

Description of S. 2740 - OTC Monograph Safety, Innovation, and Reform Act of 2019
As introduced October 30, 2019, favorably reported by the Senate HELP Committee October 31,
2019, and passed by the Senate 91-2, December 10, 2019

Section 1. Short title; table of contents.

Title I – OTC Drug Review

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

(a) In general. The federal Food, Drug, and Cosmetic Act is amended to insert a new section 505G:

(a) Monograph drugs. Drugs will be generally recognized as safe and effective (GRAS/E), not new drugs and exempt from new drug application (NDA) requirements, and nonprescription if they: - conform with a Final Monograph; - were proposed as GRAS/E and conform with a Tentative Final Monograph (TFM); - unless they fall under an administrative order regarding data needs for dosage form changes, are in a dosage form that has been used to a material time and extent; - comply with a future final administrative order from FDA; or - otherwise meet one of the preceding requirements and follow a minor change procedure.

Sunscreen drugs will be GRAS/E if they conform with a 1999 stayed Final Monograph, except that testing conditions governing labeling will be those contained in a separate, existing requirement.

Drugs may be lawfully marketed without a new drug application if they are classified as Category III and conform with a TFM or are Category I under an advance notice of proposed rulemaking and conform with the conditions of the proposal.

Category II ingredients (those proposed to not meet FDA's GRAS/E standard) currently in Tentative Final Monographs or their preambles, as well as ingredients not found GRAS/E in preambles to final monographs, will be deemed unapproved new drugs and misbranded 180 days after enactment of this section unless FDA determines it is in the interest of public health to extend the time available for marketing.

(b) Administrative orders. Changes to conditions for a monograph drug will be through an administrative order. FDA may initiate an administrative order process on its own or on a requestor's request.

In an FDA-initiated process, FDA will find a drug is not GRAS/E if evidence is inadequate to show the drug is GRAS/E within the meaning of existing law under section 201(p)(1).

FDA will propose an order, including the reasons for it. A notice of availability of the proposed order will appear in the Federal Register, with specifics on FDA's website.

After at least a 45 day comment period, FDA will provide a statement of reasons supporting the order when issuing a final administrative order. The order will not take effect until the time for requesting judicial review has expired.

For an order to determine that a drug is not GRAS/E, FDA will provide a comment period of 180 days (with a good cause exception for a shorter comment period). For such orders, FDA will provide general categories of data necessary to determine a drug is GRAS/E. Sponsors must submit data in an FDA-prescribed format.

If a requestor objects to an administrative order, within 45 days they must first pursue dispute resolution within FDA's Center for Drug Evaluation and Research (CDER). If there is still a dispute after that process, the requestor will have a right to an 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 appointed by the Commissioner, not be from 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 by experts, and cross-examine witnesses presented by other parties.

Judicial appeals will go to a U.S. District Court and must be filed within 60 days.

Expedited procedures. In instances of an imminent hazard to public health, the Secretary of Health and Human Services may issue an interim final administrative order, together with 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 label changes for new warnings and other information required for safe use of a drug where a label change is reasonably expected to mitigate a significant or unreasonable risk of a serious adverse event associated with the use of the drug.

FDA will issue a final order within 6 months after the comment period closes, and a sponsor may pursue dispute resolution and a hearing to be completed within 12 months of the final order. Judicial appeal may follow a final order.

Administrative orders initiated by a requestor. Requestor(s) may initiate an administrative order process to establish or change conditions for a drug to be found GRAS/E by filing a request in an FDA-defined format. FDA will make a determination if the request is sufficiently complete and formatted to permit a substantive review. After the filing determination, FDA will proceed under the ordinary administrative order process above. A requestor may file under protest with certain limitations.

Changes in requirements (other than a change necessary to ensure safety) for a drug supported by new human data studies essential to the approval of the change (including clinical trials of safety or effectiveness, actual use, pharmacokinetics, or bioavailability) or adding an active ingredient to a monograph will be effective only for the requestor(s) of the change for 18 months from the effective date of an order and beginning on the date the requestor may market the drug. If a

requestor does not market a drug with exclusivity within 1 year of issuance of an order, they must notify FDA, including the reason for not marketing.

A requestor filing to establish a drug not currently in a monograph is GRAS/E must include information sufficient for a threshold determination 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 comparable 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.

Packaging. FDA may include packaging requirements in an order other than an interim final order for a safety label change.

Treatment of final or tentative final monographs. Final or tentative final monographs for Category I drugs are deemed final administrative orders.

(c) Procedure for minor changes. 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 exposure to the active ingredient. FDA may demand access to a requestor's records to support a minor change. If FDA determines the information in such records is not sufficient, FDA will provide the requestor with 15 business days 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 will issue administrative orders and guidances by route of administration to provide requirements and standards for determining whether a change will affect safety or effectiveness. FDA will take into account relevant public standards and may take into account special needs of populations, including children, in developing these orders and guidances.

(d) Confidentiality. In a requestor-initiated administrative order process, FDA will keep a requestor's information confidential until publication of a proposed order. With an exception where necessary to establish standards under which a drug is GRAS/E, requestor-provided pharmaceutical quality information will remain confidential.

Information provided on demand 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.

(e) Updates to drug listing information. Updates for changes 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.

(f) No effect on approvals under Section 505. This section does not impact the new drug approval section of the law (including under abbreviated new drug applications). Determinations

that a drug is GRAS/E constitute findings of safety and effectiveness for purposes of section 505(b)(2) of the Food, Drug, and Cosmetic Act, so that applicants only need to file information needed to support the modification in a 505(b)(2) application.

(g) Public availability of administrative orders. 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 3 year period.

(h) Development advice to requestors or sponsors. FDA will establish procedures allowing requestors the opportunity for private meetings to obtain advice on studies and information necessary to support submissions.

(i) Participation of multiple sponsors. FDA will establish procedures where there are multiple sponsors or requestors on an administrative order.

(j) Electronic format. Submissions will be in electronic format.

(k) Effect on existing regulations governing nonprescription drugs. 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.

A number of operating regulations for the OTC Review Monograph system would be superseded or will need to be rescinded by FDA, and regulations on labeling or other Monograph conditions of use will move to FDA's administrative order system. FDA may make technical changes to regulations that remain in effect to ensure conformity with appropriate terminology and cross references.

(l) Guidance. FDA will issue guidance on meeting procedures and principles for sponsors or requestors, the format and content of data submissions, electronic formats, consolidated proceedings, and recommendations on how to comply with order requirements for data to be kept on file for minor product dosage form changes.

(m) Rule of construction. This section does not affect the current status of a nonprescription drug marketed without an NDA or ANDA or that is not subject to an administrative order. Nothing in this subsection limits the applicability of other provisions of the Food, Drug, and Cosmetic Act.

(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.

(o) Inapplicability of Paperwork Reduction Act. The Paperwork Reduction Act will not apply to information collections under this section.

(p) Inapplicability of Notice and Comment Rulemaking Requirements. Administrative orders are not subject to Administrative Procedure Act rulemaking requirements.

(q) Definitions. Definitions for 'nonprescription drug,' 'sponsor,' and 'requestor' are provided.

(b) GAO study. GAO will conduct a study on the overall impact of exclusivity under this provision within 4 years of enactment.

(c) Conforming amendment. Updates cross references in section 501(d)(1) of the Food, Drug, and Cosmetic Act.

Section 102. Misbranding.

Monograph drugs not in compliance are misbranded.

Monograph drugs marketed from a non-fee-paying facility are misbranded.

Section 103. Drugs excluded from the Over-the-Counter drug review.

These sections do not apply to nonprescription drugs FDA intentionally excluded from the OTC Drug Review.

Section 104. Treatment of Sunscreen Innovation Act.

(a) Review of sunscreen active ingredients. Proposed sunscreen orders under the Sunscreen Innovation Act may elect to remain under the Sunscreen Innovation Act or the sponsor 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.

(b) Sunscreen Innovation Act amendments. A final sunscreen order under SIA will be deemed a final order. Sponsors may request confidential meetings.

A final sunscreen order shall be exclusive to the requestor for 18 months beginning on the date the requestor may market the ingredient.

This subchapter will sunset at the end of fiscal year 2022.

(c) Finalization of sunscreen monograph. FDA shall amend and revise the May 1999 sunscreen monograph. A revised order shall be issued no later than 18 months after enactment of this Act and issued at least 1 year prior to the effective date of the revised order.

If a revised order does not include provisions related to SPFs and all known dosage forms, FDA must submit a report to the authorizing committees with a rationale and plans to address those provisions.

(d) Treatment of non-sunscreen time and extent applications. Any existing non-sunscreen time and extent order requests are extinguished, but a sponsor is not precluded from filing an order request through the monograph reform provisions.

Section 105. Update to Congress on Appropriate Pediatric Indication for Certain OTC Cough and Cold Drugs

Annually, FDA must submit a letter to the committees of jurisdiction describing progress in evaluating cough/cold monograph drugs for children under 6 until FDA submits a letter indicating FDA has completed its evaluation and revised, as applicable, the cough/cold monograph.

Section 106. Technical corrections

Corrects cross-references and references to level of organizational unit.

Title II – Fees Relating to Monograph Drugs

Section 201. Short title; findings.

This title may be cited as the Over-the-Counter Monograph User Fee Act of 2019. Congress finds fees will be dedicated toward the nonprescription monograph drug activities under goals identified in letters from FDA to the authorizing committees.

Section 202. Authority to Access and Use Fees.

Sec. 744L. Definitions. Among the definitions: “OTC monograph drug activities” means activities on which program funds (user fees as well as appropriated funds) can be spent, including reviewing monographs and sponsor-initiated monograph order requests; inspections arising out of increased monograph work; safety activities; and other activities needed to implement the monograph reform policy provisions.

“OTC monograph drug facility” means a foreign or domestic entity engaged in manufacturing or processing an OTC monograph drug in finished dosage form. Separate buildings in one geographic location under the supervision of the same local management count as a single facility. Research suppliers, testing facilities, or an entity solely placing outer packaging on packages containing multiple products when the products within are already in final packaged form are exempt.

“Contract manufacturing organization” means a facility where neither the owner nor any affiliate sells the OTC monograph drug produced at the facility directly to wholesalers, retailers, or consumers in the U.S.

“Tier 1 OTC monograph order request” means an order request not determined to be a Tier 2 request.

“Tier 2 OTC monograph order request” means a request for reordering existing information in the Drug Facts label of an OTC monograph drug; addition of information to the other information section of Drug Facts; modification to the directions section of the Drug Facts label consistent with otherwise approved changes; standardization of a concentration or dose; nomenclature change; or addition of an interchangeable term.

Sec. 744M. Authority to assess and use nonprescription monograph drug fees.

(a) Types of 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 by December 30 of the year immediately preceding the applicable fiscal year (ie, December 30, 2019 for FY2021) and updated its registration to reflect such changes. Facility fees are due the later of the first business day of June or 45 days after FDA publishes a notice on the fee amount (or, in years after FY2021, the first business day after enactment of appropriations authority). Fees are due ahead of the upcoming fiscal year.

Order request fees. 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.

(b) Fee revenue amounts. Before inflation adjustments or operating reserve adjustments, target fee collections from facility fees would be \$22 million for FY2019, \$22 million for FY2020, \$25 million for FY2021, \$31 million for FY2022, and \$34 million for FY2023.

(c) Adjustments; annual fee setting.

Inflation adjustment. An inflation adjustment tied to CPI and related factors is included for FY2022-2025.

Operating reserve. Carryover of unspent funds or for to cover excess work may be held in a operating reserve with a maximum carry-over: 3 weeks' worth of fees in FY2021, 7 weeks in FY2022, and 10 weeks in FY2023-25. Amounts over the maximum would result in fee reductions the following year.

Fee setting. For FY2021, by March 9, 2020, FDA shall establish facility fees. For subsequent years, FDA will set and publish the facility fee for the upcoming fiscal year by the second Monday in March. (See 744M(a) for due dates.)

(d) Identification of facilities. Manufacturers must submit facility information each year through drug establishment registration under existing FDCA Sec. 510.

(e) Effect of failure to pay fees. Failure to pay facility fees within 20 days of the due date will result in placement on a public arrears list, and all OTC monograph drugs manufactured in such facility will be deemed misbranded. OTC monograph order requests submitted by a requestor not paying fees will be considered incomplete, and parties failing to pay are ineligible for closed meetings.

(f) Crediting and availability of fees. Fees may be collected and available only to the extent provided in appropriations Acts and available solely for OTC monograph drug activities. Before FDA may spend fee revenue, FDA must allocate \$12 million/year (inflation adjusted).

Fees paid prior to the due date may be accepted.

(g) Collection of unpaid fees. Fees not received by FDA after a grace period will be treated as a U.S. Government claim.

(h) Construction. FTEs not engaged in monograph activities may not be construed to require an offset from FTEs in monograph activities.

Sec. 744N. Reauthorization; reporting requirements.

(a) Performance report. By 120 days of the end of fiscal year 2021 and each subsequent fiscal year, FDA must submit to the authorizing committees and post a report on progress against the goals identified in the goals letter and future plans for meeting such goals.

(b) Fiscal report. By 120 days of the end of fiscal year 2021 and each subsequent fiscal year, FDA must submit to authorizing committees and post a report on implementation of their fee authority, fee uses, and collections.

(c) Public availability. Performance and fiscal reports will be posted on FDA's website.

(d) Reauthorization. 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 FY2025. FDA must post a recommendations report and take comments. FDA's final recommendations will be sent to Congress no later than January 15, 2025.