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

FDA and Industry Negotiations | Meeting Summary

April 9, 2024 | 9:30am-1:40pm

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	Michael Bailey	CHPA
Christine Hunt	OC	Barbara Kochanowski	CHPA
Bharat Khanna	CDER	Wendy McManus	CHPA (Sanofi)
Jennifer Maguire	CDER	Erin Oliver	CHPA (Haleon)
Theresa Michele	CDER	David Spangler	CHPA
Celia Peacock	CDER		
Phong Pham	CDER		
Paul Phillips	CDER		
Kimberly Taylor	CDER		

CDER Manual of Policies and Procedures (MAPPs) and Content Outline for Tier 2 OMORs Guidance Proposal

FDA presented its counterproposal to Industry's proposals for MAPPs on FDA-initiated GRASE OMORs, Industry-initiated GRASE OMORs, and reviewing and finalizing a Tier 1 or Tier 2 OMOR, and a guidance to outline the content and format for Tier 2 OMORs. FDA indicated that due to the lack of experience with order processes, it is too premature for a commitment to develop comprehensive MAPPs and/or guidances on these topics in OMUFA II. In response to Industry's request to use OMUFA implementation meetings to engage FDA on various topics, FDA indicated these meetings are designed to discuss progress and issues regarding implementation of OMUFA commitments. As these meetings are not public, these meetings should not be used as a forum to share emerging policy or processes. In an effort to address Industry's desire for more transparency and engagement with the Agency, the FDA proposed to run a crowdsourcing campaign to solicit questions from external stakeholders regarding OMOR requirements and GRASE finalization. After the crowdsourcing ends, FDA would hold a webinar to answer certain questions submitted in the crowdsourcing for which the agency has established policy. In addition, FDA proposed holding a

separate webinar on how to submit an OMOR via the NextGen Portal. FDA addressed Industry's initial clarifying questions. These proposals will be discussed further at a subsequent meeting.

Minor Changes for Dose Forms Other Than Solid Oral Proposal
FDA indicated that it is developing the first order-guidance pair for minor changes to solid oral dosage forms in line with the OMUFA I commitment and consistent with the relevant statutory authority in section 505G(c) of the FD&C Act. If the proposed order for minor changes to solid oral dosage forms is issued by the OMUFA I commitment letter goal of April 1, 2025, FDA noted that it would be likely that the final order would not be issued until OMUFA II. FDA also noted that resources are needed to confirm compliance with the order. FDA presented its counterproposal regarding minor changes consistent with section 505G(c) (e.g., change in color for a tablet). FDA proposed to issue a draft guidance to provide clarity on information and documentation appropriate to support minor changes in a given dosage form. FDA addressed Industry's clarifying questions. This proposal will be discussed further at a subsequent meeting.

Advisory Committee Meetings Proposal
Industry presented its rationale for advance notification of advisory committee meetings (AdComs) related to OMORs and FDA-initiated proposed orders, in circumstances where FDA's position is that the 55 day advance notice period described in FDA's 2008 Guidance on Advisory Committee Meetings; Preparation and Public Availability is inapplicable. FDA acknowledged Industry's interest in advance notification but reiterated that AdComs are authorized under the Federal Advisory Committee Act (FACA) not section 505G. With respect to Industry's proposal that FDA include reference to a planned AdCom in the OMUFA annual forecast, FDA indicated that there are well-established Agency-wide policies and procedures in place with respect to announcing upcoming AdComs. This proposal will be discussed further at a subsequent meeting.

Protocol Assessment Proposal
Industry indicated support for part 1 of FDA's counterproposal, i.e., that FDA use Type Y and Z meetings to provide feedback on a protocol synopsis. FDA addressed Industry's questions related to full protocol assessment review, under part 2 of FDA's counterproposal. This proposal will be discussed further at a subsequent meeting.

OMUFA Facility Fee Adjuster Proposal
Industry presented feedback on FDA's counterproposal to use a three-year average for the one-time facility fee adjustment, with a threshold number of facilities as a baseline for the adjuster. FDA addressed Industry's clarifying questions. Industry stated it would provide a higher number of facilities to establish a different proposed baseline for the adjuster. This proposal will be discussed further at a subsequent meeting.

Resourcing MAPPs and Guidances Proposals
FDA presented proposed resources for Industry's proposal for FDA MAPP and guidance-related commitments which included hiring and contract work-related needs. FDA addressed Industry's initial clarifying questions. This topic will be discussed further at a subsequent meeting.

Next Steps
The final agenda for April 16th meeting will be determined by the negotiation leads at their next planning meeting.