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

FDA and Industry Negotiations | Meeting Summary

February 13, 2024 | 9:30am-2:40pm

In-Person Format

PARTICIPANTS

FDA	Office	Industry	Organization
Ashley Boam	CDER	James Kim	ACI
Joshua Brown	OC	Katie Kramer	ACI (Hogan Lovells)
Grace Carmouze-Cunningham	CDER	Barb Kochanowski	CHPA
Angela Granum	CDER	Erin Oliver	CHPA (Haleon)
Christine Hunt	OC	Michael Kaminski	CHPA (P&G)
Bharat Khanna	CDER	Wendy McManus	CHPA (Sanofi)
Theresa Michele	CDER	David Spangler	CHPA
Karen Murry	CDER	Mark Gardella	PBOA
Phong Pham	CDER	Mary Schilling	PCPC
Paul Phillips	CDER		
Kimberly Taylor	CDER		

CDER Manual of Policies and Procedures (MAPPs) Proposals

Industry presented its proposals for five new CDER Manual of Policies and Procedures (MAPPs) documents. Although acknowledging that MAPPs are documents intended for FDA internal use, Industry indicated these documents provide useful insights to Industry. Industry proposed MAPPs on the following topics: FDA-initiated GRASE orders, Industry-initiated GRASE OMORs, safety orders, expedited safety orders, and review and timelines for Tier 1 or 2 OMORs. Industry addressed FDA's initial questions. Industry agreed to provide FDA a list of MAPPs of their highest priority and the key questions Industry would like FDA to address for each. This proposal will be discussed further at a subsequent meeting.

Filing Eligibility Determination for GRASE OMORS and Related Extension of Goal Dates for Proposed and Final Order Proposal

FDA presented its proposed commitment letter language regarding timeframes for agency determinations (under section 505G(b)(6) of the FD&C Act) regarding filing eligibility for OMORs proposing new monograph drug active ingredients and for determinations (under section 505G(b)(5)(A) of the FD&C Act) regarding the sufficiency of OMOR format and content. In addition, FDA presented specific proposed timeframes for the agency to make OMOR filing eligibility determinations with respect to proposed new monograph drugs marketed under US OTC NDAs vs drugs marketed OTC outside the U.S., as well as updated information on proposed order and final order goal dates where a filing eligibility decision is needed. FDA addressed Industry's questions. This proposal will be discussed further at a subsequent meeting.

Filing Eligibility Determination Guidance Proposal

Industry presented its proposal for an FDA guidance document to clarify specific statutory requirements applicable to filing eligibility determinations under section 505G(b)(6) of the FD&C Act for OMORs proposing new monograph drug active ingredients. Industry addressed FDA's initial questions. Industry agreed to submit further details for what they hope could be addressed in such a guidance. This proposal will be discussed further at a subsequent meeting.

Cataloguing Paper Document (Scanning and Posting Documents) Proposals

FDA provided a progress update on the OMUFA I paper document catalog commitment goal of posting the catalog to FDA's website by February 2025. In response to Industry's proposed enhancements to the paper document cataloguing for OMUFA II purposes, FDA presented its counterproposal that addressed many of Industry's expressed needs. FDA addressed Industry's initial questions. This proposal will be discussed further at a subsequent meeting.

Next Steps

The agenda for the February 20th meeting will include the facility fee due date change proposals and guidance document proposals. The final agenda will be determined by the negotiation leads at their next planning meeting.