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

FDA and Industry Negotiations | Meeting Summary

March 26, 2024 | 9:45am-11:50am

Virtual Format

PARTICIPANTS

FDA	Office	Industry	Organization
Joshua Brown	OC	James Kim	ACI
Grace Carmouze-Cunningham	CDER	Katie Kramer	ACI (Hogan Lovells)
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Andrew Kish	CDER	Wendy McManus	CHPA (Sanofi)
Theresa Michele	CDER	David Spangler	CHPA
Karen Murry	CDER	Cornell Stamoran	PBOA
Phong Pham	CDER	Mary Schilling	PCPC
Paul Phillips	CDER		
Kimberly Taylor	CDER		

OMUFA II Reauthorization Overview

FDA provided an overview of the process and timelines for reauthorization once the commitment letter is ratified by both Industry and FDA. FDA explained the clearance process for the reauthorization package (i.e., commitment letter language, statutory language, and justification document for statutory changes), the process for public review of recommendations for reauthorization, and the process for Congressional review of the package.

OMUFA Facility Fee Adjuster Proposal

FDA presented its updated proposal for a facility fee adjuster that would use a three-year average of fee liable facilities (i.e., average for fiscal years (FYs) 2025, 2026, and 2027). If this average exceeds a threshold number of facilities, then a one-time adjustment would be made proportional to the number of facilities above the threshold. The number of facilities reflects the average fee liable facilities in the first three years of OMUFA I. FDA also addressed Industry's feedback and provided requested information regarding FDA's efforts with respect to hand sanitizer-only manufacturers (HSMs) during the coronavirus-19 (COVID-19) pandemic and requested FDA full-time equivalents

(FTE) data. FDA addressed Industry's questions. FDA agreed to provide information on the number of HSMs that are not identified as an "OTC monograph drug facility" as described in the January 12, 2021 HHS Federal Register notice "Notice That Persons That Entered the Over-the-Counter Drug Market To Supply Hand Sanitizer During the COVID-19 Public Health Emergency Are Not Subject to the Over-the-Counter Drug Monograph Facility Fee" and not currently paying OMUFA facility fees. Industry also presented additional information on how this proposal could potentially impact facilities. Industry addressed FDA's clarifying questions and will consider FDA's counterproposal. This proposal will be further discussed at a subsequent meeting.

CDER Manual of Policies and Procedures (MAPPs) Proposals

Industry presented its feedback on FDA's counterproposal for MAPPs to include language in the Commitment Letter on FDA developing MAPPs for all order processes as experience is gained, including MAPPs on FDA-initiated GRASE orders, Industry-initiated GRASE OMORs, Safety orders, and OMOR review. Industry noted that engaging FDA during implementation meetings on desired topics related to OMOR processes could be better than having MAPPs issued. These implementation meetings are currently held three times per year. Industry proposed increasing these meetings to quarterly in OMUFA II. These proposals will be further discussed at a subsequent meeting.

Guidance Proposals

Industry provided feedback on FDA's counterproposal to Industry's guidance proposals. Industry indicated support for FDA developing guidances for Filing Eligibility Determinations under section 505G(b)(6) of the FD&C Act (for OMORs proposing new monograph drug active ingredients) and Confidential Information. In addition, Industry emphasized the need for order-guidance pairs related to dosage form changes beyond the one committed under OMUFA I. Industry requested another order/guidance pair in OMUFA II for consideration. These proposals will be further discussed at a subsequent meeting.

Meetings Proposals

Industry provided additional feedback to FDA's counterproposals for Industry's meeting-related proposals. Industry proposed potential updates to the draft OTC monograph drug meetings guidance to address topics such as best practices for meeting agendas (e.g., no lengthy presentations, explaining to FDA what topics may require longer discussion). In addition, Industry provided additional feedback on FDA's counterproposal related to establishing a "follow-up opportunity" mechanism similar to the mechanism in the PDUFA VII commitment letter. Industry proposed a shorter timeframe for FDA to respond to a request for clarification on FDA meeting minutes or WROs for consideration. These proposals will be further discussed at a subsequent meeting.

Protocol Assessments Proposal

FDA presented its counterproposal on a mechanism for industry to request feedback on certain protocols for studies to support an OMOR. FDA provided a three-part proposal: 1) expand the scope of existing meeting types to allow for protocol synopsis review and feedback; 2) update IT systems to enable full protocol submission; and 3) establish a timeline for FDA review and feedback on certain safety issues. This proposal will be further discussed at a subsequent meeting.

IT Platform – Monograph Ingredient Website Proposal

FDA presented its approach to address Industry's request for continual updating and maintenance of the Historical Status of OTC Rulemaking webpage. Industry had no questions. This proposal will be further discussed at a subsequent meeting.

Next Steps
The final agenda for the April 9h meeting will be determined by the negotiation leads at their next planning meeting.