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

FDA and Industry Negotiations | Meeting Summary

May 20, 2024 | 9:30am-12:15pm

Virtual Format (Zoom)

Participants

FDA	Office	Industry	Organization
Ashley Boam	CDER	Katie Kramer	ACI (Hogan Lovells)
Grace Carmouze-Cunningham	CDER	Mike Bailey	CHPA
Christine Hunt	OC	Barbara Kochanowski	CHPA
Bharat Khanna	CDER	Lynn Evans	CHPA (Kenvue)
Theresa Michele	CDER	Wendy McManus	CHPA (Sanofi)
Celia Peacock	CDER	Erin Oliver	CHPA (Haleon)
Phong Pham	CDER	David Spangler	CHPA
Paul Phillips	CDER	Gil Roth	PBOA
Kimberly Taylor	CDER	-	-

OMUFA Facility Fee Adjuster Proposal and FTE Costs

Industry indicated their support for FDA's updated proposal which included an increased number of facilities to serve as the baseline for a one-time adjustment and a limiting criterion regarding firms in arrears. If the one-time adjustment is taken, it would occur in FY2028, or any subsequent year during OMUFA II. FDA addressed Industry's questions on FTE costs and how inflation impacts these costs. In response to Industry's request, FDA indicated it would provide information on current facility numbers. Industry will discuss this proposal internally. This proposal will be discussed further at a subsequent meeting.

Product Quality Proposal

Industry presented their counterproposal for the quality proposals. In addition to providing updated resourcing information, Industry proposed the following deliverables: 1) focused FDA actions in key areas (new registrant vetting, targeted fee recovery

efforts, update to FDA's site selection model, increased analysis of arrears list); 2) increased transparency of the arrears list in FDA communications and records requests information; and 3) to hold a workshop focusing on CGMP compliance for OTC monograph facilities. In addition, Industry shared additional thoughts on potential ways FDA could help reduce the number of facilities in arrears. FDA provided some initial feedback. FDA also addressed Industry's questions on the information FDA collects on facilities and what information can be made public. This proposal will be discussed further at a subsequent meeting.

Next Steps

The final agenda for the May 29th meeting will be determined by the negotiation leads at their next planning meeting.