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November 20, 2024

Over-The-Counter Monograph Drug User Fee Program (OMUFA) Reauthorization

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act, P.L. 116-136) was signed into law. The CARES Act added Section 505G to the Federal Food, Drug, and Cosmetic Act (FFDCA), which reformed the regulation of over-the-counter (OTC) monograph drugs and authorized the Food and Drug Administration (FDA) to assess and collect user fees dedicated to OTC monograph drug activities.

The OTC Monograph Drug User Fee Program (OMUFA) is modeled after other FDA human medical product user fee programs, such as the Prescription Drug User Fee Act (PDUFA). Under OMUFA, fees paid by the regulated industry help support FDA's regulatory activities related to OTC monograph drugs. FDA, in turn, agrees to adhere to performance goals negotiated by FDA and industry representatives, including specific time frames for conducting certain activities. The current legislative authority for OMUFA expires on September 30, 2025.

This product provides a general overview of FDA human medical product user fee programs, describes OMUFA and its reauthorization specifically, and provides considerations for Congress as it contemplates the upcoming reauthorization of the program.

FDA Human Medical Product User Fee Programs

To fund its regulatory activities, FDA relies on discretionary appropriations from two sources: (1) appropriations from the General Fund of the Treasury and (2) user fees paid by the regulated industry. Many user fee programs administered by FDA are permanently authorized, meaning they do not require reauthorization. Certain user fee programs, however, require reauthorization to continue. These programs include those that help fund regulatory activities like prescription brand and generic drugs, medical devices, biosimilars, and others. The authorizing legislation generally sets a total amount of fee revenue for the first year of the program, to be adjusted annually; specifies the fee types that FDA may collect; specifies that fees may be used only for specified activities (which are typically focused on premarket review and associated activities); specifies certain fee waivers; and requires that certain legal conditions be satisfied in order for FDA to collect and spend user fees.

An element shared by some FDA user fee programs is that user fees are to supplement congressional appropriations, not replace them. The authorizing laws include limiting conditions, known as "triggers," to enforce this goal. FDA may collect and use fees only if the appropriations for specified activities involved in the review of products remains at a level at least equal (adjusted for inflation) to an amount or benchmark specified in each law. In exchange for paying user fees, industry receives from FDA a commitment to meet certain performance goals, such as hiring a certain number of staff to support review activities by a specified fiscal year. Prior to each reauthorization cycle, FDA and industry representatives negotiate the performance goals, which are finalized in a written agreement, which is called a "commitment" or "goals" letter. The reauthorization process allows for input from relevant stakeholders, including academic experts and representatives of patient and consumer advocacy groups, and provides opportunity for public comment on the agreement.

FDA Regulation of OTC Drugs and OMUFA

Under the FFDCA, FDA regulates the safety and effectiveness of nonprescription (OTC) drugs sold in the United States. OTC drugs may be used without a prescription from a health care provider, provided that the drugs have an acceptable safety margin, low potential for misuse or abuse, and are adequately labeled so that consumers can self-diagnose their condition, self-select the appropriate medication, and self-manage their condition.

CARES Act Modernization of OTC Drug Regulation

To market an OTC drug, a company may follow one of two pathways. A company can either (1) submit a new drug application (NDA) to FDA for approval or (2) use the OTC drug monograph process (although not all drugs are eligible for this pathway).

Most OTC drug products are marketed by complying with an OTC monograph. A monograph functions similar to a recipe, in that it covers active ingredients, dosages, formulations, and labeling claims and sets the conditions under which OTC drug products are generally recognized as safe and effective (GRASE) for their intended use. If an OTC drug product complies with the relevant monograph, it does not need FDA approval through an NDA prior to marketing.

Prior to the enactment of the CARES Act, FDA published final monographs as regulations through a multistep public rule-making process. FDA reported several challenges with this process and, more broadly, FDA's OTC review process, such as monograph rulemaking taking too much time and limiting FDA's ability to definitely and quickly address OTC drug safety issues, and resource challenges that constrained FDA's ability to support OTC monograph review work.

FFDCA Section 505(G)(b) as added by the CARES Act replaced this rulemaking process and created a new process for issuing monographs through administrative orders. This process allows FDA, on its own initiative or upon request by any person that either markets, manufactures, processes, or develops drugs ("requestors"), to issue an administrative order determining whether there are conditions under which a drug, class, or combination of drugs is generally recognized as GRASE. The CARES Act incentivized requestors to request changes to OTC drug monographs by providing an 18-month period of marketing exclusivity if FDA makes certain requested changes. FDA publishes proposed and final administrative orders on its website. As of November 1, 2024, 33 final and two proposed orders (including a proposed order for OTC sunscreen products) are available on this website.

CARES Act Creation of a New User Fee Program

The CARES Act created a new OTC monograph User Fee Program (OMUFA). Specifically, CARES added Section 744L ("Definitions"), Section 744M ("Authority to Assess and Use OTC Monograph Fees"), and Section 744N ("Reauthorization; Reporting Requirements") to the FFDCA. FFDCA Section 744M establishes a legal framework for FDA, beginning with FY2021, to assess and collect facility fees and OTC monograph order request (OMOR) fees to support FDA's OTC monograph drug activities. With respect to facility fees, FDA annually assesses a full facility fee to each person who owns an OTC monograph drug facility (MDF), and a reduced facility fee (i.e., two-thirds of the MDF fee) to each person who owns a facility identified as a contract manufacturing organization (CMO). For FY2024, the OMUFA target facility fee revenue was $32,253,000, with each MDF facility paying $34,166 and each CMO facility paying $22,777. In addition to the facility fees, under OMUFA, FDA also assesses a fee to each person upon submission of an OMOR. For FY2024, a Tier 1 OMOR was $537,471, and a Tier 2 OMOR was $107,494.

Fees may be collected and spent only to the extent and in the amount provided in advance in appropriations acts, may remain available until expended, and may be transferred as specified for monograph drug activities only. Because this user fee program is authorized through FY2025, its reauthorization schedule diverges from the reauthorization of other medical product user fee programs (e.g., PDUFA), which are currently authorized through FY2027.

FFDCA Section 744N requires the HHS Secretary, through FDA, to submit annual performance and financial reports on OMUFA fee collection and spending to Congress. The performance and financial reports must be made publicly available on FDA's website.

In exchange for FDA collection of OMUFA fees, FDA has agreed to meet certain performance goals (e.g., issuing guidance documents, reviewing OMORs in a specified period of time, hiring of personnel by a specific time).

Reauthorization of OMUFA

The current legislative authority for OMUFA expires September 30, 2025. FFDCA Section 744N also specifies the process for reauthorizing OMUFA, requiring the HHS Secretary to consult with stakeholders on recommendations for future monograph activities and to transmit the final recommendations to Congress no later than January 15, 2025.

Prior to initiating negotiations with industry stakeholders, the HHS Secretary must consult with Congress, scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry to develop recommendations for performance goals. As a part of this consultative process, FDA held a public meeting with various representatives from various industry and consumer stakeholder groups on September 28, 2023.

After negotiations with the industry stakeholders have been concluded, the HHS Secretary is to publish a draft recommendation for public review. The HHS Secretary must present this draft to select congressional committees, publish recommendations in the *Federal Register* with a 30-day public comment period, hold a public meeting, and revise the draft recommendations as necessary. Lastly, the HHS Secretary must transmit the final recommendations to Congress by January 15, 2025.

Considerations for Congress

As the first iteration of OMUFA approaches reauthorization, various industry, public health, and consumer stakeholders have provided assessments of the program's performance. For example, one industry stakeholder group has identified as priorities for reauthorization measures that will affirm industry confidence in FDA approval of OTC products (e.g., by confirming standards used to make GRASE determinations) and bolster efficiencies in how FDA administers its OTC drug program (e.g., by encouraging FDA to initiate administrative orders updating a drug monograph). Some industry stakeholders have also called for a reduction in user fee values or the implementation of a user fee waiver for certain industry stakeholders.

Meanwhile, public health and consumer representative stakeholders have called for attention to particular issues, such as the revision and modernization of OTC drug monographs for children's cough and cold medicines, during OMUFA's reauthorization. Further calls have been made for increased transparency about FDA/industry negotiations and OMUFA performance goals.

FDA OMUFA priorities will become clearer as FDA moves toward finalizing and making available the draft OMUFA II performance goals for FY2026 to FY2030.

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