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

## FDA and Industry Negotiations | Meeting Summary

*January 30, 2024 |9:30am-11:30am*

*Virtual Format (Zoom)*

### PARTICIPANTS

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

**Filing Eligibility Determination for GRASE OMORS and related Extension of Goal Dates for Proposed and Final Order Proposal**

Industry provided feedback on FDA's proposal to align the goals document language regarding filing eligibility for OMORs proposing new monograph active ingredients with the statute, i.e., section 505G(b)(6). FDA presented follow-up information on the Agency's proposed timelines for filing eligibility review. FDA addressed Industry's clarifying questions. This proposal will be discussed further at a subsequent meeting.

**IT Platform – Information on Proposed FDA Website Regarding Final Orders Providing Exclusivity**

Industry presented requested follow-up information on their proposal for an FDA website to contain information about OTC monograph drug marketing exclusivity provided by final orders. Industry addressed FDA's clarifying questions regarding their proposal. FDA will discuss the information provided internally. This proposal will be discussed further at a subsequent meeting.

**Monograph Testing Procedures Proposals**

FDA addressed Industry's additional questions on the two monograph testing procedure proposals (i.e., (1) recharacterization and changes to monograph testing procedures and (2) amending statutory definition of Tier 2 OMOR to include OMORs proposing certain changes in monograph testing procedures). FDA agreed to provide requested information on test methods included in Deemed Final Orders (DFOs). This proposal will be discussed further at a subsequent meeting.

**Next Steps**

The agenda for February 6th meeting will be determined by the negotiation leads at their next planning meeting.