**Calendar No. 518**

115TH CONGRESS
2D SESSION

# H. R. 5333

IN THE SENATE OF THE UNITED STATES

JULY 17, 2018
Received; read twice and placed on the calendar

# AN ACT

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

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

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''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 rule-

making 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 sec-

tion 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 ap-

propriate 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 pro-

posed 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 Sec-

retary 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 testi-

mony 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 ad-

ministrative 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 re-

spect 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 re-

quest 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 suffi-

cient 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 non-prescription 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 5 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 3-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 con-

fidential 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 1 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 re-

questor 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 con-

cerning 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 million for fiscal year 2020.

"(ii) $6 million for fiscal year 2021.

''(iii) $7 million for fiscal year 2022.

''(iv) $3 million 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 million; 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 equiv-

alent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of 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 million for fiscal year 2019;

"(B) $7 million for fiscal year 2020;

"(C) $4 million for fiscal year 2021;

"(D) $3 million for fiscal year 2022; and

"(E) $3 million 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 million, 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 para-

graph, and any changes made to the recommendations in response to such views and comments.''.

Passed the House of Representatives July 16, 2018.

Attest: KAREN L. HAAS,

*Clerk.*

**Calendar No. 518**

115TH CONGRESS
2D SESSION

# H. R. 5333

# AN ACT

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.

JULY 17, 2018

Received; read twice and placed on the calendar