FDA-University of Maryland CERSI Public Workshop:
Nonprescription Analgesic/Antipyretic Drug Development in
Children 2 to Less Than 12 Years of Age Agenda
Friday, November 15, 2024 (9:00am – 4:00pm)
Hybrid (FDA Great Room Bldg 31 & Zoom)

Welcome & Introduction

9:00 AM – 9:10 AM **Welcome and Opening Remarks**
Nushin Todd, Director, Division of Nonprescription Drugs 1 (DNPD1)
U.S. Food and Drug Administration (FDA)

9:10 AM – 9:20 AM **Introductory Remarks**
Theresa Michele, Director, Office of Nonprescription Drugs, FDA

9:20 AM – 9:35 AM **Regulatory Background for Children's Nonprescription Pain and Fever Products**
Shila Azodi, Medical Officer, DNPD1, FDA

9:35 AM – 9:45 AM **Pediatric Research Equity Act (PREA)**
Ndidi Nwokorie, Medical Officer, Division of Pediatrics and Maternal Health (DPMH), FDA

Session 1: Current Perspectives on Consumer Use of Nonprescription Pain and Fever Products and Potential Unmet Needs

9:45 AM – 10:00 AM **Clinical Considerations for OTC Antipyretic-Analgesics Among 2–12-Year-Old Children**
Ian Paul, University Professor of Pediatrics, Pediatrician, Penn State College of Medicine

10:00 AM – 10:15 AM **Current Perspectives on Consumer Use of Nonprescription Pain and Fever Products and Potential Unmet Needs: Epidemiology of Symptoms**
Diane Hindman, Attending Physician, University of Arizona College of Medicine

10:15 AM – 10:30 AM **Collaboration Leads to Improved OTC Solutions for Children**
Leanne West, President, International Children's Advisory Network
Casey Cashman, Director, Pediatric Pain Warrior, U.S. Pain Foundation

10:30 AM – 10:45 AM **Patient Perspectives: Case Study Series**
Jody Thomas, Founder/CEO, Meg Foundation

10:45 AM – 11:00 AM **The National Consumers League**
Sally Greenberg, Chief Executive Officer, National Consumers League

11:00 AM – 11:15 AM **BREAK**

11:15 AM – 12:15 PM	**Panel Discussion** ***Moderators:*** *Aklil Getachew, Medical Officer, DNPD1, FDA* *Ndidi Nwokorie, Medical Officer, DPMH, FDA* ***Panelists (in addition to Speakers):*** *John Alexander, Deputy Division Director, DPMH, FDA* *Corrie Chumpitazi, Pediatric Emergency Medicine Specialist, Duke Department of Pediatrics* *Samina Ali, Professor, Department of Pediatrics, University of Alberta, Canada* *Susan Sirota, Founding Partner and CEO, PediaTrust LLC*
12:15 PM – 1:00 PM	**LUNCH**

Session 2: Potential Unintended Consequences of Deviating from One or More Existing Product Characteristics

1:00 PM – 1:15 PM	**Protecting Access to Pain Relief (PAPR) Coalition** *Wade Delk, Board Member and Treasurer, Protecting Access to Pain Relief Coalition*
1:15 PM – 1:30 PM	**Preventing Pediatric Medication Overdose: Strategies, Challenges and Innovations** *Maribeth Sivilus, Epidemiologist, CDC Protect* *Jennifer Lind, Partnership and Prevention Lead, Medication Safety Program, CDC Protect*
1:30 PM – 1:45 PM	**Lessons from Product Safety Changes to Reduce Pediatric Medication Errors to Acetaminophen (Poison Center Analysis)** *Kate Reynolds, Director of Research, Rocky Mountain Poison and Drug Safety*
1:45 PM – 2:00 PM	**Changes to Existing Product Characteristics – the Pharmacist Prospective** *Petrea Cober, Professor of Pharmacy Practice, Northeast Ohio Medical University*
2:00 PM – 2:15 PM	**Nonprescription Analgesic/Antipyretic Drug Development in Children 2 to <12 years of Age: A Health Literacy Perspective** *Shonna Yin, Associate Professor Pediatrics, New York University*
2:15 PM – 2:30 PM	**Consume Behavior Research: Evaluating When Product Characteristics Might Introduce Problems for Consumers** *Russ Bradford, Senior VP Medical Affairs, PEGUS Research*
2:30 PM – 2:40 PM	**BREAK**
2:40 PM – 3:40 PM	**Panel Discussion** ***Moderators:*** *Dorothy Chang, Deputy Director for Safety, DNPD1, FDA* *Mona Khurana, Medical Team Leader, DPMH, FDA*

Panelists (in addition to Speakers):
Casey Cashman, Director, Pediatric Pain Warrior, U.S. Pain Foundation
Diane Hindman, Attending Physician, University of Arizona College of Medicine
Routt Reigart, Professor Emeritus of Pediatrics, Medical University of South Carolina
Jonathan Zipursky, Clinician-Scientist, Sunnybrook Research Institute, Toronto Canada

3:40 PM – 4:00 PM **Closing Remarks and Next Steps**
Lynne Yao, Division Director, DPMH, FDA
