

**CENTER FOR DRUG EVALUATION AND RESEARCH
(CDER)
FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Part 15 Hearing - October 2, 2008
Over the Counter Cough and Cold Medications
For Pediatric Uses**

AGENDA

8:00 – 8:15

Jane A. Axelrad, JD
Associate Director for Policy, CDER

Opening Remarks
Introduction of Panel Members
Logistics

8:15 - 09:30

Joshua M. Sharfstein, MD
Commissioner of Health, Baltimore City Health Department

Daniel Jay Levy, MD, FAAP
Maryland Chapter, American Academy of Pediatrics

David I. Bromberg, MD, FAAP
American Academy of Pediatrics

Wayne R. Snodgrass, MD, PhD
Medical Director, Texas Poison Center—Houston/Galveston
University of Texas Medical Branch

Michael Shannon, MD
Children's Hospital Boston
Harvard Medical School

Janet Serwint, MD
Johns Hopkins University School of Medicine

9:30 – 9:45 BREAK

9:45 - 10:45

Linda Suydam

President, Consumer Healthcare Products Association

Paul Desjardins, MD

Wyeth Consumer Healthcare

Cathy Gelotte, MD

McNeil Consumer Healthcare

Edward Kuffner, MD

McNeil Consumer Healthcare

Barbara Kochanowski, MD

The Procter & Gamble Company

Virginia Cox

Senior Vice President, Consumer Healthcare Products Association

10:45 - 11:00 BREAK

11:00 - 12:00

Saul Shiffman, PhD

Senior Scientific Advisor, Pinney Associates (sponsoring attendance)
and Professor of Psychology and Pharmaceutical Sciences, University of Pittsburgh

Phillip D. Walson, MD

Georg-August-Universiitat Goettingen, Faculty of Medicine & The University Hospital,
Dept. of Lab. Medicine

Retired Prof. of Pediatrics and Pharmacology,
University of Cincinnati and Cincinnati Children's Hospital

J. Steven Leeder, Pharm D, PhD

Children's Mercy Hospital

Michael Fien

Comar, Inc.

Samuel Maldonado, MD

Johnson and Johnson Pharmaceutical Research and Development

Marc R. Gastonguay, Ph.D.

Metrum Research Group LLC

12:00 - 1:00 LUNCH

1:00 - 2:00

Malaz A. AbuTarif, BSc(Pharmacy), PhD., GCPM., MBA
Schering-Plough Research Institute

Jeffrey Blumer, PhD, MD
Rainbow Babies and Children's Hospital/Case Western Reserve University

Natella Rakhmanina, MD, FAAP, AAHIVS,
Children's National Medical Center,
The George Washington University

Michael Spigarelli, MD, PhD
Clinical Trials Office
Cincinnati Children's Hospital Medical Center

Richard Kingham, JD
Covington & Burling, LLP,

2:00 – 2:15 BREAK

2:15 – 3:15
Paul Brown, Government Relations Manager
National Research Center for Women & Families

Diana Zuckerman, PhD
National Research Center for Women & Families

Mimi Johnson
Health Policy Associate
National Consumers League

Kenneth Kim, MD
West Coast Clinical Trials LLC

Ronald B. Turner, MD
University of Virginia School of Medicine

Birgit Winther, MD;DSc
Department of Otolaryngology
University of Virginia Health System

3:15 – 3:30 BREAK

3:30 - 4:45
Open Public comment

5:00 ADJOURN