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

FDA and Industry Negotiations | Meeting Summary

April 23, 2024 | 9:30am-11:50am

Virtual 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
Angela Granum	CDER	Lynn Evans	CHPA (Kenvue)
Christine Hunt	OC	Michael Kaminski	CHPA (P&G)
Bharat Khanna	CDER	Barbara Kochanowski	CHPA
Jennifer Maguire	CDER	Wendy McManus	CHPA (Sanofi)
Theresa Michele	CDER	Erin Oliver	CHPA (Haleon)
Karen Murry	CDER	David Spangler	CHPA
Celia Peacock	CDER	Cornell Stamoran	PBOA
Phong Pham	CDER		
Paul Phillips	CDER		
Kimberly Taylor	CDER		

Product Quality Proposal

FDA presented its updated proposal incorporating Industry's feedback to increase focus on unpaid fee recovery efforts, increase visibility of the arrears list, hold a quality-related workshop, and consider a new order-guidance pair to facilitate minor dosage form changes. Additionally, FDA presented resourcing for the updated proposal. FDA addressed Industry's clarifying questions. This proposal will be discussed further at a subsequent meeting.

IT Platform – Proposal addressing Information on FDA Website Regarding Active Ingredients that were not Subject to a Final FDA GRASE Determination

FDA presented its counterproposal for the posting and maintaining on FDA's website a list of drugs FDA identified as deemed to be new drugs under section 505G(a)(4) of the FD&C Act (i.e., Part I) and a list of drugs FDA determined were not GRASE via the order process under section 505G(b) (Part II). FDA also presented resources needed to accomplish parts I and II. FDA addressed Industry's initial clarifying questions. This proposal will be discussed further at a subsequent meeting.

Overview of FDA's Approach to MAPP Development

In response to previous discussion on Industry's MAPPs proposals, FDA presented information to help industry understand FDA's approach to MAPP development. FDA indicated that MAPPs are written and issued for internal FDA purposes, not as a guide for industry. In contrast, FDA issues guidance to assist industry in understanding and complying with FDA requirements. It was noted that a MAPP may involve the development of one or more internal processes.

MAPP Proposals

FDA shared draft commitment letter language for Industry consideration on the two-part MAPP counterproposal. The first part involves FDA running a crowdsourcing campaign to solicit questions related to GRASE finalization from external stakeholders and hold a follow-up with an educational webinar. The second part involves holding another webinar to walk through the steps to submit an OMOR in the CDER NextGen Portal. These proposals will be discussed further at a subsequent meeting.

Advisory Committee Meetings Proposal

Industry asked about including a list of potential Advisory Committee (AC) meetings in the OMUFA annual forecast. FDA indicated that the forecast is intended to give notice regarding potential orders authorized under section 505G of the FD&C Act and not information on AC meetings. Industry indicated FDA is not precluded from including information about potential AC meeting topics in the OMUFA annual forecast. FDA is still considering options for communicating AC topics. FDA provided Industry information on the relatively new mechanism of posting information on the FDA website about certain upcoming AC meetings prior to the *Federal Register* notice. FDA addressed Industry's clarifying questions. This proposal will be discussed further at a subsequent meeting.

Next Steps

The final agenda for April 30th meeting will be determined by the negotiation leads at their next planning meeting.