

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

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| 9:00 AM – 9:10 AM | Welcome and Opening Remarks <i>Nushin Todd, Director, Division of Nonprescription Drugs 1 (DNPD1)</i> <i>U.S. Food and Drug Administration (FDA)</i> |
| 9:10 AM – 9:20 AM | Introductory Remarks <i>Theresa Michele, Director, Office of Nonprescription Drugs, FDA</i> |
| 9:20 AM – 9:35 AM | Regulatory Background for Children’s Nonprescription Pain and Fever Products <i>Shila Azodi, Medical Officer, DNPD1, FDA</i> |
| 9:35 AM – 9:45 AM | Pediatric Research Equity Act (PREA) <i>Ndidi Nwokorie, Medical Officer, Division of Pediatrics and Maternal Health (DPMH), FDA</i> |

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

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| 9:45 AM – 10:00 AM | Clinical Considerations for OTC Antipyretic-Analgesics Among 2–12-Year-Old Children <i>Ian Paul, University Professor of Pediatrics, Pediatrician, Penn State College of Medicine</i> |
| 10:00 AM – 10:15 AM | Current Perspectives on Consumer Use of Nonprescription Pain and Fever Products and Potential Unmet Needs: Epidemiology of Symptoms <i>Diane Hindman, Attending Physician, University of Arizona College of Medicine</i> |
| 10:15 AM – 10:30 AM | Collaboration Leads to Improved OTC Solutions for Children <i>Leanne West, President, International Children’s Advisory Network</i> <i>Casey Cashman, Director, Pediatric Pain Warrior, U.S. Pain Foundation</i> |
| 10:30 AM – 10:45 AM | Patient Perspectives: Case Study Series <i>Jody Thomas, Founder/CEO, Meg Foundation</i> |
| 10:45 AM – 11:00 AM | The National Consumers League <i>Sally Greenberg, Chief Executive Officer, National Consumers League</i> |
| 11:00 AM – 11:15 AM | BREAK |

11:15 AM – 12:15 PM

Panel Discussion

Moderators:

Aklil Getachew, Medical Officer, DNP1, 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 Perspective

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, DNP1, 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
