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

FDA and Industry Negotiations | Meeting Summary

April 30, 2024 | 9:30am-2:50pm

Virtual Format

PARTICIPANTS

FDA	Office	Industry	Organization
Ashley Boam	CDER	Katie Kramer	ACI (Hogan Lovells)
Joshua Brown	OC	Michael Bailey	CHPA
Grace Carmouze-Cunningham	CDER	Barbara Kochanowski	CHPA
Angela Granum	CDER	Michael Kaminski	CHPA (P&G)
Christine Hunt	OC	Wendy McManus	CHPA (Sanofi)
Bharat Khanna	CDER	Erin Oliver	CHPA (Haleon)
Theresa Michele	CDER	David Spangler	CHPA
Karen Murry	CDER	Cornell Stamoran	PBOA
Celia Peacock	CDER		
Phong Pham	CDER		
Paul Phillips	CDER		
Kimberly Taylor	CDER		

Resourcing for Industry Proposals

FDA reviewed proposed resourcing presented at the last meeting and addressed Industry's clarifying questions. FDA also presented proposed resourcing on the following remaining proposals: the proposal for a "follow-up opportunity" for Industry to submit clarifying questions related to FDA's meeting minutes; the proposal for protocol assessment synopsis review and feedback; and the three IT-related proposals (i.e., post a list of drugs FDA has identified as being deemed to be new drugs under section 505G(a)(4) on FDA's website, maintain FDA's Historical Status of OTC Rulemaking webpage, and post information related to exclusivity afforded by final orders on FDA's website). Industry asked about the possibility of tracking of certain metrics in OMUFA II. FDA indicated that it would take this into consideration.

After internal discussion, Industry withdrew their IT-related proposal to have FDA post a list of drugs FDA has identified as being deemed to be new drugs under section 505G(a)(4). FDA

addressed Industry's initial clarifying questions. This topic will be discussed further at a subsequent meeting.

Product Quality Proposal
Industry provided its feedback on the FDA updated product quality proposal. In response to Industry's question on what work could be done with fewer full-time equivalents (FTEs), FDA indicated it would discuss this internally. In addition, there was discussion on potential ways to address the firms on the OMUFA facility fee arrears list. FDA addressed Industry's clarifying questions. This proposal will be discussed further at a subsequent meeting.

Minor Changes for Dosage Forms Other Than Solid Oral Guidance Proposal
Industry proposed an additional order/guidance pair related to minor dosage form changes for topical products. FDA indicated that topical product development is notably difficult and that this would need further internal vetting. Developing such an order/guidance pair would need additional resources for guidance development and enforcement. This proposal will be discussed further at a subsequent meeting.

Filing Eligibility and Filing Assessment Proposal
FDA responded to feedback received on its revised proposal. FDA proposed an option that would reduce the previously proposed filing eligibility review timelines for certain Tier 1 OMORs proposing a new monograph active ingredient (i.e., the subset of such OMORs supported by US marketing data under an approved nonprescription NDA). In addition, this option included a guidance that would outline the data requirements for filing eligibility under section 505G(b)(6) of the FD&C Act. FDA addressed Industry's clarifying questions. This proposal will be discussed further at a subsequent meeting.

Advisory Committee Meetings Proposal
Industry indicated that FDA's proposal for advanced notification (55 business days) via FDA's website prior to a monograph-related advisory committee meeting (AC) was an insufficient amount of time. Industry explained that more time is necessary for industry to coordinate and gather and prepare materials for an AC. This proposal will be discussed further at a subsequent meeting.

OMUFA Program funding
FDA addressed Industry's clarifying question on the "base" budget authority (BA) level and the ratio of BA to fees under the OMUFA spending trigger.

Next Steps
The final agenda for the May 7th meeting will be determined by the negotiation leads at their next planning meeting.