TESTIMONY

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"LEGISLATIVE PROPOSALS TO MAINTAIN AND IMPROVE THE PUBLIC HEALTH WORKFORCE, RURAL HEALTH, AND OVER-THE-COUNTER MEDICINES"

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Introduction

Chairman Griffith, Ranking Member DeGette, and Members of the subcommittee, thank you for the opportunity to testify today on the reauthorization of the Over-the-Counter Monograph Drug User Fee Program, commonly referred to as OMUFA.

Over-the-Counter (OTC) drugs have long provided an effective, low-cost way for Americans to take care of everyday health needs without having to visit a doctor and obtain a prescription, saving American consumers time, effort, and money. Nonprescription drugs, including those for allergies, pain, fever, and various other ailments are widely available through online and retail outlets, providing safe and effective healthcare options to American consumers nationwide. One powerful example of the impact of nonprescription drugs are the approvals of naloxone nasal spray, which is used to reverse opioid overdoses. Availability of this medication without a prescription allows this life-saving medication to be sold directly to American consumers in drug stores, convenience stores, grocery stores, gas stations, and online. Although regulated under an approved application rather than the OTC monograph system, this example demonstrates how critical nonprescription products can be to individuals' lives and public health.

The work of this Committee, leading to enactment of OTC monograph reform and OMUFA in 2020 laid critical groundwork, establishing a long overdue, transformational framework for modernizing the regulation of many over-the-counter drugs. Now, with congressional support and timely reauthorization of OMUFA, we have the opportunity to realize the full potential of the OTC monograph reform program – ensuring a more nimble regulatory process, fostering innovation to better serve patients and consumers, and enhancing transparency and accountability from FDA and industry.

History of Regulating OTC Drugs

More than 100,000 OTC drug products are marketed in the United States under what is known as the OTC monograph system. A monograph is essentially a rule book or a recipe book that establishes conditions under which an OTC drug in a given therapeutic category (e.g., antacids, pain or cold medicines) is generally recognized as safe and effective (GRASE) for its intended use. Monograph conditions may include acceptable ingredients, doses, formulations, labeling,

and testing. Products that meet the conditions outlined in a monograph[1] may be marketed without FDA premarket approval, in contrast to other drugs that must be approved before being marketed.

The OTC monograph process was established over 50 years ago and was largely envisioned as a "once and done" system. The science supporting these products was already considered established and innovation in this space was believed to be unlikely, which we now know is not true. The system utilized a three-phase multistep public rulemaking process to establish or change OTC monographs, significantly limiting the pace of innovation in these critical products. In particular, the time required for these process steps resulted in delays in finalizing monographs, challenges in responding quickly to urgent safety issues, and difficulty keeping pace with evolving science and a changing market.

Monograph Reform & User Fees

In March 2020, the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law No. 116-136, added section 505G to the Federal Food, Drug, and Cosmetic (FD&C) Act. Section 505G reformed and modernized the framework for the regulation of OTC monograph drugs. These reforms, supported by OMUFA user fees, replaced rulemaking for monograph purposes with a more streamlined, efficient process – using Administrative Orders – that can be initiated by either FDA or industry (i.e., any person or group of persons marketing, manufacturing, processing, or developing a drug) to add, remove, or change a monograph. Under section 505G, industry can request that FDA issue an administrative order by submitting an OTC monograph order request (OMOR) to FDA. Section 505G also authorized establishment of new procedures under which FDA may meet with sponsor(s) or requestor(s) in advance of submission, and FDA has issued guidance regarding the process for those meetings. If FDA accepts the OMOR for filing, FDA will the review the OMOR and develop and issue a proposed order. FDA can also initiate the process by developing and issuing a proposed order; in both instances, there is an

[1] Products must meet the conditions outlined in a monograph, as established under section 505G of the FD&C Act, as well as other applicable requirements. Examples of other applicable requirements for OTC drugs include, but are not limited to, format and content requirements for OTC drug product labeling under 21 CFR 201.66, and conditions under 21 CFR 330.1, such as being manufactured in compliance with Current Good Manufacturing Practice (CGMP) regulations under 21 CFR 210 and 211, and using only safe and suitable inactive ingredients.

opportunity for public review and comment before a final order. FDA can also initiate an expedited process for developing and issuing an administrative order when a drug poses an imminent hazard to public health or a change in the labeling of a drug is expected to mitigate a significant risk of a serious adverse event associated with use of the drug.

Notably, the CARES Act also facilitated these reforms by amending the FD&C Act to authorize FDA to assess and collect user fees from industry to support the Agency's OTC monograph drug activities. These activities involve evaluating OMORs, including reviewing safety and efficacy information for proposed new monograph active ingredients as part of GRASE determinations, developing and issuing proposed and final orders, conducting inspections of OTC monograph drug facilities, and monitoring OTC monograph drug safety, among other regulatory functions. This user fee program, commonly referred to OMUFA, also supports modernizing IT systems, and recruiting and training skilled staff. Typically, accompanying authorization of such user fee programs is an agreement negotiated between FDA and industry, often referred to as a "goals document" or "commitment letter", in which FDA agrees to adhere to performance goals in terms of conducting fee-supported activities, including specific time frames to review and respond to certain industry submissions. FDA reports on its accomplishment of these goals annually in publicly available reports, which increases transparency and accountability for review work.

By improving the efficiency of FDA's OTC regulatory process, consumers will have increased access to innovative, effective and safe OTC drug products.

OMUFA I

Background

Under the OMUFA program, industry-paid fees help support FDA's regulatory activities related to OTC monograph drugs. However, in order for FDA to annually collect and spend authorized OMUFA user fees, the fees must be appropriated, and FDA must allocate for OTC monograph drug activities a minimum of $12 million of appropriations (excluding user fees) multiplied by an adjustment factor. During each of the fiscal years under OMUFA I to date, FDA met both legal conditions.

Under OMUFA, FDA collects two types of fees: facility fees and OMOR fees. FDA calculates both fees in accordance with our statutory authority. OMOR fee rates for FY 2021 were specified in statute, and are adjusted for inflation each year. Tier 1 OMORs represent significant changes to a monograph (e.g., new ingredients, indications, or therapeutic categories), while Tier 2 OMORs represent more minor changes to the monograph. Additionally, the statute mandates a process FDA follows to calculate the target total revenue from facility fees each year. FDA establishes facility fee rates with the goal of generating that target total facility fee revenue amount. Facility fees are assessed on qualifying persons who own an OTC monograph drug facility, including contract manufacturing organization facilities which pay a reduced fee. Over the course of OMUFA I, the target revenue for facility fees ramped up from $23.3 million in FY 2021 to $36.5 million in FY 2025. The total target revenue for OMUFA I was $141.3 million over five years.

Building Infrastructure

Overall, FDA has been successful in implementing OTC monograph reform and meeting the goals set out in the first OMUFA user fee goals document, i.e., under OMUFA I. Notably, the CARES Act amendments established a new statutory framework for regulating OTC monograph drugs, under section 505G of the FD&C Act, and *concurrently* established authority in the FD&C Act for the OMUFA user fee program. Simultaneous enactment of both these programs created additional steps for implementation. In contrast, the statutory framework for new drug applications had been in place for decades before authority for the prescription drug user fee program was enacted and implemented. Therefore, during this first five years of the OMUFA user fee program, FDA has been focused on building an entirely new OTC monograph drug regulatory program from the ground up, which meant hiring and training staff, developing new procedures, and creating a system that could efficiently handle the review of OMORs and issuance of proposed and final monograph orders. OMUFA I supported hiring of 105 full-time equivalents, spread over the five year period, to supplement the 35 that were estimated to be working on monograph issues when the program was negotiated. At the end of FY24, FDA had filled 85 of the 105 positions; however, three program staff have voluntarily left the FDA. Nine of the outstanding positions were agreed to be added during FY25.

During the first three years following passage of the CARES Act, the majority of FDA's effective capacity with respect to OTC monograph drug activities was focused on developing the system to implement the statutory mandates for OTC monograph reform and OMUFA, including associated infrastructure development activities. In particular, significant resources were dedicated to the development of the first IT system to manage OTC monographs and the reformed OTC monograph process, allowing for more transparency and public access to OTC monographs and related administrative orders.

By Year 3, FDA's OTC monograph-related resources grew to the point where some OMUFA performance goals began for meetings with industry as agreed to in the OMUFA I goals document. In Years 4 and 5, FDA has been implementing the agreed upon timelines and progressive performance goals for reviewing OMOR submissions, meeting management, guidance development, and other activities.

Specifically, FDA issued five draft and one final guidance related to OTC monograph drugs, including in fulfillment of statutory requirements. These guidances serve as "how to" guides for navigating the new system established by Congress, and were written while the system was being operationalized. FDA has been working diligently to finalize the remaining draft guidances in a timely manner. In accordance with the OMUFA I goals document, FDA has also posted an annual monograph forecast outlining FDA's intended monograph activities over the next three years. This level of planning helps provide predictability for industry while fostering FDA accountability for progress. All of these activities laid the groundwork for realizing the full benefit of OTC monograph reform in the coming years.

Taking Action

In addition to building the extensive infrastructure needed to implement monograph reform, in years 4 and 5, FDA has begun to meaningfully use the modernized OTC regulatory process supported by OMUFA I. As required by statute, FDA has posted 33 final administrative orders that were deemed established by section 505G upon its enactment under the CARES Act.

Additionally, in June 2024, FDA issued a proposed order (the first discretionary proposed order initiated by the Agency) to address a safety issue related to OTC monograph drug products containing acetaminophen. If finalized, this proposed order would require drug companies to add a warning to the labeling of these products to alert American consumers that the use of acetaminophen may cause severe skin reactions. Although FDA alerted the public to this safety concern in 2013 via a drug safety communication, the complex rulemaking process applicable to OTC monograph drugs at that time limited the Agency's ability to rapidly modify the relevant monograph to require this warning to align labeling with nonprescription acetaminophen drug products with approved applications.

Also in 2024, FDA issued a proposed order to amend the relevant OTC monograph to remove oral phenylephrine as an active ingredient for temporary relief of nasal congestion because it is not effective for this use. This proposed order also re-assesses the risks and benefits of this cough/cold active ingredient in children under 6 years of age. Before making the decision to issue the proposed order, FDA held an advisory committee meeting to discuss the GRASE status of oral phenylephrine as a nasal decongestant. Based on review of the current data and a unanimous recommendation from the advisory committee, FDA published the proposed order to inform the public and garner comments. If, after considering comments on the proposed order, FDA concludes that oral phenylephrine is not effective as a nasal decongestant, FDA would issue a final order amending the applicable OTC monograph to remove this ingredient as an oral nasal decongestant.[2]

FDA also published a proposed order on sunscreens, proposing new monograph conditions under which nonprescription sunscreen drug products would be determined to be generally recognized as safe and effective (GRASE) under the FD&C Act. Notably, in September 2024, FDA received the first OMOR submitted by industry, requesting to add a new ingredient to the sunscreen monograph, potentially increasing choice for American consumers. FDA is actively reviewing that submission according to the timelines established in the user fee goals document, and has a current goal date of late February 2026.

[2] https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-results-recent-advisory-committee-meeting-oral-phenylephrine

Overall, these accomplishments during the first five years of the OMUFA program demonstrate that OMUFA I fee resources not only helped make the OTC monograph system more efficient, but supported the development of the infrastructure needed for continued success.

OMUFA II Reauthorization

Reauthorization of OMUFA is instrumental to build upon the successes of OMUFA I to create a transparent, modernized regulatory system for safe and effective OTC monograph drugs.

OMUFA resources are key to supporting the safety of the OTC drug products consumers use every day. For example, in 2023, there was a worldwide safety alert regarding over-the-counter medicines, primarily children's cold medicines, contaminated with diethylene glycol (DEG) and ethylene glycol, the main ingredient in antifreeze, resulting in more than 300 deaths in children in multiple countries. Because of quick work by FDA to issue guidance for testing, request for records from manufacturers, and issue import alerts for affected products, American consumers were spared this tragedy. FDA continues to conduct quality surveillance for this contaminant—with multiple import alerts issued so far this year for toothpaste products potentially contaminated with DEG. Although a disaster prevented often goes unnoticed, having a robust system for ensuring drug safety, efficacy, and quality is why American consumers can confidently choose OTC drugs in the United States. The resources and commitments related to improved quality surveillance and transparency included in the OMUFA II proposal are needed to help ensure this consumer confidence is both maintained and enhanced.

Similarly, without the resources from OMUFA, FDA will not have sufficient capacity to help ensure the safety and efficacy of OTC monograph products. If OMUFA were not reauthorized, some of the actions FDA has planned could take a decade or longer to implement. These are actions that impact our most vulnerable Americans – including pregnant women and children. For example, FDA will be working to address:

- pediatric weight-based dosing for acetaminophen,
- pregnancy labeling for non-steroidal anti-inflammatory drugs,
- risks associated for codeine-containing cough medicine in adults and children,

- the safety and efficacy of oral anesthetics containing benzocaine, including for infants,
- greater availability of child-friendly options of certain oral medications for children.

Process to Development OMUFA II Recommendations

Many stakeholders including consumer groups, medical societies, pharmacy associations, academics, and regulated industry recognize OMUFA's critical role in establishing and maintaining an efficient and transparent OTC monograph system. To ensure the OMUFA II reauthorization recommendations reflect shared priorities, FDA held two public meetings and gathered additional feedback via a public docket. In addition, we held 25 extensive negotiation sessions with industry stakeholders.[3]

Because OMUFA I was authorized from fiscal years 2021-2025, this was the first negotiation with industry to develop reauthorization recommendations, for fiscal years 2026-2030. Throughout the negotiation, FDA and industry remained aligned on the common goal of advancing public health while maintaining scientific standards and promoting innovation. Given the relative newness of the OTC monograph reform program, recommendations for OMUFA II focus on ensuring stable funding for the program, enhanced transparency of the OMOR process, and enhanced regulatory efficiency and predictability.

With Congress' support and a timely OMUFA reauthorization, we are excited to begin realizing the full potential of OMUFA – to meaningfully advance our efforts to help American families have access to safe and effective drugs regulated through the OTC monograph system, including by reviewing OMORs and developing and issuing proposed and final administrative orders, facilitating innovation and up-to-date safety information about these important products. The commitments FDA can achieve with timely reauthorization thematically fall into the following categories, discussed below:

- Funding Stability
- Monograph Drug Product Quality Enhancement
- Financial efficiency and transparency

[3] https://www.fda.gov/industry/fda-user-fee-programs/omufa-reauthorization-fiscal-years-2026-2030

- Information transparency
- Meetings with industry and notice of Advisory Committee meetings
- Education for industry
- Updating testing methods in monographs

The reauthorization proposals for OMUFA that are described below were submitted to Congress in January, under the previous Administration. The Trump Administration looks forward to working with Congress toward reauthorization of the important OMUFA program to build upon the successes of OMUFA I and facilitate a transparent, modernized regulatory system for safe and effective OTC monograph drugs.

Funding Stability

OMUFA II recommendations reflect the goal of ensuring stable funding for the program, including avoiding large fee increases. Under OMUFA, FDA sets annual facility fees to generate the total facility fee revenues for each fiscal year established by section 744M(b) of the FD&C Act. The yearly base revenue amount is the starting point for setting annual facility fee rates. The OMUFA II proposal resets the starting base revenue under the statute for OMUFA II to include the additional direct cost adjustment of $3 million from the final year of OMUFA I, which is approximately eight percent of the total revenue in fiscal year 2025. This adjustment helps ensure that the OTC monograph drug program is adequately resourced to meet increasing demands. The proposed base revenue for FY 2026 will be approximately $36.5 million, and the additional proposed funding will increase fee revenue by 12 percent over the course of the five-year authorization period, in addition to inflationary increases. Overall, total target revenue for OMUFA II is proposed to be an estimated $206.8 million, including estimated inflation. These increases will continue to support increased efficiency of the OTC program in FDA, creating value for the American consumer.

The OMUFA II reauthorization recommendations support an addition of 11 new full-time equivalents (FTEs), added over the first three years of the reauthorization period. These new hires will support the growing responsibilities and commitments associated with conducting FDA's OTC monograph drug activities, and will bring total OMUFA funded FTEs to 116. In

addition to personnel, the proposal supports a modest allocation for contract expenses tied to the proposed new OMUFA II commitments.

Monograph Drug Product Quality Enhancement

The OMUFA II recommendations include commitments to enhance monograph product quality surveillance and transparency. The commitment letter agreement includes a new commitment from FDA to more quickly vet new registrants to confirm whether they should be included in CDER's catalog of OTC monograph drugs and establishments. Today, when a new facility registers with FDA and lists the drugs that they make for the U.S. market, FDA commonly needs to correspond with the registrant to obtain further information to confirm, for example, that the registrant is making a drug and not a cosmetic, or that a foreign registrant is actively shipping to the U.S. The proposed OMUFA II funding will provide additional resources to enable FDA to more quickly gain accurate information from registrants about the drugs they are producing as well to request and review information about the registrant's compliance with applicable current good manufacturing practice (CGMP) requirements to inform FDA's risk-based manufacturing facility inspections.

Additionally, FDA agreed to hold a workshop aimed at helping industry stakeholders enhance quality and ensure compliance with CGMP requirements. FDA also committed to updating the risk-based inspection site selection model, which is used to prioritize surveillance inspections, and the associated Manual of Policies and Procedures (MAPP), to include risk factors specific to OTC monograph drugs. For example, given an initial observed association between failure to pay OMUFA fees and violative surveillance inspection outcomes, FDA will evaluate the failure to pay OMUFA fees as an important risk factor to be included. These commitments from both FDA and industry to enhance product quality will help ensure American consumers continue to have access to safe and effective OTC drugs.

Financial Efficiency and Transparency

The OMUFA II recommendations address industry concerns about financial transparency and management through several key initiatives. The proposed statutory amendments aim to enhance financial efficiency by aligning the annual OMUFA facility fee due date with the October 1 fiscal

year-start due date for annual fees under other drug user fee programs, helping streamline the assessment and collection process for both FDA and industry. This common-sense reform benefits both the Agency and industry (who may pay other annual drug user fees), enhancing efficiency and predictability.

Additionally, to improve unpaid fee recovery and transparency, OMUFA II commitments will increase visibility of facilities that have not paid fees, including breakdowns of foreign and domestic firms in arrears. This will promote accountability in the industry and help level the playing field for American manufacturers. FDA will also use information obtained from records requests to focus recovery efforts on outstanding OMUFA user fee delinquencies. Additionally, the proposed OMUFA II amendments to statutory fee setting introduce a new contingent adjustment to annual target revenue, allowing for a one-time upward adjustment if the number of fee-liable OMUFA facilities increases over a specified level. If necessary, this would help ensure that FDA can accommodate the additional work required to oversee a growing number of facilities, both foreign and domestic, without compromising quality or efficiency. These financial enhancements demonstrate FDA's commitment to responsible fiscal management while maintaining robust oversight.

Information Transparency

FDA commitments under OMUFA II would take significant strides in terms of information transparency, including through agreeing to post information on FDA's website about monograph-related exclusivity, updating and maintaining monograph-related website links, and ensuring website accessibility of historic monograph-related materials and regulatory information. These measures address industry demands for clear, more consistent information about the OTC monograph process, including FDA's review of OMORs and development and issuance of proposed and final orders addressing safe and effective conditions of use for OTC monograph drugs. In particular, the information regarding monograph-related exclusivity will ensure uniform access to such information for all OTC manufacturers and stakeholders. FDA will post a page on its website addressing monograph-related exclusivity afforded by final administrative orders, including a table of relevant monograph change(s), requestor(s), the final order date, and relevant listing updates for drugs subject to the final order.

FDA will also report annually on its website aggregate information about records requests issued to OTC monograph drug manufacturers under section 704(a)(4) of the FD&C Act. This reporting provides industry with more transparency regarding the information FDA is requesting related to compliance with CGMP requirements and how often the information provided leads to FDA action. Reporting will begin in FY2027 if the aggregate number of requests issued exceeds 20; otherwise, reporting will begin in FY2028. Similarly, FDA will enhance the Agency's warning letter webpage to improve its search capability for warning letters issued to OTC monograph drug manufacturers. Both of these actions will not only improve transparency, but also will contribute to efforts aimed at ensuring product quality and safety – key pillars of the OTC monograph reform program supported by OMUFA.

Meeting and Advisory Committee Refinement

OMUFA II commitments significantly enhance the utility of FDA-industry meetings, including by providing for advance notice of certain Advisory Committee meetings, which directly addresses industry's requests for more productive and transparent communication with FDA. OMUFA II commitments also include a new follow up opportunity which allows OMOR requestors to confirm or clarify with FDA something in meeting minutes or written response, similar to a PDUFA VII enhancement. It also includes the potential for extended meeting options for complex topics, allowing more meaningful engagement for sponsors. Similarly, OMUFA II will facilitate the ability of requestors to seek feedback on protocol synopses, improving both regulatory efficiency and predictability.

Regarding Advisory Committee meetings specifically, FDA has agreed to provide at least 100 business days' advance notice for a specific subset of OTC monograph-related Advisory Committee meetings. FDA recognizes that this advance notice can help provide stakeholders time to coordinate and prepare for meaningful Advisory Committee discussion. This commitment will not apply to situations where the Advisory Committee is planning to discuss an emerging safety issue or if existing policy on advanced notice for certain Advisory Committee meetings applies.

Education for Industry

The OMUFA II proposal also demonstrates FDA's commitment to transparency and predictability through ongoing education and outreach efforts for industry to facilitate innovation and safe and effective OTC monograph drug products for Americans. In addition to the CGMP webinar mentioned above, FDA has agreed to host a webinar on OMOR submission through the Next Gen Portal, as well as a crowdsourced session on OMOR submissions and GRASE determinations. Finally, FDA has committed to introducing draft guidance on filing eligibility for OMORs proposing new monograph active ingredients and another on the handling of confidential information submitted to the Agency in connection with proceedings on an OTC monograph order. Taken together, the recommendations for OMUFA II demonstrate a significant commitment to addressing the priorities of the public, the regulated industry, FDA, and public health.

Conclusion

OTC monograph reform, supported by OMUFA I, has been transformative for OTC drug regulation and has created a faster, more transparent, and more predictable system that benefits American consumers. Through additional resources provided under OMUFA I, FDA built the necessary infrastructure for implementing OTC monograph reform, hired and trained staff, launched a modern IT system to facilitate efficiency, and issued important guidance for industry. In just a few years, we met OMUFA performance goals, issued five key guidances, and provided a forward-looking monograph forecast. We also posted 33 final administrative orders defining baseline monograph conditions for various therapeutic categories of OTC drugs, as established upon enactment of section 505G of the FD&C Act, and issued two FDA-initiated proposed orders to update the monograph conditions for safety and efficacy of certain OTC drugs. These achievements would have been impossible under the previous regulatory framework.

This progress cannot continue without OMUFA reauthorization. OMUFA II resources are critical to maintaining efficiency, ensuring safety, and fostering innovation in the OTC market. Without it, we risk losing the gains we have made and returning to slower responses to safety and fewer innovative choices for American consumers. I look forward to working with you to authorize OMUFA II and secure the future of a modern, responsive OTC monograph system.