



**Public Meeting on
Over-The-Counter Monograph User Fees
June 10, 2016**
(modified 6/8/2016)



- 8:00 a.m. – 9:00 a.m. **Registration**
- 9:00 a.m. – 9:05 a.m. **Welcome**
Chris Shreeve, Center for Drug Evaluation and Research, FDA
Meeting Moderator & Director, Office of Communications
- 9:05 a.m. – 9:15 a.m. **Opening Remarks**
Janet Woodcock M.D., Center for Drug Evaluation and Research, FDA
Center Director
- 9:15 a.m. – 9:35 a.m. **Overview of the Over-the-Counter Drug Monograph Process**
Karen Mahoney M.D., F.A.C.E., Center for Drug Evaluation and Research, FDA
Deputy Director, Division of Non-prescription Drugs
- 9:35 a.m. – 9:45 a.m. **User Fee Considerations in the Context of Over-the-Counter Monograph Drugs**
Donal Parks, Center for Drug Evaluation and Research, FDA
Director, Division of User Fee Management and Budget Formulation
- 9:45 a.m. – 10:25 a.m. **Panel 1 — Consumer Perspectives**
Alliance for Aging Research
Cynthia Bens
Vice President, Public Policy
- National Center for Health Research
Diana Zuckerman Ph.D.
President
- National Consumers League
Sally Greenburg
Executive Director
- Audience Questions for the Panel
- 10:25 a.m. – 10:40 a.m. **Break**



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10:40 a.m. – 11:10 a.m. **Panel 2 — Health Care Professionals Perspectives**

American Academy of Pediatrics

David Bromberg M.D., F.A.A.P.

Member, Board of Directors

American Pharmacists Association

Stacie S. Maass B.S. Pharm., J.D.

Senior Vice President, Pharmacy Practice and Government Affairs

Audience Questions for the Panel

11:10 a.m. – 12:00 p.m. **Panel 3 — Industry Perspectives**

Consumer Healthcare Products Association

Barbara A. Kochanowski Ph.D.

Vice President, Regulatory & Scientific Affairs

International Pharmaceutical Excipients Council of the Americas

Priscilla Zawislak

Global Regulatory Affairs Manager, Pharmaceutical and Nutritional Ingredients

Ashland Specialty Ingredients

Personal Care Products Council

Mark Pollak

Senior Executive Vice President -Strategic Initiatives & Assistant Secretary

Pharma and Bio-Pharma Outsourcing Association

Cornell Stamon Ph.D.

Vice President, Corporate Strategy

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Audience Questions for the Panel

12:00 p.m. – 1:00 p.m. **Lunch Break**



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- 1:00 p.m. – 1:30 p.m. **Panel 4 — Scientific Community Perspectives**
Northwestern University
Michael Wolf M.A., M.P.H., Ph.D.
Professor, Medicine & Learning Sciences
- University of Pittsburgh School of Pharmacy
Randy P. Juhl Ph.D.
Distinguished Service Professor Emeritus, Pharmaceutical Sciences
- Audience Questions for the Panel
- 1:30 p.m. – 2:30 p.m. **Open Public Comment**
- 2:30 p.m. – 2:35 p.m. **Closing**