



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

## FDA and Industry Negotiations | Meeting Summary

May 14, 2024 | 9:30am-1:45pm

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	Barbara Kochanowski	CHPA
Christine Hunt	OC	Michael Kaminski	CHPA (P&G)
Bharat Khanna	CDER	Wendy McManus	CHPA (Sanofi)
Theresa Michele	CDER	Erin Oliver	CHPA (Haleon)
Karen Murry	CDER	David Spangler	CHPA
Celia Peacock	CDER	Gil Roth	PBOA
Phong Pham	CDER	-	-
Paul Phillips	CDER	-	-
Kimberly Taylor	CDER	-	-

### OMOR Filing Eligibility and Filing Assessment Proposal

Industry indicated their support for this proposal with the revised timelines and the proposed guidance.

### OMUFA Facility Fee Adjuster Proposal

FDA presented an updated counterproposal based on industry feedback. The proposal increased the baseline number of facilities that would trigger the adjustment. The new number represented approximately 5% growth in workload. The timing of the one-time adjustment was also updated to FY2028 or any subsequent year. The proposal still used a lagging 3-year average to determine whether the criteria for triggering the adjustment were met. Once an adjustment was made to fee revenue under this proposal, it would be

part of the fee revenue baseline for future fiscal years. FDA proposed adding an additional limiting criterion regarding the number of firms in arrears, to help reduce the risk to Industry that a fee increase under the adjustment would primarily serve to cost-shift unpaid fees to fee payors, since that was a concern Industry had expressed. FDA addressed Industry's clarifying questions. This proposal will be discussed further at a subsequent meeting.

### **Arrears List**

There was discussion on firms in arrears and their impact on OMUFA facility fees. Also discussed were the penalties for non-payment of fees under sections 502(ff) and 744M(e) of the FD&C Act. FDA indicated that the draft guidance [Assessing User Fees Under the Over-the-Counter Monograph Drug User Fee Program](#) specifically addresses firms in arrears and suggested that Industry submit their ideas to the [public docket for that guidance](#). Industry indicated they would take this suggestion under consideration.

### **Test Methods Proposals**

Industry updated their test-methods-related proposals to the following: 1) amend the statutory definition of Tier 2 OMOR to include OMORs proposing new test methods (once recognized by a consensus standards organization and CDER's program for the recognition of voluntary consensus standards related to pharmaceutical quality, as described in the guidance on that program<sup>1</sup>); 2) have FDA publish a *Federal Register* notice (FRN) to solicit stakeholder feedback; 3) have FDA run a crowdsourcing campaign to obtain additional stakeholder feedback. Industry and FDA agreed that additional resources would be needed for these commitments for FTEs and one-time direct cost funding that would be needed to support the crowdsourcing campaign. Industry addressed FDA'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 indicated they were withdrawing this proposal based on FDA's resource estimate and lack of experience with the solid oral order-guidance pair, which under the OMUFA I commitment letter is due in draft form in 2025.

### **Product Quality Proposal**

Based on discussions, FDA updated their proposal to the following potential actions: enhancing FDA's warning letters database, creating education materials, and annual reporting of aggregate information on FDA's website about records requests directed to OTC monograph drug facilities. Industry and FDA discussed resources for this revised proposal. FDA addressed Industry's clarifying questions. This proposal will be discussed further at a subsequent meeting.

### **Resourcing for Industry Proposals**

FDA presented updated information on resourcing (hiring and one-time costs) and the timing when these resources to implement each proposal would be needed. FDA addressed Industry's clarifying questions. This topic will be discussed further at a

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<sup>1</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cders-program-recognition-voluntary-consensus-standards-related-pharmaceutical-quality>

subsequent meeting.

**Next Steps**

The final agenda for the May 20th meeting will be determined by the negotiation leads at their next planning meeting.