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

FDA and Industry Negotiations | Meeting Summary

May 7, 2024 | 9:30am-2:45pm

Virtual Format (Zoom)

Participants

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

Minor Changes for Dosage Forms Other Than Solid Oral Guidance Proposal
FDA and Industry discussed Industry's proposal for an order/guidance pair related to minor dosage form changes for topical products. Industry acknowledged that topicals are broad-ranging but noted they are the second largest segment behind solid oral dosage forms and that the proposed order-guidance pair was important for innovation. Industry offered further details on the types of topical products for consideration (skin (externally applied) and oral with a primary mode of action as locally acting). FDA suggested narrowing the scope to locally acting oral products. FDA presented its resource estimates for the final order for solid oral dosage forms (following from an OMUFA I commitment) and for an order/guidance pair on locally acting oral topical products. FDA addressed Industry's clarifying questions. After internal discussion, Industry presented

its counterproposal on resources. Given the complexity of topical oral products, Industry suggested having a small working group during OMUFA II (after the final order for solid orals) to keep the topical orals discussion ongoing. FDA indicated that it would take this into consideration. This proposal will be discussed further at a subsequent meeting.

Quality Proposal

Industry proposed withdrawing the FDA proposal for a guidance on quality expectations for OTC monograph products because it is already covered in CGMP regulations, stating that provision of information was best accomplished by the already-proposed workshop. Industry addressed FDA's clarifying questions. FDA indicated that having this guidance would be helpful, noting that the more information that can be put into a guidance, the more questions FDA is potentially able to answer proactively in the workshop. FDA proposed adding back the FTE to support the guidance. FDA addressed Industry's clarifying questions. This proposal will be discussed further at a subsequent meeting.

Test Methods Proposals

Industry presented the number of FTEs it was willing to resource for the test methods proposals. Industry also proposed areas of focus, including a topic to include for the workshop. FDA will consider a smaller proposal regarding resources proposed by Industry. This proposal will be discussed further at a subsequent meeting.

Advisory Committee Meeting Proposal

Industry emphasized the importance to members of industry of avoiding surprises with advisory committee (AC) meetings relating to OTC monograph products. There was discussion on potentially using the "current data request" column within the OMUFA annual forecast to help publicly communicate potential topics that might need to go to an AC meeting. Industry indicated that preparing responses to FDA data calls may require a significant amount of work and having FDA indicate whether a data request is expected would be helpful. It was noted that how FDA intends to use such data requests is still under discussion. FDA indicated that while many topics on the forecast have already been presented at an AC meeting, this would not preclude these same topics from being discussed again. In addition, since the forecast covers a 3-year period, FDA may not necessarily know if an AC meeting is needed for a topic until an OMOR is submitted. Industry indicated that knowing the exact date of an AC meeting is not as significant as knowing the likelihood of an AC meeting for a given topic. Industry also indicated that it would be helpful if this column could be updated, as needed, rather than strictly on an annual basis. FDA will consider Industry's suggestion about the forecast. This proposal will be discussed further at a subsequent meeting.

OMUFA Support of OTC Monograph Drug Activities

In response to Industry's question on OMOR fees, FDA indicated that the OMUFA facility and OMOR fees can be used for any OTC monograph drug activities specified in the statute. It was noted that the OMOR fees are not part of the statutory target revenue calculations. In addition, the OMUFA-supported hiring plan is based on resources from facilities fees because of the unpredictability of the number of OMOR submissions and associated OMOR fees. It was noted that if there is an operating reserve of carryover fees above 10 weeks, FDA would implement the applicable operating reserve

adjustment in accordance with the statute.

Review of Goals Letter, Proposed Statutory Changes, and Justification for Statutory Changes

In response to Industry's question, FDA noted the draft goals letter shell was being updated to generally reflect the commitment letter format used for other UFA programs and to remove OMUFA I commitment letter language no longer relevant or applicable given the superseding enactment of section 505G of the FD&C Act. Because developing the goals letter shell is taking longer than anticipated, FDA offered to send a separate document with commitment language to use for negotiation while the shell is finalized. FDA is currently updating a proposed statutory changes document and a justification of statutory changes document and will send them to industry when finalized. Industry indicated its preference for seeing the whole package at once but could proceed with FDA's approach. In addition, Industry indicated that it would like to have the negotiation package ready to send to their ratifiers by May 31st. FDA will schedule additional meetings to finish negotiations.

Next Steps

The final agenda for the May 14th meeting will be determined by the negotiation leads at their next planning meeting.