.

TABLE 3.—ESTIMATED SPENDING SUBJECT TO APPROPRIATION FOR BILLS WITH ESTIMATED AUTHORIZATIONS

	By fiscal year, in millions of dollars—						
	2018	2019	2020	2021	2022	2023	2019–2023
INCREASES IN SPENDING SUBJECT TO APPROPRIATION							
H.R. 449, Synthetic Drug Awareness Act of 2018:							
Estimated Authorization Level	0	*	*	*	0	0	1
Estimated Outlays	0	*	*	*	0	0	1
H.R. 4005, Medicaid Reentry Act:							
Estimated Authorization Level	*	*	0	0	0	0	*
Estimated Outlays	*	*	0	0	0	0	*
H.R. 4275, Empowering Pharmacists in the Fight Against Opioid Abuse Act:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*
H.R. 5009, Jessie's Law:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*
H.R. 5041, Safe Disposal of Unused Medication Act:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*
H.R. 5272, Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse Act of 2018:							
Estimated Authorization Level	0	1	1	1	1	1	4
Estimated Outlays	0	1	1	1	1	1	4
H.R. 5333, Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018: [a]							
Food and Drug Administration:							
Collections from fees:							
Estimated Authorization Level	0	−22	−22	−26	−35	−42	−147
Estimated Outlays	0	−22	−22	−26	−35	−42	−147
Spending of fees:							
Estimated Authorization Level	0	22	22	26	35	42	147
Estimated Outlays	0	6	17	30	44	41	137
Net effect on FDA:							
Estimated Authorization Level	0	0	0	0	0	0	0
Estimated Outlays	0	−17	−6	4	9	*	−10
Government Accountability Office:							
Estimated Authorization Level	0	0	0	0	0	*	*
Estimated Outlays	0	0	0	0	0	*	*
Total, H.R. 5333:							
Estimated Authorization Level	0	0	0	0	0	0	*
Estimated Outlays	0	−17	−6	4	9	*	−10
H.R. 5473, Better Pain Management Through Better Data Act of 2018:							
Estimated Authorization Level	0	*	*	*	*	0	1
Estimated Outlays	0	*	*	*	*	*	1
H.R. 5483, Special Registration for Telemedicine Clarification Act of 2018:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*
H.R. 5554, Animal Drug and Animal Generic Drug User Fee Amendments of 2018:							
Collections from fees:							
Animal drug fees	0	−30	−31	−32	−33	−34	−159
Generic animal drug fees	0	−18	−19	−19	−20	−21	−97
Total, Estimated Authorization Level	0	−49	−50	−51	−53	−55	−257
Total, Estimated Outlays	0	−49	−50	−51	−53	−55	−257
Spending of fees:							
Animal drug fees	0	30	31	32	33	34	159
Generic animal drug fees	0	18	19	19	20	21	97
Total, Estimated Authorization Level	0	49	50	51	53	55	257
Total, Estimated Outlays	0	39	47	51	52	54	243
Net changes in fees:							
Estimated Authorization Level	0	0	0	0	0	0	0
Estimated Outlays	0	−10	−3	*	*	*	−14

TABLE 3.—ESTIMATED SPENDING SUBJECT TO APPROPRIATION FOR BILLS WITH ESTIMATED AUTHORIZATIONS—Continued

	By fiscal year, in millions of dollars—						
	2018	2019	2020	2021	2022	2023	2019–2023
Other effects:							
Estimated Authorization Level	0	3	1	1	1	1	6
Estimated Outlays	0	2	1	1	1	1	6
Total, H.R. 5554:							
Estimated Authorization Level	0	3	1	1	1	1	6
Estimated Outlays	0	−8	−2	1	*	*	−8
H.R. 5582, Abuse Deterrent Access Act of 2018:							
Estimated Authorization Level	0	0	*	0	0	0	*
Estimated Outlays	0	0	*	0	0	0	*
H.R. 5590, Opioid Addiction Action Plan Act:							
Estimated Authorization Level	*	*	*	*	*	*	2
Estimated Outlays	*	*	*	*	*	*	2
H.R. 5687, Securing Opioids and Unused Narcotics with Deliberate Disposal and Packaging Act of 2018:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*
H.R. 5715, Strengthening Partnerships to Prevent Opioid Abuse Act:							
Estimated Authorization Level	0	2	2	2	2	2	9
Estimated Outlays	0	2	2	2	2	2	9
H.R. 5789, a bill to require the Secretary of Health and Human Services to issue guidance to improve care for infants with neonatal abstinence syndrome and their mothers, and to require the Comptroller General of the United States to conduct a study on gaps in Medicaid coverage for pregnant and postpartum women with substance use disorder:							
Estimated Authorization Level	0	2	0	0	0	0	2
Estimated Outlays	0	2	0	0	0	0	2
H.R. 5795, Overdose Prevention and Patient Safety Act:							
Estimated Authorization Level	0	1	0	0	0	0	1
Estimated Outlays	0	1	0	0	0	0	1
H.R. 5800, Medicaid IMD ADDITIONAL INFO Act:							
Estimated Authorization Level	0	1	0	0	0	0	1
Estimated Outlays	0	*	*	0	0	0	1
H.R. 5804, Post-Surgical Injections as an Opioid Alternative Act: [a]							
Estimated Authorization Level	0	0	0	0	1	1	1
Estimated Outlays	0	0	0	0	1	1	1
H.R. 5811, a bill to amend the Federal Food, Drug, and Cosmetic Act with respect to postapproval study requirements for certain controlled substances, and for other purposes:							
Estimated Authorization Level	0	*	*	*	*	*	*
Estimated Outlays	0	*	*	*	*	*	*

Annual amounts may not sum to totals because of rounding. * = between −$500,000 and $500,000.
[a] This bill also would affect mandatory spending (see Table 1).

H.R. 5009, Jessie's Law, would require HHS, in collaboration with outside experts, to develop best practices for displaying information about opioid use disorder in a patient's medical record. HHS also would be required to develop and disseminate written materials annually to health care providers about what disclosures could be made while still complying with federal laws that govern health care privacy. Based on spending patterns for similar activities, CBO estimates that implementing H.R. 5009 would have an insignificant effect on spending over the 2019–2023 period.

H.R. 5041, the Safe Disposal of Unused Medication Act, would require hospice programs to have written policies and procedures for

the disposal of controlled substances after a patient's death. Certain licensed employees of hospice programs would be permitted to assist in the disposal of controlled substances that were lawfully dispensed. Using information from the Department of Justice (DOJ), CBO estimates that implementing the bill would cost less than $500,000 over the 2019–2023 period.

H.R. 5272, the Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse Act of 2018, would require the newly established National Mental Health and Substance Use Policy Laboratory to issue guidance to applicants for SAMHSA grants that support evidence-based practices. Using information from HHS about the historical cost of similar activities, CBO estimates that enacting this bill would cost approximately $4 million over the 2019–2023 period.

H.R. 5333, the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018, would change the FDA's oversight of the commercial marketing of OTC medicines and authorize the collection and spending of fees through 2023 to cover the costs of expediting the FDA's administrative procedures for certain regulatory activities relating to OTC products. Under H.R. 5333, CBO estimates, the FDA would assess about $147 million in fees over the 2019–2023 period that could be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts. Because the FDA could spend those fees, CBO estimates that the estimated budget authority for collections and spending would offset each other exactly in each year, although CBO expects that spending initially would lag behind collections. Assuming appropriation action consistent with the bill, CBO estimates that implementing H.R. 5333 would reduce net discretionary outlays by $10 million over the 2019–2023 period, primarily because of that lag. The bill also would require the Government Accountability Office to study exclusive market protections for certain qualifying OTC drugs authorized by the bill—a provision that CBO estimates would cost less than $500,000. (If enacted, H.R. 5333 also would affect mandatory spending; see Table 1.)

H.R. 5473, the Better Pain Management Through Better Data Act of 2018, would require that the FDA conduct a public meeting and issue guidance to industry addressing data collection and labeling for medical products that reduce pain while enabling the reduction, replacement, or avoidance of oral opioids. Using information from the agency, CBO estimates that implementing H.R. 5473 would cost about $1 million over the 2019–2023 period.

H.R. 5483, the Special Registration for Telemedicine Clarification Act of 2018, would direct DOJ, within one year of the bill's enactment, to issue regulations concerning the 21 practice of telemedicine (for remote diagnosis and treatment of patients). Using information from DOJ, CBO estimates that implementing the bill would cost less than $500,000 over the 2019–2023 period.

H.R. 5554, the Animal Drug and Animal Generic Drug User Fee Amendments of 2018, would authorize the FDA to collect and spend fees to cover the cost of expedited approval for the development and marketing of certain drugs for use in animals. The legislation would extend through fiscal year 2023, and make several changes to, the FDA's existing approval processes and fee programs for brand-name and generic veterinary drugs, which expire at the end

of fiscal year 2018. CBO estimates that implementing H.R. 5554 would reduce net discretionary outlays by $8 million over the 2019–2023 period, primarily because the spending of fees lags somewhat behind their collection.

Fees authorized under the bill would supplement funds appropriated to cover the FDA's cost of reviewing certain applications and investigational submissions for brand-name and generic drugs for use in animals. Those fees could be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts. Under H.R. 5554, CBO estimates, the FDA would assess about $257 million in fees over the 2019–2023 period. Because the FDA could spend those funds, CBO estimates that budget authority for collections and spending would offset each other exactly in each year. CBO estimates that the delay between collecting and spending fees under the reauthorized programs would reduce net discretionary outlays by $14 million over the 2019–2023 period, assuming appropriation actions consistent with the bill.

Enacting H.R. 5554 would increase the FDA's workload because the legislation would expand eligibility for conditional approval for certain drugs. The agency's administrative costs also would increase because of regulatory activities required by a provision concerning petitions for additives intended for use in animal food. H.R. 5554 also would require the FDA to publish guidance or produce regulations on a range of topics, transmit a report to the Congress, and hold public meetings. CBO expects that the costs associated with those activities would not be covered by fees, and it estimates that implementing such provisions would cost $6 million over the 2019–2023 period.

H.R. 5582, the Abuse Deterrent Access Act of 2018, would require the Secretary of HHS to report to the Congress on existing barriers to access to "abuse-deterrent opioid formulations" by Medicare Part C and D beneficiaries. Such formulations make the drugs more difficult to dissolve for injection, for example, and thus can impede their abuse. Assuming the availability of appropriated funds and based on historical spending patterns for similar activities, CBO estimates that implementing the legislation would cost less than $500,000 over the 2019–2023 period.

H.R. 5590, the Opioid Addiction Action Plan Act, would require the Secretary of HHS to develop an action plan by January 1, 2019, for increasing access to medication-assisted treatment among Medicare and Medicaid enrollees. The bill also would require HHS to convene a stakeholder meeting and issue a request for information within three months of enactment, and to submit a report to the Congress by June 1, 2019. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5590 would cost approximately $2 million over the 2019–2023 period.

H.R. 5687, the Securing Opioids and Unused Narcotics with Deliberate Disposal and Packaging Act of 2018, would permit the FDA to require certain packaging and disposal technologies, controls, or measures to mitigate the risk of abuse and misuse of drugs. Based on information from the FDA, CBO estimates that implementing H.R. 5687 would not significantly affect spending over the 2019–2023 period. This bill would also require that the GAO study the effectiveness and use of packaging technologies for controlled sub-

stances—a provision that CBO estimates would cost less than $500,000.

H.R. 5715, the Strengthening Partnerships to Prevent Opioid Abuse Act, would require the Secretary of HHS to establish a secure Internet portal to allow HHS, Medicare Advantage plans, and Medicare Part D plans to exchange information about fraud, waste, and abuse among providers and suppliers no later than two years after enactment. H.R. 5715 also would require organizations with Medicare Advantage contracts to submit information on investigations related to providers suspected of prescribing large volumes of opioids through a process established by the Secretary no later than January 2021. Based on historical spending patterns for similar activities, CBO estimates that implementing H.R. 5715 would cost approximately $9 million over the 2019–2023 period.

H.R. 5789, a bill to require the Secretary of Health and Human Services to issue guidance to improve care for infants with neonatal abstinence syndrome and their mothers, and to require the Comptroller General of the United States to conduct a study on gaps in Medicaid coverage for pregnant and postpartum women with substance use disorder, would direct the Secretary of HHS to issue guidance to states on best practices under Medicaid and CHIP for treating infants with neonatal abstinence syndrome. H.R. 5789 also would direct the Government Accountability Office to study Medicaid coverage for pregnant and postpartum women with substance use disorders. Based on information from HHS and historical spending patterns for similar activities, CBO estimates that enacting H.R. 5789 would cost approximately $2 million over the 2019–2023 period.

H.R. 5795, the Overdose Prevention and Patient Safety Act, would amend the Public Health Service Act so that requirements pertaining to the confidentiality and disclosure of medical records relating to substance use disorders align with the provisions of the Health Insurance Portability and Accountability Act of 1996. The bill would require the Office of the Secretary of HHS to issue regulations prohibiting discrimination based on data disclosed from such medical records, to issue regulations requiring covered entities to provide written notice of privacy practices, and to develop model training programs and materials for health care providers and patients and their families. Based on spending patterns for similar activities, CBO estimates that implementing H.R. 5795 would cost approximately $1 million over the 2019–2023 period.

H.R. 5800, Medicaid IMD ADDITIONAL INFO Act, would direct the Medicaid and CHIP Payment and Access Commission to study institutions for mental diseases in a representative sample of states. Based on information from the commission about the cost of similar work, CBO estimates that implementing H.R. 5800 would cost about $1 million over the 2019–2023 period.

H.R. 5804, the Post-Surgical Injections as an Opioid Alternative ACt, would freeze the Medicare payment rate for certain analgesic injections provided in ambulatory surgical centers. The bill also would mandate two studies of Medicare coding and payments arising from enactment of this legislation. Based on the cost of similar activities, CBO estimates that those reports would cost $1 million over the 2019–2023 period. (If enacted, H.R. 5804 also would affect mandatory spending; see Table 1.)

H.R. 5811, a bill to amend the Federal Food, Drug, and Cosmetic Act with respect to postapproval study requirements for certain controlled substances, and for other purposes, would allow the FDA to require that pharmaceutical manufacturers study certain drugs after they are approved to assess any potential reduction in those drugs' effectiveness for the conditions of use prescribed, recommended, or suggested in labeling. CBO anticipates that implementing H.R. 5811 would not significantly affect the FDA's costs over the 2019–2023 period.

Other Authorizations. The following nine bills would increase authorization levels, but CBO has not completed estimates of amounts. All authorizations would be subject to future appropriation action.

- H.R. 4284, Indexing Narcotics, Fentanyl, and Opioids Act of 2017
- H.R. 5002, Advancing Cutting Edge Research Act
- H.R. 5228, Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act (see Table 1 for an estimate of the revenue effects of H.R. 5228)
- H.R. 5752, Stop Illicit Drug Importation Act of 2018 (see Table 1 for an estimate of the revenue effects of H.R. 5752)
- H.R. 5799, Medicaid DRUG Improvement Act (see Table 1 for an estimate of the direct spending effects of H.R. 5799)
- H.R. 5801, Medicaid Providers and Pharmacists Are Required to Note Experiences in Record Systems to Help In-Need Patients (PARTNERSHIP) Act (see Table 1 for an estimate of the direct spending effects of H.R. 5801)
- H.R. 5806, 21st Century Tools for Pain and Addiction Treatments Act
- H.R. 5808, Medicaid Pharmaceutical Home Act of 2018 (see Table 1 for an estimate of the direct spending effects of H.R. 5808)
- H.R. 5812, Creating Opportunities that Necessitate New and Enhanced Connections That Improve Opioid Navigation Strategies Act (CONNECTIONS) Act

Pay-As-You-Go considerations: The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. Twenty-two of the bills discussed in this document contain direct spending or revenues and are subject to pay-as-you-go procedures. Details about the amount of direct spending and revenues in those bills can be found in Table 1.

Increase in long-term direct spending and deficits: CBO estimates that enacting H.R. 4998, the Health Insurance for Former Foster Youth Act, would increase net direct spending by more than $2.5 billion and on-budget deficits by more than $5 billion in at least one of the four consecutive 10-year periods beginning in 2029.

CBO estimates that none of the remaining 58 bills included in this estimate would increase net direct spending by more than $2.5 billion or on-budget deficits by more than $5 billion in any of the four consecutive 10-year periods beginning in 2029.

Mandates: One of the 59 bills included in this document, H.R. 5795, would impose both intergovernmental and private-sector mandates as defined in UMRA. CBO estimates that the costs of that bill's mandates on public and private entities would fall below

UMRA's thresholds ($80 million and $160 million, respectively, for public- and private-sector entities in 2018, adjusted annually for inflation).

In addition, five bills would impose private-sector mandates as defined in UMRA. CBO estimates that the costs of the mandates in three of those bills (H.R. 5333, H.R. 5554, and H.R. 5811) would fall below the UMRA threshold. Because CBO does not know how federal agencies would implement new authority granted in the other two of those five bills, H.R. 5228 and 5687, CBO cannot determine whether the costs of their mandates would exceed the threshold.

For large entitlement grant programs, including Medicaid and CHIP, UMRA defines an increase in the stringency of conditions on states or localities as an intergovernmental mandate if the affected governments lack authority to offset those costs while continuing to provide required services. Because states possess significant flexibility to alter their responsibilities within Medicaid and CHIP, the requirements imposed by various bills in the markup on state administration of those programs would not constitute mandates as defined in UMRA.

Mandates Affecting Public and Private Entities

H.R. 5795, the Overdose Prevention and Patient Safety Act, would impose intergovernmental and private-sector mandates by requiring entities that provide treatment for substance use disorders to notify patients of their privacy rights and also to notify patients in the event that the confidentiality of their records is breached. In certain circumstances, H.R. 5795 also would prohibit public and private entities from denying entry to treatment on the basis of information in patient health records. Those requirements would either supplant or narrowly expand responsibilities under existing law, and compliance with them would not impose significant additional costs. CBO estimates that the costs of the mandates would fall below the annual thresholds established in UMRA.

Mandates Affecting Private Entities

Five bills included in this document would impose private-sector mandates:

H.R. 5228, the Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act, would require drug distributors to cease distributing any drug that the Secretary of HHS determines might present an imminent or substantial hazard to public health. CBO cannot determine what drugs could be subject to such an order nor can it determine how private entities would respond. Consequently, CBO cannot determine whether the aggregate cost of the mandate would exceed the annual threshold for private-sector mandates.

H.R. 5333, the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018, would require developers and manufacturers of OTC drugs to pay certain fees to the FDA. CBO estimates that about $30 million would be collected each year, on average, for a total of $147 million over the 2019–2023 period. Those amounts would not exceed the annual threshold for private-sector mandates in any year during that period.

H.R. 5554, the Animal Drug and Animal Generic Drug User Fee Amendments of 2018, would require developers and manufacturers of brand-name and generic veterinary drugs to pay application, product, establishment, and sponsor fees to the FDA. CBO estimates that about $51 million would be collected annually, on average, for a total of $257 million over the 2019–2023 period. Those amounts would not exceed the annual threshold for private-sector mandates in any year during that period.

H.R. 5687, the Securing Opioids and Unused Narcotics with Deliberate Disposal and Packaging Act of 2018, would permit the Secretary of HHS to require drug developers and manufacturers to implement new packaging and disposal technology for certain drugs. Based on information from the agency, CBO expects that the Secretary would use the new regulatory authority provided in the bill; however, it is uncertain how or when those requirements would be implemented. Consequently, CBO cannot determine whether the aggregate cost of the mandate would exceed the annual threshold for private entities.

H.R. 5811, a bill to amend the Federal Food, Drug, and Cosmetic Act with respect to postapproval study requirements for certain controlled substances, and for other purposes, would expand an existing mandate that requires drug developers to conduct postapproval studies or clinical trials for certain drugs. Under current law, in certain instances, the FDA can require studies or clinical trials after a drug has been approved. H.R. 5811 would permit the FDA to use that authority if the reduction in a drug's effectiveness meant that its benefits no longer outweighed its costs. CBO estimates that the incremental cost of the mandate would fall below the annual threshold established in UMRA because of the small number of drugs affected and the narrow expansion of the authority that exists under current law.

None of the remaining 53 bills included in this document would impose an intergovernmental or private-sector mandate.

Previous CBO Estimate

On June 6, 2018, CBO issued an estimate for seven opioid-related bills ordered reported by the House Committee on Ways and Means on May 16, 2018. Two of those bills contain provisions that are identical or similar to the legislation ordered reported by the Committee on Energy and Commerce, and for those provisions, CBO's estimates are the same.

In particular, five bills listed in this estimate contain provisions that are identical or similar to those in several sections of H.R. 5773, the Preventing Addiction for Susceptible Seniors Act of 2018:

- H.R. 5675, which would require prescription drug plans to implement drug management programs, is identical to section 2 of H.R. 5773.
- H.R. 4841, regarding electronic prior authorization for prescriptions under Medicare's Part D, is similar to section 3 of H.R. 5773.
- H.R. 5715, which would mandate the creation of a new Internet portal to allow various stakeholders to exchange information, is identical to section 4 of H.R. 5773.
- H.R. 5684, which would expand medication therapy management, is the same as section 5 of H.R. 5773.

• H.R. 5716, regarding prescriber notification, is identical to section 6 of H.R. 5773.

In addition, in this estimate, a provision related to Medicare beneficiary education in H.R. 5686, the Medicare Clear Health Options in Care for Enrollees Act of 2018, is the same as a provision in section 2 of H.R. 5775, the Providing Reliable Options for Patients and Educational Resources Act of 2018, in CBO's estimate for the Committee on Ways and Means.

Estimate prepared by: Federal Costs: Rebecca Yip (Centers for Disease Control and Prevention), Mark Grabowicz (Drug Enforcement Agency), Julia Christensen, Ellen Werble (Food and Drug Administration), Emily King, Andrea Noda, Lisa Ramirez-Branum, Robert Stewart (Medicaid and Children's Health Insurance Program), Philippa Haven, Lara Robillard, Colin Yee, Rebecca Yip (Medicare), Philippa Haven (National Institutes of Health), Alice Burns, Andrea Noda (Office of the Secretary of the Department of Health and Human Services), Philippa Haven, Lori Housman, Emily King (Substance Abuse and Mental Health Services Administration, Health Resources and Services Administration); Federal Revenues: Jacob Fabian, Peter Huether, and Cecilia Pastrone; Fact Checking: Zachary Byrum and Kate Kelly; Mandates: Andrew Laughlin.

Estimate reviewed by: Tom Bradley, Chief, Health Systems and Medicare Cost Estimates Unit; Chad M. Chirico, Chief, Low-Income Health Programs and Prescription Drugs Cost Estimates Unit; Sarah Masi, Special Assistant for Health; Susan Willie, Chief, Mandates Unit; Leo Lex, Deputy Assistant Director for Budget Analysis; Theresa A. Gullo, Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to change the FDA's oversight of the commercial marketing of OTC medicines and authorize the collection and spending of fees through 2023 to cover the costs of expediting the FDA's administrative procedures for certain regulatory activities relating to OTC products.

DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 5333 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111–139 or the most recent Catalog of Federal Domestic Assistance.

COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congres-

sional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 5333 contains no earmarks, limited tax benefits, or limited tariff benefits.

DISCLOSURE OF DIRECTED RULE MAKINGS

Pursuant to section 3(i) of H. Res. 5, the Committee finds that H.R. 5333 contains no directed rule makings.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

The section provides that the Act may be cited as the "Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018."

TITLE I—OTC DRUG REVIEW

Section 101. Regulation of certain nonprescription drugs marketed without an approved new drug application

Section 101 clarifies how nonprescription drugs marketed without a new drug application (NDA) as of the date of enactment shall be treated. Drugs that are in conformity with a final monograph will be deemed to be generally recognized as safe and effective (GRASE), and not a new drug and not subject to NDA requirements. Drugs that are in conformity with a tentative final monograph will be deemed to be GRASE and not a new drug and not subject to NDA requirements, unless such drug falls under an administrative order regarding dosage form changes, is in a dosage form that has been used to a material time and extent, complies with a future final administrative order from FDA, or otherwise meets one of the preceding requirements and follows a minor change of procedure. Drugs that are classified as Category III and in conformity with a tentative final monograph or Category I and in conformity with the conditions proposed in an advanced notice of proposed rule-making may be legally marketed without a NDA. Drugs classified in Category II for safety and effectiveness under a tentative final monograph or that is subject to a determination not to be safe or effective in a proposed rule shall be deemed to be a new drug, misbranded, and subjected to the NDA requirements 180 days after enactment unless the Secretary determines it is in the interest of public health to extend such period.

Sunscreen drugs will be GRASE if they conform with a stayed final monograph, except that testing conditions governing labeling will be those contained in a separate, existing requirement.

Section 101 also transitions the OTC monograph regulatory process from a rule-making process to an administrative order process. Administrative orders may be initiated by the Secretary or by requestors. Such administrative orders will specify conditions under which specific drugs, classes of drugs, or combinations of drugs will be subject to a NDA and GRASE. Administrative orders initiated by the Secretary must be published on the web site of the FDA and include the reasons for such order. Sponsors should be notified no later than two business days before issuance of the proposed orders, and a public comment period of not less than 45 calendar days shall be provided. After such comment period, the Secretary will provide a detailed statement of reasons supporting the issuance of a final administrative order. The order will not take effect until the time for requesting judicial review has expired. If the Secretary is initiating a proposed administrative order determining that a drug is not GRASE, the Secretary shall provide the general categories of data supporting such determination, the format for submissions by interested persons, and a comment period of 180 days (with a good cause exception for a shorter comment period). Final or tentative final monographs for Category I drugs are deemed final administrative orders.

The section also specifies a hearing procedure to address concerns with the final administrative order. If a sponsor objects to an administrative order, they must first pursue dispute resolution within FDA's Center for Drug Evaluation and Research (CDER) within 45 days. If there is still a dispute after that process, the sponsor may pursue a FDA hearing, which must be requested within 30 days after the CDER dispute process. CDER may deny a hearing if the hearing request and administrative record do not establish a genuine and substantial question of material fact based on data using relevant and reliable scientific principles and methodologies. FDA may consolidate hearing requests. The presiding officer for the hearing will be designated by the Secretary, may not be an employee of CDER, and may not have been involved in the development of the administrative order. Parties to the hearing will have a right to present testimony, including experts, and to cross-examine witnesses presented by other parties. Judicial appeals will go to a U.S. District Court and must be filed within 60 days.

In instances of an imminent hazard to public health, the Secretary may issue an interim final administrative order, together with a detailed statement of the reasons for the order, which would take effect on a specified date. An interim final order will include at least a 45-day comment period and would substitute for a proposed order. The interim final order process will apply to safety labeling changes if the Secretary determines that such changes are reasonably expected to mitigate a significant or unreasonable risk of a serious adverse event associated with the use of a drug. FDA will issue a final administrative order and a sponsor may pursue dispute resolution and a hearing within 12 months. Judicial appeal may follow a final order.

Requestors may initiate an administrative order process to establish or change conditions for a drug to be found GRASE by filing

a request in a FDA-defined format. FDA will make a determination if the request is sufficiently complete and formatted to permit a substantive review. Such administrative order should be reviewed under the ordinary administrative order process described above. A requestor may file under protest with certain limitations. Changes to an order, other than a change necessary to ensure safety, that provide for a drug to contain a new active ingredient or a change in the conditions of use of a drug supported by new human data essential to the approval of the change, including clinical trials of safety or effectiveness, actual use studies, or pharmacokinetics or bioavailability studies will be provided with an exclusivity period of 18 months from drug listing.

The Comptroller General of the United States is required to conduct a study not later than four years after enactment to consider the effectiveness and overall impact of exclusivity under this section. The study shall include the number of drugs granted and exclusivity and the indication for which the drug was determined to be GRASE; whether the exclusivity was for a drug with a new active ingredient of changes in the conditions of use; whether and to what extent the exclusivity impacted the requestor's decision to develop the drug; an analysis of the implementation of the exclusivity provision, including the resources used by FDA, the impact on innovation and research and development, the impact on competition, the impact on consumer access, the impact on nonprescription drug prices, and whether the requestor-initiated order process has been sufficient to encourage the development of nonprescription drugs that would likely not be otherwise developed or developed in as timely a manner; and whether the requestor-initiated order process has been sufficient to encourage innovation in the nonprescription drug market.

Requests filed to establish a drug not currently in a monograph is GRASE must include information sufficient for a threshold determination that the drug has been marketed and safely used by consumers in the U.S. under comparable conditions of use; information to demonstrate the drug was marketed and safely used in a foreign country under conditions of use for a reasonable period of time and under a regulatory body of a country listed in section 802(b)(1)(A) or a country designated by FDA under 802(b)(1)(B); or if FDA determines such information is not needed to provide a threshold demonstration that the drug can be safely marketed as an OTC drug.

Administrative orders initiated by the Secretary, requestor, or posing an imminent hazard to public health may include packaging requirements. Such requirements may include unit dose packaging, requirements for products intended for use by children, requirements to reduce harm from unsupervised ingestion, or other appropriate requirements.

Minor changes in dosage forms that otherwise are consistent with the requirements of a monograph may take place without prior notice at a requestor's discretion so long as that requestor maintains information on file to demonstrate the change will not affect safety or effectiveness and will not materially affect absorption or other exposure to the active ingredient, and updates drug listing information within 30 days after introduction of the drug. Requestors shall submit records to the Secretary regarding minor

changes within 15 days of such request. If the Secretary determines the information in such records is not sufficient, the Secretary will inform the requestor in writing and provide with reasonable opportunity to provide additional information. If the requestor fails to provide necessary additional information, the drug as modified will be an unapproved new drug and misbranded.

FDA shall issue administrative orders and guidance about whether minor changes made by a requestor 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 by specific dosage forms. FDA will take into account relevant public standards and may take into account special needs of children in developing these orders and guidance.

Reports of testing related to requestor-initiated administrative orders will be kept confidential unless the requestor consents to the disclosure. Other information, other than raw data sets, submitted in support of the request shall be made public on the date of the proposed order unless the information is related to pharmaceutical quality. Information provided to support a minor change will remain confidential. Information submitted in a requestor-initiated process may be withdrawn by the requestor before a proposed order under FDA procedures.

Updates for changes to monograph drugs must be submitted to FDA's drug listing system within 30 days of introduction or, for drugs under a requestor-initiated administrative order, prior to introduction into commerce.

This section does not preclude requestors from seeking new drug approval, including under abbreviated new drug applications. Determinations that a drug is GRASE constitute findings of safety and effectiveness for the purposes of section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA), so that applicants only need to file information needed to support the modification in a section 505(b)(2) application.

FDA will establish a repository of administrative orders, including interim final orders, in effect with their complete text. FDA will list, at least annually, administrative orders in development with FDA's current expectations for issuance over a three-year period. FDA will also establish procedures allowing requestors the opportunity for private meetings to obtain advice on studies and information necessary to support submissions, as well as procedures where there are multiple sponsors or requestors on an administrative order. Submissions will be in electronic format. Except as otherwise provided, FDA will continue to use the existing notice and comment rulemaking for rules that would apply to OTC drugs in general. Regulations related to certain active ingredients in OTC drugs for certain uses that are in effect prior to enactment shall be deemed to be final. Regulations prior to enactment establishing requirements for specific OTC drugs, such as labeling and misbranding, are deemed to be final as they apply to the order process of this section. FDA may make technical changes to regulations that remain in effect to ensure conformity with appropriate terminology and cross references. Finally, FDA will issue guidance on meeting procedures and principles for sponsors or requestors, the format and content of data submissions, format of electronic formats, consolidated proceedings, and recommendations on how to

comply with order requirements for on data to be kept on file for minor product dosage form changes.

This section does not affect the current status of a nonprescription drug marketed under a NDA or ANDA or that is not subject to an administrative order. The Paperwork Reduction Act will not apply to information collections under this section, and administrative orders will not be subject to Administrative Procedure Act rulemaking requirements.

Definitions for "nonprescription drug," "sponsor," and "requestor" are provided.

Section 102. Misbranding

Section 102 provides that monograph drugs not in compliance or marketed from a non-fee paying facility are misbranded.

Section 103. Drugs excluded from the Over-the-Counter Drug Review

Section 103 provides that these sections do not apply to nonprescription drugs FDA intentionally excluded from the OTC Drug Review.

Section 104. Treatment of Sunscreen Innovation Act

Section 104 provides the sponsor of a proposed sunscreen order under the Sunscreen Innovation Act (SIA) may elect to remain under the SIA or may notify FDA that the order will follow the process under Monograph reform. If in the Monograph reform process, it will be deemed an order request accepted for filing. Such election shall be made within 180 calendar days of enactment. A final sunscreen order under SIA will be deemed a final order. Sponsors may request confidential meetings, and the Secretary shall convene such meeting within a reasonable time period. The Secretary may refuse to grant additional meetings if the Secretary determines that additional confidential meetings are not reasonably necessary to advance a proposed sunscreen order, or if the request fails to include sufficient information upon which to base a substantive conversation. The Secretary shall publish post-meeting summaries. SIA sunsets at the end of fiscal year (FY) 2022.

Section 105. Update to Congress on appropriate pediatric indication for certain OTC cough and cold drugs

Not later than one year after the date of enactment, and annually thereafter, the Secretary must submit a letter to the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor, and Pensions describing HHS' progress in evaluating cough and cold monograph drugs for children under age six until FDA submits a letter indicating it has completed its evaluation and revised, as applicable, the cough and cold monograph.

TITLE II—FEES RELATING TO MONOGRAPH DRUGS

Section 201. Short title; findings

Section 201 provides that the title may be cited as the "Over-the-Counter Monograph User Fee Act of 2018." Congress finds fees will be dedicated toward the nonprescription monograph drug activities

under goals identified in letters from FDA to the committees of jurisdiction.

Section 202. Authority to access and use fees

Section 202 provides definitions, including "OTC monograph drug activities," "OTC monograph drug facility," "Contract manufacturing organization," "Tier 1 OTC monograph order request," and "Tier 2 OTC monograph order request."

Section 202 authorizes FDA to assess and use OTC monograph fees. Each person that owns a monograph drug facility on December 31 or at any time in the preceding year shall be assessed a facility fee unless the facility has ceased all activities related to monograph drugs and updated its registration to reflect such changes. Fees for contract manufacturing organization facilities shall be equal to the amount that is two-thirds of the fee for an OTC monograph drug facility. For FY 2019, facility fees are due 45 days after FDA publishes a notice on the fee amount. For fiscal years after 2019, fees are due on the later of June 1 or the first business day after enactment of an appropriations Act providing for collection.

Sponsor-initiated OTC monograph order requests are subject to an inflation-adjusted $500,000 fee for Tier 1 requests, and $100,000 for Tier 2 requests. Safety-related label change OTC monograph order requests are exempt from the fee. Partial refunds are possible for withdrawals before filing, before substantial work was performed, or in tier reclassifications.

Before inflation adjustments or operating reserve adjustments, target fee collections from facility fees would be $22 million for FY 2018, $22 million for FY 2019, $25 million for FY 2020, $31 million for FY 2021, and $34 million for FY 2022.

An inflation adjustment tied to the Consumer Price Index (CPI) and related factors is included for fiscal years 2020–2023. Carryover of unspent funds or for to cover excess work may be held in an operating reserve with a maximum carry-over of: three weeks' worth of fees in FY 2019, seven weeks in FY 2020, and ten weeks in FY 2021–23. Amounts over the maximum would result in fee reductions the following year.

Based on facility assessments through drug registrations as of December 31, FDA will set and publish the facility fee for that fiscal year by January 31, with fees due before April 1. Manufacturers must submit facility information each year through drug establishment registration under existing section 510 of the FFDCA. Nonprescription monograph drug order requests submitted by a sponsor or requestor not paying fees will be considered incomplete, and ineligible for closed meetings. Fees may be collected and available only to the extent provided in appropriations Acts and available solely for nonprescription monograph drug activities. Before FDA may spend fee revenue, FDA must allocate $12 million year, adjusted for inflation. Fees paid prior to the due date may be accepted, however, fees not received by FDA after a grace period will be treated as a U.S. Government claim. Full-time equivalent positions (FTEs) at the Department of Health and Human Services not engaged in monograph activities may not be construed to require an offset from FTEs in monograph activities.

Starting in 2019, by February 1 of each year, FDA must submit to Congress reports on its progress in meeting the goals identified in the goals letter and future plans for meeting such goals and the status of FDA's implementation of its fee authority, fee uses, and collections. Such reports will be posted on FDA's website.

FDA is directed to consult with Congress, scientific experts, healthcare professionals, patient and advocacy groups, and industry in preparing recommendations for Congress for reauthorization beyond FY 2022. FDA must post a recommendations report and take comments. FDA's final recommendations will be sent to Congress no later than January 15, 2022.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * * * *

CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

* * * * * * *

MISBRANDED DRUGS AND DEVICES

SEC. 502. A drug or device shall be deemed to be misbranded—

(a)(1) If its labeling is false or misleading in any particular. Health care economic information provided to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs for coverage or reimbursement, shall not be considered to be false or misleading under this paragraph if the health care economic information relates to an indication approved under section 505 or under section 351(a) of the Public Health Service Act for such drug, is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug under section 505 or under section 351 of the Public Health Service Act. The requirements set forth in section 505(a) or in subsections (a) and (k) of section 351 of the Public Health Service Act shall not apply to health care economic information provided to such a payor, committee, or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request.

(2)(A) For purposes of this paragraph, the term "health care economic information" means any analysis (including the clinical data,

inputs, clinical or other assumptions, methods, results, and other components underlying or comprising the analysis) that identifies, measures, or describes the economic consequences, which may be based on the separate or aggregated clinical consequences of the represented health outcomes, of the use of a drug. Such analysis may be comparative to the use of another drug, to another health care intervention, or to no intervention.

(B) Such term does not include any analysis that relates only to an indication that is not approved under section 505 or under section 351 of the Public Health Service Act for such drug.

(b) If in a package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided,* That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(e)(1)(A) If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula)—

(i) the established name (as defined in subparagraph (3)) of the drug, if there is such a name;

(ii) the established name and quantity or, if determined to be appropriate by the Secretary, the proportion of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not the established name and quantity or if determined to be appropriate by the Secretary, the proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein, except that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subclause, shall not apply to nonprescription drugs not intended for human use; and

(iii) the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package and, if determined to be appropriate by the Secretary, on the immediate container, as prescribed in regulation promulgated by the Secretary, except that nothing in this subclause shall be deemed to require that any trade secret be divulged, and except that the requirements of this subclause with respect to alphabetical order shall apply only to nonprescription drugs that are not also cosmetics and that this subclause shall not apply to nonprescription drugs not intended for human use.

(B) For any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) shall be printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient, except that to the extent that compliance with the requirements of subclause (ii) or (iii) of clause (A) or this clause is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(2) If it is a device and it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name (as defined in subparagraph (4)) prominently printed in type at least half as large as that used thereon for any proprietary name or designation for such device, except that to the extent compliance with the requirements of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(3) As used in subparagraph (1), the term "established name", with respect to a drug or ingredient thereof, means (A) the applicable official name designated pursuant to section 508, or (B) if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient, except that where clause (B) of this subparagraph applies to an article recognized in the United States Pharmacopeia and in the Homeopathic Pharmacopeia under different official titles, the official title used in the United States Pharmacopeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopeia shall apply.

(4) As used in subparagraph (2), the term "established name" with respect to a device means (A) the applicable official name of the device designated pursuant to section 508, (B) if there is no such name and such device is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then any common or usual name of such device.

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments may be made available solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper

form, and after such request, promptly provides the requested information without additional cost.

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein. The method of packing may be modified with the consent of the Secretary. Whenever a drug is recognized in both the United States Pharmacopeia and the Homeopathic Pharmacopeia of the United States, it shall be subject to the requirements of the United States Pharmacopeia with respect to packaging, and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopeia of the United States, and not to those of the United States Pharmacopeia, except that in the event of inconsistency between the requirements of this paragraph and those of paragraph (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail.

(h) If it has been found by the Secretary to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Secretary shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Secretary shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i)(1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(j) If it is dangerous to health when used in the dosage or manner; or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

(m) If it is a color additive the intended use of which is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, as may be contained in regulations issued under section 721.

(n) In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in section 502(e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under section 502(e), and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with section 701(a), and in the case of published direct-to-consumer advertisements the following statement printed in conspicuous text: "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1–800-FDA-1088.", except that (A) except in extraordinary cir-

cumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement, and (B) no advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs, shall, with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of sections 12 through 17 of the Federal Trade Commission Act, as amended (15 U.S.C. 52–57). This paragraph (n) shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 201(m) of this Act. Nothing in the Convention on Psychotropic Substances, signed at Vienna, Austria, on February 21, 1971, shall be construed to prevent drug price communications to consumers. In the case of an advertisement for a drug subject to section 503(b)(1) presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous, and neutral manner.

(o) If it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510, if it is a drug and was imported or offered for import by a commercial importer of drugs not duly registered under section 801(s), if it was not included in a list required by section 510(j), if a notice or other information respecting it was not provided as required by such section or section 510(k), or if it does not bear such symbols from the uniform system for identification of devices prescribed under section 510(e) as the Secretary by regulation requires.

(p) If it is a drug and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

(q) In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 520(e).

(r) In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device (1) a true statement of the device's established name as defined in section 502(e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing. Except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement and no advertisement of a restricted device, published after the effective date of this paragraph shall, with respect

to the matters specified in this paragraph or covered by regulations issued hereunder, be subject to the provisions of sections 12 through 15 of the Federal Trade Commission Act (15 U.S.C. 52–55). This paragraph shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 201(m).

(s) If it is a device subject to a performance standard established under section 514, unless it bears such labeling as may be prescribed in such performance standard.

(t) If it is a device and there was a failure or refusal (1) to comply with any requirement prescribed under section 518 respecting the device, (2) to furnish any material or information required by or under section 519 respecting the device, or (3) to comply with a requirement under section 522.

(u)(1) Subject to paragraph (2), if it is a reprocessed single-use device, unless it, or an attachment thereto, prominently and conspicuously bears the name of the manufacturer of the reprocessed device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer.

(2) If the original device or an attachment thereto does not prominently and conspicuously bear the name of the manufacturer of the original device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, a reprocessed device may satisfy the requirements of paragraph (1) through the use of a detachable label on the packaging that identifies the manufacturer and is intended to be affixed to the medical record of a patient.

(v) If it is a reprocessed single-use device, unless all labeling of the device prominently and conspicuously bears the statement "Reprocessed device for single use. Reprocessed by ____." The name of the manufacturer of the reprocessed device shall be placed in the space identifying the person responsible for reprocessing.

(w) If it is a new animal drug—

(1) that is conditionally approved under section 571 and its labeling does not conform with the approved application or section 571(f), or that is not conditionally approved under section 571 and its label bears the statement set forth in section 571(f)(1)(A); or

(2) that is indexed under section 572 and its labeling does not conform with the index listing under section 572(e) or 572(h), or that has not been indexed under section 572 and its label bears the statement set forth in section 572(h).

(x) If it is a nonprescription drug (as defined in section 760) that is marketed in the United States, unless the label of such drug includes a domestic address or domestic phone number through which the responsible person (as described in section 760) may receive a report of a serious adverse event (as defined in section 760) with such drug.

(y) If it is a drug subject to an approved risk evaluation and mitigation strategy pursuant to section 505(p) and the responsible person (as such term is used in section 505–1) fails to comply with a requirement of such strategy provided for under subsection (d), (e), or (f) of section 505–1.

(z) If it is a drug, and the responsible person (as such term is used in section 505(o)) is in violation of a requirement established under paragraph (3) (relating to postmarket studies and clinical trials) or paragraph (4) (relating to labeling) of section 505(o) with respect to such drug.

(aa) If it is a drug, or an active pharmaceutical ingredient, and it was manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid as required by section 744B(a)(4) or for which identifying information required by section 744B(f) has not been submitted, or it contains an active pharmaceutical ingredient that was manufactured, prepared, propagated, compounded, or processed in such a facility.

(bb) If the advertising or promotion of a compounded drug is false or misleading in any particular.

(cc) If it is a drug and it fails to bear the product identifier as required by section 582.

(dd) If it is an antimicrobial drug, as defined in section 511A(f), and its labeling fails to conform with the requirements under section 511A(d).

(ee) If it is a nonprescription drug that is subject to section 505G, 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 and it was manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid as required by section 744O.

* * * * * * *

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

(a) NONPRESCRIPTION DRUGS MARKETED WITHOUT AN APPROVED APPLICATION.—Nonprescription drugs marketed without an approved new drug application under section 505, as of the date of the enactment of the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018, shall be treated in accordance with this subsection.

(1) DRUGS SUBJECT TO A FINAL MONOGRAPH; CATEGORY I DRUGS SUBJECT TO A TENTATIVE FINAL MONOGRAPH.—A drug is deemed to be generally recognized as safe and effective within the meaning of section 201(p)(1), not a new drug under section 201(p), and not subject to section 503(b)(1), if—

(A) the drug is—

(i) in conformity with the requirements for nonprescription use of a final monograph issued under part 330 of title 21, Code of Federal Regulations (except as provided in paragraph (2)), the general requirements for nonprescription drugs, and requirements under subsections (b), (c), and (k); and

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

(B) the drug is—

(i) classified in category I for safety and effectiveness under a tentative final monograph that is the most recently applicable proposal or determination issued under part 330 of title 21, Code of Federal Regulations;

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

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

(2) TREATMENT OF SUNSCREEN DRUGS.—With respect to sunscreen drugs subject to this section, the applicable requirements shall be the requirements specified in part 352 of title 21, Code of Federal Regulations, as published on May 21, 1999, beginning on page 27687 of volume 64 of the Federal Register, except that the applicable requirements governing effectiveness and labeling shall be those specified in section 201.327 of title 21, Code of Federal Regulations, subject to the requirements of subsections (b), (c), and (k).

(3) CATEGORY III DRUGS SUBJECT TO A TENTATIVE FINAL MONOGRAPH; CATEGORY I DRUGS SUBJECT TO PROPOSED MONOGRAPH OR ADVANCE NOTICE OF PROPOSED RULEMAKING.—A drug that is not described in paragraphs (1), (2), or (4) is not required to be the subject of an application approved under section 505, and is not subject to section 503(b)(1), if—

(A) the drug is—

(i) classified in category III for safety or effectiveness in the preamble of a proposed rule establishing a tentative final monograph that is the most recently applicable proposal or determination for such drug issued under part 330 of title 21, Code of Federal Regulations;

(ii) in conformity with—

(I) the conditions of use, including indication and dosage strength, if any, described for such category III drug in such preamble or in an applicable subsequent proposed rule;

(II) the proposed requirements for drugs classified in such tentative final monograph in category I in the most recently proposed rule establishing requirements related to such tentative final monograph and in any final rule establishing requirements that are applicable to the drug; and

(III) the general requirements for nonprescription drugs and requirements under subsections (b) or (k); and

(iii) in a dosage form that, immediately prior to the date of the enactment of this section, was not required to have satisfied the requirements of section 330.14 of

title 21, Code of Federal Regulations (as in effect at that time), in order for such drug to be lawfully marketed without an application approved under section 505; or

(B) the drug is—

(i) classified in category I for safety and effectiveness under a proposed monograph or advance notice of proposed rulemaking that is the most recently applicable proposal or determination for such drug issued under part 330 of title 21, Code of Federal Regulations;

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

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

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

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

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

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

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

(b) ADMINISTRATIVE ORDERS.—

(1) IN GENERAL.—

(A) DETERMINATION.—The Secretary may, on the initiative of the Secretary or at the request of one or more requestors, issue administrative orders determining whether there are conditions under which specific drugs, classes of such

drugs, or combinations of such drugs are determined to be—

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

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

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

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

(ii) is marketed in conformity with an administrative order under this subsection;

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

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

(C) STANDARD.—The Secretary shall find that a drug is not generally recognized as safe and effective within the meaning of section 201(p)(1) if—

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

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

(2) ADMINISTRATIVE ORDERS INITIATED BY THE SECRETARY.—

(A) IN GENERAL.—In issuing an administrative order under paragraph (1) upon the Secretary's initiative, the Secretary shall—

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

(ii) after any such reasonable efforts of notification—

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

(II) publish a 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 completion of the proceedings specified in 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, which order shall not take effect until the time for requesting judicial review under paragraph (3)(D)(ii) has expired;

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

(III) afford requestors of drugs 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 must 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 persons which sought such dispute resolution of their right to request a hearing.

(B) EXCEPTIONS.—When issuing an administrative order under paragraph (1) on the Secretary's initiative proposing to determine that a drug described in subsection (a)(3) 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 no less than 180 calendar days with respect to such proposed order, except when the Secretary determines, for good cause, that a shorter period is in the interests 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).

(3) HEARINGS; JUDICIAL REVIEW.—

(A) IN GENERAL.—Only a person who participated in each stage of formal dispute resolution under subclause (III) of paragraph (2)(A)(iv) of an administrative order with respect to a drug may request a hearing concerning a final administrative order issued under such paragraph with respect to such drug. Such person must submit a request for a hearing, which shall be based solely on 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.—

(i) IN GENERAL.—The Secretary shall not be 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 (a)(3)(A); and

(II) with respect to which no human or non-human data studies 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.

(ii) HUMAN DATA STUDIES AND NON-HUMAN DATA DEFINED.—In this subparagraph:

(I) The term "human data studies" means clinical trials of safety or effectiveness (including actual use studies), pharmacokinetics studies, or bioavailability studies.

(II) The term "non-human data" means data from testing other than with human subjects which provides information concerning safety or effectiveness.

(C) HEARING PROCEDURES.—

(i) DENIAL OF REQUEST FOR HEARING.—If the Secretary determines that information submitted in a request for a hearing under subparagraph (A) with respect to a final administrative order issued under paragraph (2)(A)(iv), does not identify 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 presiding officer of a hearing requested under subparagraph (A) shall—

(I) be designated by the Secretary;

(II) not be an employee of the Center for Drug Evaluation and Research; and

(III) not have been previously involved in the development of the administrative order involved or 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 in-

terests be consolidated to promote efficiency and avoid duplication.

(v) FINAL DECISION.—

(I) 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.

(II) 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) PERIOD TO SUBMIT A REQUEST FOR JUDICIAL REVIEW.—A person eligible to request a hearing under this paragraph and seeking judicial review of a final administrative order issued under this subsection shall file such request for judicial 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 a hearing with respect to such order is denied under subparagraph (B) or (C)(i);

(III) the date on which a final decision is made following a hearing 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 drug, class of drugs, or combination of drugs subject to this section poses an imminent hazard to the public health, the Secretary, after first making reasonable efforts to notify, not later than 48 hours before issuance of such order under this subparagraph, sponsors who have a listing in effect under section 510(j) for such drug or combination of drugs—

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

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

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

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

(B) SAFETY LABELING CHANGES.—

(i) IN GENERAL.—In the case of a determination by the Secretary that a change in the labeling of a drug, class of drugs, or combination of drugs subject to this section is reasonably expected to mitigate a significant or unreasonable risk of a serious adverse event associated with use of the drug, the Secretary may—

(I) make reasonable efforts to notify informally, not later than 48 hours before the issuance of the interim final order, the sponsors of drugs who have a listing in effect under section 510(j) for such drug or combination of drugs;

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

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

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

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

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

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

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

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

(iii) afford sponsors of such 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 must initially 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.—A sponsor of a drug subject to a final order issued under subparagraph (D) and that participated in each stage of formal dispute resolution under clause (iii) of such subparagraph may request a hearing on such order. The provisions of subparagraphs (A), (B), and (C) of paragraph (3), other than paragraph (3)(C)(v)(II), shall apply with respect to a hearing on such order in the same manner and to the same extent as such provisions apply with re-

spect to a hearing on an administrative order issued under paragraph (2)(A)(iv).

(F) TIMING.—

(i) FINAL ORDER AND HEARING.—The Secretary shall—

(I) not later than 6 months after the date on which the comment period closes under subparagraph (A) or (B), issue a final order in accordance with paragraph (1); and

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

(ii) DISPUTE RESOLUTION REQUEST.—The Secretary shall specify in an interim final order issued under subparagraph (A) or (B) such shorter periods for requesting dispute resolution under subparagraph (D)(iii) as are necessary to meet the requirements of this subparagraph.

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

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

(A) IN GENERAL.—In issuing an administrative order under paragraph (1) at the request of a requestor with respect to certain drugs, classes of drugs, or combinations of drugs—

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

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

(I) file the request; and

(II) initiate proceedings with respect to issuing an administrative order in accordance with paragraphs (2) and (3); and

(iii) except as provided in paragraph (6), if the Secretary determines that a request does not meet the requirements for filing or is not sufficiently complete and formatted to permit a substantive review, the requestor may demand that the request be filed 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 under paragraph (1) with respect to certain drugs, classes of drugs, or combinations of drugs, shall submit to the Secretary a request to initiate proceedings for such order in the form and manner as specified by the Secretary. Such requestor may submit a request under this subparagraph for the issuance of an administrative order—

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

(II) determining whether a change to a condition of use of a drug is generally recognized as safe and effective within the meaning of section 201(p)(1), exempt from section 503(b)(1), and not required to be the subject of an approved application under section 505, if, absent such a changed condition of use, such drug is—

(aa) generally recognized as safe and effective within the meaning of section 201(p)(1) in accordance with subsection (a)(1), (a)(2), or an order under this subsection; or

(bb) subject to subsection (a)(3), 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).

(ii) EXCEPTION.—The Secretary is not required to complete review of a request for a change described in clause (i)(II) if the Secretary determines that there is an inadequate basis to find the drug is generally recognized as safe and effective within the meaning of section 201(p)(1) under paragraph (1) and issues a final order announcing that determination.

(iii) WITHDRAWAL.—The requestor may withdraw a request under this paragraph, according to the procedures set forth pursuant to subsection (d)(2)(B). Notwithstanding any other provision of this section, if such request is withdrawn, the Secretary may cease proceedings under this subparagraph.

(C) EXCLUSIVITY.—

(i) IN GENERAL.—A final administrative order issued in response to a request under this section 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), for a period of 18 months following the effective date of such final order, to market drugs—

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

(II) beginning on the date the requestor (or any such licensees, assignees, or successors in interest) may lawfully market such drugs pursuant to the order; and

(III) 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 in-

gredient) 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 subsection (a)(1), (a)(2), or (a)(3);

(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 (m)(1), other than drugs subject to an active enforcement action under chapter III of this Act.

(iv) LIMITATIONS ON EXCLUSIVITY.—

(I) IN GENERAL.—Only one period of exclusivity shall be granted, under each order described in clause (i), with respect to changes (to the drug subject to such order) which are either—

(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) NO EXCLUSIVITY ALLOWED.—No exclusivity shall apply to changes to a drug which are—

(aa) the subject of a Tier 2 OTC monograph order request (as defined in section 744N);

(bb) safety-related changes, as defined by the Secretary, or any other changes the Secretary considers necessary to assure safe use; or

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

(v) NEW HUMAN DATA STUDIES DEFINED.—In this subparagraph, the term "new human data studies" means clinical trials of safety or effectiveness (including actual use studies), pharmacokinetics studies, or bioavailability studies, the results of which—

(I) have not been relied on by the Secretary 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 that was approved under section 505; and

(II) do not duplicate the results of another study that was relied on by the Secretary 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 that was approved under section 505.

(vi) EFFECTIVE DATE.—A final order subject to clause (i) shall take effect on the date when the order requestor (or the licensees, assignees, or successors in interest of such requestor with respect to such order) submits updated drug listing information under subsection (e) with respect to the change which is permitted under such order.

(vii) GAO STUDY.—Not later than 4 years after the date of enactment of the Over-the-Counter Monograph, Safety, Innovation, and Reform Act of 2018, the Comptroller General of the United States shall submit a study to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate addressing the effectiveness and overall impact of exclusivity under this section, including its impact on consumer access. Such study shall include—

(I) the number of nonprescription drug products that were granted exclusivity and the indication for which the nonprescription drug products were determined to be generally recognized as safe and effective;

(II) whether the exclusivity for such drug products was granted for—

(aa) a new active ingredient (including any ester or salt of the active ingredient); or

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

(III) whether, and to what extent, the exclusivity impacted the requestor's or sponsor's decision to develop the drug product;

(IV) an analysis of the implementation of the exclusivity provision in this subparagraph, including—

(aa) the resources used by the Food and Drug Administration;

(bb) the impact of such provision on innovation, as well as research and development in the nonprescription drug market;

(cc) the impact of such provision on competition in the nonprescription drug market;

(dd) the impact of such provision on consumer access to nonprescription drug products;

(ee) the impact of such provision on the prices of nonprescription drug products; and

(ff) whether the administrative orders initiated by requestors under this section have been sufficient to encourage the development of

nonprescription drug products that would likely not be otherwise developed, or developed in as timely a manner; and

(V) whether the administrative orders initiated by requestors under this section have been sufficient incentive to encourage innovation in the nonprescription drug market.

(6) INFORMATION REGARDING SAFE NONPRESCRIPTION MARKETING AND USE AS CONDITION FOR FILING A GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE REQUEST.—

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

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

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

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

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

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

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

(C) INFORMATION DEMONSTRATING PRIMA FACIE SAFE NONPRESCRIPTION MARKETING AND USE.—Information specified in this subparagraph, with respect to a request described in subparagraph (A)(i), is—

(i) information sufficient for a prima facie 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 prima facie demonstration that the drug was marketed and safely used under comparable conditions of marketing and use in a country listed in section 802(b)(1)(A) or designated by the Secretary in accordance with section 802(b)(1)(B)—

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

(II) during such time was subject to sufficient monitoring by a regulatory body considered acceptable by the Secretary for such monitoring purposes, including for adverse events associated with nonprescription use of the drug; or

(iii) if the Secretary determines that information described in clauses (i) or (ii) is not needed to provide a

prima facie demonstration that the drug can be safely marketed and used as a nonprescription drug, such other information the Secretary determines is sufficient for such purposes.

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

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

(ii) during such time period, one million retail packages of the drug, or an equivalent quantity as determined by the Secretary, were distributed for retail sale, as determined in such manner as the Secretary finds appropriate.

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

(7) PACKAGING.—An administrative order issued under paragraph (2), (4)(A), or (5) may include requirements for the packaging of a drug to encourage use in accordance with labeling. Such requirements may include unit dose packaging, requirements for products intended for use by children, requirements to reduce risk of harm from unsupervised ingestion, and other appropriate requirements. This paragraph does not authorize the Food and Drug Administration to require standards or testing procedures as described in part 1700 of title 16, Code of Federal Regulations.

(8) FINAL AND TENTATIVE FINAL MONOGRAPHS FOR CATEGORY I DRUGS DEEMED FINAL ADMINISTRATIVE ORDERS.—

(A) IN GENERAL.—A final monograph or tentative final monograph described in subparagraph (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 is described in this subparagraph if it—

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

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

(C) DEEMED ORDERS INCLUDE HARMONIZING TECHNICAL AMENDMENTS.—The deemed establishment of a final administrative order under subparagraph (A) shall be construed to include any technical amendments to such order as the Secretary determines necessary to ensure that such order is appropriately harmonized, in terms of terminology

or cross-references, with the applicable provisions of this Act (and regulations thereunder) and any other orders issued under this section.

(c) PROCEDURE FOR MINOR CHANGES.—

(1) IN GENERAL.—Minor changes in the dosage form of a drug that is described in paragraph (1) or (2) of subsection (a) or the subject of an order issued under subsection (b) may be made by a requestor without the issuance of an order under subsection (b) if—

(A) the requestor maintains such information as is necessary to demonstrate that the change—

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

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

(B) the 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.—A sponsor shall submit records requested by the Secretary relating to such a minor change under section 704(a)(4), within 15 business days of receiving such a 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 sponsor of the drug in writing; and

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

(C) FAILURE TO SUBMIT SUFFICIENT INFORMATION.—If the sponsor 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 A CHANGE WILL AFFECT SAFETY OR EFFECTIVENESS.—

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

(B) STANDARD PRACTICES.—The orders and guidance issued by the Secretary under subparagraph (A) shall take into account relevant public standards and standard practices for evaluating the quality of drugs, and may take into account the special needs of populations, including children.

(d) CONFIDENTIALITY OF INFORMATION SUBMITTED TO THE SECRETARY.—

(1) IN GENERAL.—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 order under this section (including any minor change under subsection (c)) 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.—

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

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

(ii) make any information submitted by any other person with respect to an order requested (or initiated by the Secretary) under subsection (b), available to the public upon such submission.

(B) LIMITATIONS ON PUBLIC AVAILABILITY.—Information described in subparagraph (A) shall not be made public if—

(i) the information pertains to pharmaceutical quality information, 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);

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

(iii) the Secretary requests and obtains the information under subsection (c) and such information is not submitted in relation to an order under subsection (b); or

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

(e) 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 section 510(j) within 30 calendar days of the date when the drug is first commercially marketed, except that a sponsor who was the order requestor with respect to an order subject to subsection (b)(5)(C) (or a licensee, assignee, or successor in interest of such re-

questor) shall submit updated drug listing information on or before the date when the drug is first commercially marketed.

(f) APPROVALS UNDER SECTION 505.—The provisions of this section shall not be construed to preclude a person from seeking or maintaining the approval of a drug under sections 505(b)(1), 505(b)(2), and 505(j). 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 that the drug is safe and effective that may be relied upon for purposes of an application under section 505(b)(2), so that the applicant shall be required to submit for purposes of such application only information needed to support any modification of the drug that is not covered by such determination under this section.

(g) PUBLIC AVAILABILITY OF ADMINISTRATIVE ORDERS.—The Secretary shall establish, maintain, update (as determined necessary by the Secretary but no less frequently than annually), and make publicly available, with respect to orders issued under this section—

(1) a repository of each final order and interim final order in effect, including the complete text of the order; and

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

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

(B) the Secretary's expectations, if resources permit, for issuance of proposed orders over a three-year period.

(h) DEVELOPMENT ADVICE TO SPONSORS OR REQUESTORS.—The Secretary shall establish procedures under which sponsors or requestors may meet with appropriate officials of the Food and Drug Administration to obtain advice on the studies and other information necessary to support submissions under this section and other matters relevant to the regulation of nonprescription drugs and the development of new nonprescription drugs under this section.

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

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

(k) 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) The provisions of section 310.545 of title 21, Code of Federal Regulations, as in effect on the day before the date

of the enactment of this section, shall be deemed to be a final order under subsection (b).

(B) Regulations in effect on the day before the date of the enactment of this section, establishing requirements for specific nonprescription drugs marketed pursuant to this section (including such requirements in parts 201 and 250 of title 21, Code of Federal Regulations), shall be deemed to be final orders under subsection (b), only as they apply to drugs—

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

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

(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 the enactment of this section), or make technical changes to such regulations to ensure conformity with appropriate terminology and cross references. Notwithstanding subchapter II of chapter 5 of title 5, United States Code, any such withdrawal or technical changes shall be made without public notice and comment and shall be effective upon publication through notice in the Federal Register (or upon such date as specified in such notice).

(l) GUIDANCE.—The Secretary shall issue guidance that specifies—

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

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

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

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

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

(m) RULE OF CONSTRUCTION.—

(1) IN GENERAL.—This section shall not affect the treatment or status of a nonprescription drug—

(A) that is marketed without an application approved under section 505 as of the date of the enactment of this section;

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

(C) to which paragraphs (1), (2), (3), (4), or (5) of subsection (a) do not apply.

(2) TREATMENT OF PRODUCTS PREVIOUSLY FOUND TO BE SUBJECT TO TIME AND EXTENT REQUIREMENTS.—

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

(B) A drug described in this subparagraph is a drug which, prior to the date of the enactment of this section, the

Secretary had determined in a proposed or final rule to be ineligible for review under the OTC drug review (as such phrase "OTC drug review" was used in section 330.14 of title 21, Code of Federal Regulations, as in effect on the day before the date of the enactment of this section).

(3) PRESERVATION OF AUTHORITY.—

(A) Nothing in paragraph (1) shall be construed to preclude or limit the applicability of any other provision of this Act.

(B) Nothing in subsection (a) 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 within the meaning of section 201(p)(1), as the Secretary determines appropriate.

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

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

(p) INAPPLICABILITY OF NOTICE AND COMMENT RULEMAKING AND OTHER REQUIREMENTS.—The requirements of subsection (b) shall apply with respect to orders issued under this section instead of the requirements of subchapter II of chapter 5 of title 5, United States Code.

(q) DEFINITIONS.—In this section:

(1) The term "nonprescription drug" refers to a drug not subject to the requirements of section 503(b)(1).

(2) The term "sponsor" refers to any person marketing, manufacturing, or processing a drug that—

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

(B) is or will be subject to an administrative order of the Food and Drug Administration.

(3) The term "requestor" refers to any person or group of persons marketing, manufacturing, processing, or developing a drug.

* * * * * * *

Subchapter I—Nonprescription Sunscreen and Other Active Ingredients

* * * * * * *

SEC. 586C. GRASE DETERMINATION.

(a) REVIEW OF NEW REQUEST.—

(1) PROPOSED SUNSCREEN ORDER.—In the case of a request under section 586A, not later than 300 calendar days after the date on which such request is filed under subsection (b)(2)(A) or (b)(3)(B)(ii)(III) of section 586B, the Secretary—

(A) may convene a meeting of the Advisory Committee to review such request; and

(B) shall complete the review of such request and issue a proposed sunscreen order with respect to such request.

(2) PROPOSED SUNSCREEN ORDER BY COMMISSIONER.—If the Secretary does not issue a proposed sunscreen order under

paragraph (1)(B) within such 300-day period, the sponsor of such request may notify the Office of the Commissioner of such request and request review by the Office of the Commissioner. If such sponsor so notifies the Office of the Commissioner, the Commissioner shall, not later than 60 calendar days after the date of notification under this paragraph, issue a proposed sunscreen order with respect to such request.

(3) PUBLIC COMMENT PERIOD.—A proposed sunscreen order issued under paragraph (1)(B) or (2) with respect to a request shall provide for a period of 45 calendar days for public comment.

(4) MEETING.—A sponsor may request, in writing, a meeting with respect to a proposed sunscreen order issued under this subsection and described in subparagraph (B) or (C) of section 586(7), not later than 30 calendar days after the Secretary issues such order. The Secretary shall convene a meeting with such sponsor not later than 45 calendar days after such request for a meeting.

(5) FINAL SUNSCREEN ORDER.—With respect to a proposed sunscreen order under paragraph (1)(B) or (2)—

(A) the Secretary shall issue a final sunscreen order—

(i) in the case of a proposed sunscreen order described in subparagraph (A) or (B) of section 586(7), not later than 90 calendar days after the end of the public comment period under paragraph (3); or

(ii) in the case of a proposed sunscreen order described in subparagraph (C) of section 586(7), not later than 210 calendar days after the date on which the sponsor submits the additional information requested pursuant to such proposed sunscreen order; or

(B) if the Secretary does not issue such final sunscreen order within such 90- or 210-calendar-day period, as applicable, the sponsor of such request may notify the Office of the Commissioner of such request and request review by the Office of the Commissioner.

(6) FINAL SUNSCREEN ORDER BY COMMISSIONER.—The Commissioner shall issue a final sunscreen order with respect to a proposed sunscreen order subject to paragraph (5)(B) not later than 60 calendar days after the date of notification under such paragraph.

(b) REVIEW OF PENDING REQUESTS.—

(1) IN GENERAL.—The review of a pending request shall be carried out by the Secretary in accordance with this subsection.

(2) INAPPLICABILITY OF SECTIONS 586A AND 586B.—Sections 586A and 586B shall not apply with respect to any pending request.

(3) FEEDBACK LETTERS AS PROPOSED SUNSCREEN ORDER.—Notwithstanding the requirements of section 586(7), a letter issued pursuant to section 330.14(g) of title 21, Code of Federal Regulations before the date of enactment of the Sunscreen Innovation Act, with respect to a pending request, shall be deemed to be a proposed sunscreen order and displayed on the Internet website of the Food and Drug Administration. Notification of the availability of such letter shall be published in the

Federal Register not later than 45 calendar days after the date of enactment of such Act.

(4) PROPOSED SUNSCREEN ORDER.—In the case of a pending request for which the Secretary has not issued a letter pursuant to section 330.14(g) of title 21, Code of Federal Regulations before the date of enactment of the Sunscreen Innovation Act, the Secretary shall complete review of such request and, not later than 90 calendar days after the date of enactment of such Act, issue a proposed sunscreen order with respect to such request.

(5) PROPOSED SUNSCREEN ORDER BY COMMISSIONER.—If the Secretary does not issue a proposed sunscreen order under paragraph (4), or the Secretary does not publish a notification of the availability of a letter under paragraph (3), as applicable, the sponsor of such request may notify the Office of the Commissioner of such request and request review by the Office of the Commissioner. The Commissioner shall, not later than 60 calendar days after the date of notification under this paragraph, issue a proposed order with respect to such request.

(6) PUBLIC COMMENT PERIOD.—A proposed sunscreen order issued under paragraph (4) or (5), or a notification of the availability of a letter under paragraph (3), with respect to a pending request shall provide for a period of 45 calendar days for public comment.

(7) MEETING.—[A sponsor may request]

(A) IN GENERAL.—A sponsor may request, in writing, a meeting with respect to a proposed sunscreen order issued under this subsection, including a letter deemed to be a proposed sunscreen order under paragraph (3), not later than 30 calendar days after the Secretary issues such order or the date upon which such feedback letter is deemed to be a proposed sunscreen order, as applicable. The Secretary shall convene a meeting with such sponsor not later than 45 calendar days after the date of such request for a meeting.

(B) CONFIDENTIAL MEETINGS.—A sponsor may request one or more confidential meetings with respect to a proposed sunscreen order, including a letter deemed to be a proposed sunscreen order under paragraph (3), to discuss matters involving confidential commercial information or trade secrets. The Secretary shall convene a confidential meeting with such sponsor in a reasonable time period. 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 that such additional confidential meeting is not reasonably necessary for the sponsor to advance its proposed sunscreen order, or if the request for a confidential meeting fails to include sufficient information upon which to base a substantive discussion. The Secretary shall publish a post-meeting summary of each confidential meeting under this subparagraph that does not disclose confidential commercial information or trade secrets.

(8) ADVISORY COMMITTEE.—In the case of a proposed sunscreen order under paragraph (3), (4), or (5), an Advisory Committee meeting may be convened for the purpose of reviewing and providing recommendations regarding the pending request.

(9) FINAL SUNSCREEN ORDER.—In the case of a proposed sunscreen order under paragraph (3), (4), or (5)—

(A) the Secretary shall issue a final sunscreen order with respect to the request—

(i) in the case of a proposed sunscreen order described in subparagraph (A) or (B) of section 586(7), not later than 90 calendar days after the end of the public comment period under paragraph (6); or

(ii) in the case of a proposed sunscreen order described in subparagraph (C) of section 586(7)—

(I) if the Advisory Committee is not convened under paragraph (8), not later than 210 calendar days after the date on which the sponsor submits the additional information requested pursuant to such proposed sunscreen order, which shall include a rationale for not convening such Advisory Committee; or

(II) if the Advisory Committee is convened under paragraph (8), not later than 270 calendar days after the date on which the sponsor submits such additional information; or

(B) if the Secretary does not issue such final sunscreen order within such 90-, 210-, or 270-calendar-day period, as applicable, the sponsor of such request may notify the Office of the Commissioner about such request and request review by the Office of the Commissioner.

(10) FINAL SUNSCREEN ORDER BY COMMISSIONER.—The Commissioner shall issue a final sunscreen order with respect to a proposed sunscreen order subject to paragraph (9)(B) not later than 60 calendar days after the date of notification under such paragraph.

(c) ADVISORY COMMITTEE.—The Secretary shall not be required to—

(1) convene the Advisory Committee—

(A) more than once with respect to any request under section 586A or any pending request; or

(B) more than twice in any calendar year with respect to the review under this section; or

(2) submit more than a total of 3 requests under section 586A or pending requests to the Advisory Committee per meeting.

(d) NO DELEGATION.—Any responsibility vested in the Commissioner by subsection (a)(2), (a)(6), (b)(5), or (b)(10) shall not be delegated.

(e) EFFECT OF FINAL SUNSCREEN ORDER.—

(1) IN GENERAL.—

(A) SUNSCREEN ACTIVE INGREDIENTS DETERMINED TO BE GRASE.—Upon issuance of a final sunscreen order determining that a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is GRASE and is not misbranded, a sunscreen con-

taining such ingredient or combination of ingredients shall be permitted to be introduced or delivered into interstate commerce for use under the conditions described in such final sunscreen order, in accordance with all requirements applicable to drugs not subject to section 503(b)(1), for so long as such final sunscreen order remains in effect.

(B) SUNSCREEN ACTIVE INGREDIENTS DETERMINED NOT TO BE GRASE.—Upon issuance of a final sunscreen order determining that a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is not GRASE and is misbranded, a sunscreen containing such ingredient or combination of ingredients shall not be introduced or delivered into interstate commerce, for use under the conditions described in such final sunscreen order, unless an application is approved pursuant to section 505 with respect to a sunscreen containing such ingredient or combination of ingredients, or unless conditions are later established under which such ingredient or combination of ingredients is later determined to be GRASE and not misbranded under the over-the-counter drug monograph system.

(2) AMENDMENTS TO FINAL SUNSCREEN ORDERS.—

(A) AMENDMENTS AT INITIATIVE OF SECRETARY.—In the event that information relevant to a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients becomes available to the Secretary after issuance of a final sunscreen order, the Secretary may amend such final sunscreen order by issuing a new proposed sunscreen order under subsection (a)(1) and following the procedures set forth in this section.

(B) PETITION TO AMEND FINAL ORDER.—Any interested person may petition the Secretary to amend a final sunscreen order under section 10.30, title 21 Code of Federal Regulations (or any successor regulations). If the Secretary grants any petition under such section, the Secretary shall initiate the process for amending a final sunscreen order by issuing a new proposed sunscreen order under subsection (a)(1) and following the procedures set forth in this section.

(C) APPLICABILITY OF FINAL ORDERS.—Once the Secretary issues a new proposed sunscreen order to amend a final sunscreen order under subparagraph (A) or (B), such final sunscreen order shall remain in effect and paragraph (3) shall not apply to such final sunscreen order until the Secretary has issued a new final sunscreen order or has determined not to amend the final sunscreen order.

[(3) INCLUSION OF INGREDIENTS THAT ARE SUBJECTS OF FINAL ORDERS IN THE SUNSCREEN MONOGRAPH.—

[(A) AMENDING REGULATIONS.—

[(i) REQUIREMENT.—At any time that the Secretary proposes to amend part 352 of title 21, Code of Federal Regulations (or any successor regulations) concerning nonprescription sunscreen, including pursuant to section 586E, except as provided in clause (iv), the Secretary shall include in such part 352 (or any successor

regulations) any nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that is the subject of an effective final sunscreen order of the type described in section 586(2)(A) and issued since the time that the Secretary last amended such regulations. Such regulation shall set forth conditions of use under which each such ingredient or combination of ingredients is GRASE and not misbranded. If these conditions differ from, or are in addition to, those previously set forth in the applicable final sunscreen order, the Secretary shall provide notice and opportunity for comment on such conditions in the rulemaking, and the applicable final sunscreen order shall continue in effect until the effective date of a final regulation, as set forth in clause (iii).

[(ii) INCLUSION OF ORDERS.—In proposing to amend the regulations as described in clause (i), the Secretary shall include in the proposed regulations a list of final sunscreen orders that shall cease to be effective on the effective date of a resulting final regulation. Such list shall include all final sunscreen orders of the type described in section 586(2)(A) that are in effect on the date that such regulations are proposed, with the exception that such list shall not include any final sunscreen orders that, on the date that the regulations are proposed, the Secretary is in the process of amending under paragraph (2).

[(iii) ORDERS NO LONGER EFFECTIVE.—Any final sunscreen order included by the Secretary in a list described in clause (ii) and in a list included in resulting final regulations shall cease to be effective on the date that such final regulations including such order in such list become effective.

[(iv) INGREDIENTS NOT GRASE.—If, notwithstanding a final sunscreen order stating that a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is GRASE and is not misbranded if marketed in accordance with such order, while amending the regulations as described in clause (i), the Secretary concludes that such ingredient or combination of ingredients is no longer GRASE for use in nonprescription sunscreen, the Secretary shall, at the discretion of the Secretary, either initiate the process for amending the final sunscreen order set forth in paragraph (2) of this subsection or include in a proposed regulation an explanation and information supporting the determination of the Secretary that such ingredient or combination of ingredients is no longer GRASE for use in nonprescription sunscreen.

[(B) PROCEDURE FOR UPDATING REGULATIONS.—After the Secretary amends and finalizes the regulations under part 352 of title 21, Code of Federal Regulations under section 586E and such regulations become effective, the Secretary

may use direct final rulemaking to include in such regulations any nonprescription sunscreen active ingredients that are the subject of effective final sunscreen orders.]

(3) RELATIONSHIP TO ORDERS UNDER SECTION 505G.—A final sunscreen order shall be deemed to be a final order under section 505G.

* * * * * * *

[SEC. 586E. SUNSCREEN MONOGRAPH.

[(a) IN GENERAL.—Not later than 5 years after the date of enactment of the Sunscreen Innovation Act, the Secretary shall amend and finalize regulations under part 352 of title 21, Code of Federal Regulations concerning nonprescription sunscreen that are effective not later than 5 years after such date of enactment. The Secretary shall publish such regulations not less than 30 calendar days before the effective date of such regulations.

[(b) REPORTS.—If the regulations promulgated under subsection (a) do not include provisions related to the effectiveness of various sun protection factor levels, and do not address all dosage forms known to the Secretary to be used in sunscreens marketed in the United States without a new drug approval 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 such provisions not being included in such regulations, and a plan and timeline to compile any information necessary to address such provisions through final regulations.]

* * * * * * *

SEC. 586H. SUNSET.

This subchapter shall cease to be effective at the end of fiscal year 2022.

* * * * * * *

CHAPTER VII—GENERAL AUTHORITY

* * * * * * *

SUBCHAPTER C—FEES

* * * * * * *

PART 10—FEES RELATING TO OVER-THE-COUNTER DRUGS

SEC. 744N. DEFINITIONS.

In 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 an OTC monograph drug facility where neither the owner of such manufacturing facility nor any affiliate of such owner or facility sells the OTC monograph drug produced at such facility directly to wholesalers, retailers, or consumers in the United States.

(3) The term "costs of resources allocated for OTC monograph drug activities" means the expenses in connection with OTC 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 costs related 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 744O and accounting for resources allocated for OTC monograph drug activities.

(4) The term "FDA establishment identifier" is the unique number automatically generated by Food and Drug Administration's Field Accomplishments and Compliance Tracking System (FACTS) (or any successor system).

(5) The term "OTC monograph drug" means a nonprescription drug without an approved new drug application which is governed by the provisions of section 505G.

(6) The term "OTC monograph drug activities" means activities of the Secretary associated with OTC monograph drugs and inspection of facilities associated with such products, including the following activities:

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

(i) orders proposing or finalizing applicable conditions of use for OTC monograph drugs;

(ii) orders affecting status regarding general recognition of safety and effectiveness of an OTC monograph ingredient or combination of ingredients under specified conditions of use;

(iii) all OTC monograph drug development and review activities, including intraagency collaboration;

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

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

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

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

(viii) regulatory science activities related to OTC monograph drugs.

(B) Inspections related to OTC monograph drugs.

(C) Monitoring of clinical and other research conducted in connection with OTC monograph drugs.

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

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

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

(7) The term "OTC monograph order request" means a request for an order submitted under section 505G(b)(5).

(8) The term "Tier 1 OTC monograph order request" means any OTC monograph order request not determined to be a Tier 2 OTC monograph order request.

(9)(A) The term "Tier 2 OTC monograph order request" means, subject to subparagraph (B), an OTC monograph order request for—

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

(ii) the addition of information to the other information section of the drug facts label of an OTC monograph drug, as limited by section 201.66(c)(7) of title 21, Code of Federal Regulations (or any successor regulations);

(iii) modification to the directions for use section of the drug facts label of an OTC monograph drug, if such changes conform to changes made pursuant to section 505G(c)(3)(A);

(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 section 330.1 of title 21, Code of Federal Regulations (or any successor regulations).

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

(10)(A) The term "OTC monograph drug facility" means a foreign or domestic business or other entity that—

(i) is—

(I) under one management, either direct or indirect; and

(II) at one geographic location or address engaged in manufacturing or processing the finished dosage form of an OTC monograph drug;

(ii) includes a finished dosage form manufacturer facility in a contractual relationship with the sponsor of one or more OTC monograph drugs to manufacture or process such drugs; and

(iii) does not include a business or other entity whose only manufacturing or processing activities are one or more of the following: production of clinical research supplies, or testing.

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

(i) closely related to the same business enterprise;

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

(iii) under a single FDA 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 criteria specified in subparagraph (A), 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.

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

(12) The term "person" includes an affiliate of a person.

(13) The terms "requestor" and "sponsor" have the meanings given such terms in section 505G.

SEC. 744O. AUTHORITY TO ASSESS AND USE OTC MONOGRAPH 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.—Each person that owns a facility identified as an OTC 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) EXCEPTIONS.—

(i) A fee shall not be assessed under subparagraph (A) if the identified OTC monograph drug facility has ceased all activities related to OTC monograph drugs prior to the date specified in subparagraph (D)(ii) and has updated its registration to reflect such change under the requirements for drug establishment registration set forth in section 510.

(ii) The amount of the fee for a contract manufacturing organization facility shall be equal to ⅔ the amount of the fee for an OTC monograph drug facility that is not a contract manufacturing organization facility.

(C) AMOUNT.—The amount of fees established under subparagraph (A) shall be established under subsection (c).

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

(2) OTC MONOGRAPH ORDER REQUEST FEE.—

(A) IN GENERAL.—Each person that submits an OTC monograph order request shall be subject to a fee for an OTC monograph order request. The amount of such fee shall be—

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

(ii) for a Tier 2 OTC monograph order request, $100,000 adjusted for inflation for the fiscal year (as determined under subsection (c)(1)(B)).

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

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

(D) REFUND OF FEE IF ORDER REQUEST IS RECATEGORIZED AS A TIER 2 OTC MONOGRAPH ORDER REQUEST.—If the Secretary determines that an OTC monograph request initially characterized as Tier 1 shall be re-characterized as a Tier 2 OTC monograph order request, and the requestor has paid a Tier 1 fee in accordance with subparagraph (A)(i), the Secretary shall refund the requestor the difference between the Tier 1 and Tier 2 fees determined under subparagraphs (A)(i) and (A)(ii), respectively.

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

(F) FEES FOR ORDER REQUESTS PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—An OTC mono-

graph 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 subparagraph shall not be reviewable.

(3) REFUNDS.—

(A) IN GENERAL.—Other than refunds provided in subparagraphs (D) through (G) of paragraph (2), the Secretary shall not refund any fee paid under paragraph (1) 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 paragraph (1) or (2), a person shall submit to the Secretary a written request justifying such return within 180 calendar days after such fee was paid.

(4) NOTICE.—Within the timeframe specified in subsection (c), the Secretary shall publish in the Federal Register the amount of the fees under paragraph (1) for such fiscal year.

(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 inflation 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 (C).

(B) OTC MONOGRAPH ORDER REQUEST FEES.—For purposes of subsection (a)(2), the dollar amount of the inflation adjustment to the fee for OTC monograph order requests for fiscal year 2020 and each subsequent fiscal year shall be equal to the product of—

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

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

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

(i) for each of fiscal years 2020 and 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 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 OTC monograph drug activities 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 bene-

fits costs to total costs of OTC monograph drug activities for the first 3 years of the preceding 4 fiscal years.

(2) OPERATING RESERVE ADJUSTMENT.—

(A) IN GENERAL.—For fiscal year 2019 and subsequent fiscal years, for purposes of subsections (b)(1)(B) and (b)(2)(C), the Secretary may, in addition to adjustments under paragraph (1), further increase the fee revenue and fees if such an adjustment is necessary to provide operating reserves of carryover user fees for OTC monograph drug activities for not more than the number of weeks specified in subparagraph (B).

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

(i) 3 weeks for fiscal year 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) DECREASE.—If the Secretary has carryover balances for such process in excess of 10 weeks of the operating reserves referred to in subparagraph (A), the Secretary shall decrease the fee revenue and fees referred to in such subparagraph to provide for not more than 10 weeks of such operating reserves.

(D) RATIONALE FOR ADJUSTMENT.—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 (4) 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 and fees for purposes of subsection (b)(2)(D) 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 OTC monograph drug facility fees for fiscal year 2019 under subsection (a), based on the revenue amount for such year under subsection (b) and the adjustments provided under this subsection; and

(ii) publish fee revenue, facility fees, and OTC monograph order requests 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) OTC monograph drug facility fees under subsection (a)(1);

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

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

(d) IDENTIFICATION OF FACILITIES.—Each person that owns an OTC 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 an OTC monograph drug facility.

(e) EFFECT OF FAILURE TO PAY FEES.—

(1) OTC MONOGRAPH DRUG FACILITY FEE.—

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

(i) The Secretary shall place the facility on a publicly available arrears list.

(ii) All OTC monograph drugs manufactured in such a facility or containing an ingredient manufactured in such a facility shall be deemed misbranded under section 502(a).

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

(2) ORDER REQUESTS.—An OTC monograph 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 under this section have been paid.

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

(f) 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 OTC 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 OTC 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 collected under this section) no less than $12,000,000, multiplied by the adjustment factor applicable to the fiscal year involved under subsection (c)(1).

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

(D) PROVISION FOR EARLY PAYMENTS IN SUBSEQUENT YEARS.—Payment of fees authorized under this section for a fiscal year (after fiscal year 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.

(g) 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, United States Code.

(h) 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 OTC monograph drug activities, be reduced to offset the number of officers, employees, and advisory committees so engaged.

SEC. 744P. 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 Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(b) of the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2018 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 Energy and Commerce of the House of

Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate 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 the Congress with respect to the goals described in subsection (a), and plans for meeting the goals, for OTC 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 Energy and Commerce of the House of Representatives;

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

(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 the 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.

* * * * * * *

ADDITIONAL VIEWS

In addition to the creation of a user fee program for over-the-counter (OTC) drugs, H.R. 5333 would transition the regulatory process for OTC drugs from one that establishes the safety and effectiveness of active ingredients through the finalization of a monograph under rule-making to administrative order. This streamlined process would also create a new pathway that would allow OTC drug manufacturers to pursue innovative changes to OTC drugs. This pathway would allow manufacturers to initiate a request for the Food and Drug Administration (FDA) to review a change in an active ingredient to a monograph, or to establish a drug not currently in a monograph. If FDA finds the drug or change in the monograph to be generally recognized as safe and effective (GRASE), the manufacturer would be rewarded with an exclusivity period of 18 months.

While I am supportive of the creation of the OTC user fee program, as well as streamlining the safety and effectiveness determination of OTC active ingredients from a rule-making process to administrative order process, I have concerns about the inclusion of an exclusivity reward for OTC drug manufacturers. As we heard from Dr. Janet Woodcock, Director of FDA's Center for Drug Evaluation and Research (CDER), FDA has not been able to finalize many monographs to accommodate product innovation or marketing changes and as a result there has not been much innovation in the OTC market. More specifically, the current rule-making process is not flexible or nimble enough to accommodate advances in science or innovation and has resulted in many manufacturers shelving innovative ideas given the inability to bring them to market under the current monograph process. H.R. 5333 works to address this issue by creating a new pathway where manufacturers can initiate changes to a monograph through the streamlined administrative order process. This is an opportunity for innovation that does not exist today. It is my hope and belief that this new pathway will create an incentive for manufacturers to innovate that does not exist today by providing a timely and workable process for making changes to an OTC monograph.

However, before implementing this new innovation pathway, and before even understanding whether this new innovation pathway is working to encourage innovation as Congress intends, H.R. 5333 would also create an exclusivity reward to provide OTC drug manufacturers with 18 months of exclusivity for innovations found to be GRASE under this new pathway. Such a step is not consistent with the creation of other user fee programs. Congress has not generally contemplated the creation of an exclusivity reward until it has been demonstrated that the current regulatory landscape and marketplace are not incentivizing needed innovation. For example, this was the case when Congress extended six months of exclu-

sivity to manufacturers that conduct pediatric studies, and more recently when Congress extended six months of exclusivity to generic manufacturers that develop a competitor to current sole source drug products. H.R. 5333 would abandon this precedent and would award 18 months of exclusivity before any evidence is presented that the industry-initiated innovation pathway has not been sufficient in incentivizing innovation in the OTC drug market.

Supporters of this exclusivity award have made many arguments as to why an exclusivity award may be necessary, such as claims that negotiations with retailers may be lengthy or that private label competition may begin right after an innovative product is launched. However, there has been no evidence that these arguments are justified, and further, there has not been a compelling policy argument presented as to why the new innovation pathway created under H.R. 5333 is not sufficient on its own to incentivize innovation.

This Committee should take seriously the award of exclusivity in any context, and examine closely any policy proposal that holds the potential to keep affordable medications off the market for an extended period of time. While I have supported incentives in the past to encourage certain development and innovation, it has been after a compelling case has been made that the current marketplace and regulatory pathways were not working sufficiently. In considering such proposals, I have also always wanted to ensure that the incentives would not burden or impede access to the medications patients rely on. I do not believe that the current inclusion of an 18-month exclusivity award in H.R. 5333 meets this careful balance.

FRANK PALLONE, Jr.,
Ranking Member.

○