



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

November 20, 2024

- 9:00–9:05 AM **Welcome and Introduction**
- 9:05–9:15 AM **Opening Remarks**
Patrizia Cavazzoni, Center for Drug Evaluation and Research, FDA
Center Director
- 9:15–9:30 AM **OMUFA Background and Reauthorization Process**
Theresa Michele, Center for Drug Evaluation and Research, FDA
Director, Office of Non-Prescription Drugs (ONPD), Office of New Drugs
- 9:30–9:50 AM **OMUFA II Agreement Overview**
Karen Murry, Center for Drug Evaluation and Research, FDA
Deputy Director, Office of Nonprescription Drugs (ONPD), Office of New Drugs
J. Paul Phillips, Center for Drug Evaluation and Research, FDA
Director, Office of Program Operations (OPO), Office of New Drugs
Angela Granum, Center for Drug Evaluation and Research, FDA
Division Director, Division of User Fee Management (DUFM), Office of Management,
- 9:50 –10:00 AM **Break**
- 10:00–11:00 AM **Panel 1 – Regulated Industry Perspectives**
Mike Bailey, Consumer Healthcare Products Association
Senior Vice President, Regulatory and Scientific Affairs
Dan Selechnik, Fragrance Creators Association
Director of Regulatory Science
Gil Roth, Pharma and Biopharma Outsourcing Association
President
Emily Manoso, Personal Care Products Council
General Council and EVP for Legal and Regulatory Affairs
James Kim, American Cleaning Institute
Senior Vice President, Science & Regulatory Affairs
Meredith Petillo, Independent Beauty Association
VP, Technical and Regulatory Affairs



11:00–11:20 AM

Panel 2– Academic and Advocacy Perspectives

Eric P. Brass, University of California, Los Angeles (UCLA)
Professor Emeritus of Medicine

Diana Zuckerman, National Center for Health Research
President

11:20 –12:25 PM

Public Comments

12:25–12:30 PM

Closing Remarks

Theresa Michele, Center for Drug Evaluation and Research, FDA
Director, Office of Non-Prescription Drugs (ONPD), Office of New Drugs