

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 (9:00 am – 4:00 pm)
Hybrid (FDA Great Room Bldg 31 & Zoom)

Welcome & Introduction

9:00 AM – 9:10 AM	Welcome and Opening Remarks <i>Nushin Todd, Division of Nonprescription Drugs 1 (DNPD1) US Food and Drug Administration (FDA)</i>
9:10 AM – 9:20 AM	Introductory Remarks <i>TBD</i>
9:20 AM – 9:35 AM	Regulatory Background for Children’s Nonprescription Pain and Fever Products <i>Shila Azodi, DNPD1, FDA</i>
9:35 AM – 9:45 AM	Pediatric Research Equity Act (PREA) <i>Ndidi Nwokorie, DPMH, FDA</i>

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

9:45 AM – 10:00 AM	<i>Dr. Ian Paul, Penn State Health</i>
10:00 AM – 10:15 AM	<i>Dr. Diane Hindman, University of Arizona College of Medicine</i>
10:15 AM – 10:30 AM	<i>Dr. Leanne West, iCAN Research</i>
10:30 AM – 10:45 AM	<i>Dr. Jody Thomas, The Meg Foundation</i>
10:45 AM – 11:00 AM	TBD
11:00 AM – 11:15 AM	BREAK
11:15 AM – 12:15 PM	Panel Discussion
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	<i>TBD</i>
1:15 PM – 1:30 PM	<i>Kate Reynolds, Rocky Mountain Poison and Drug Safety (MPDC)</i>
1:30 PM – 1:45 PM	<i>Dr. Shonna Yin, New York University</i>
1:45 PM – 2:00 PM	<i>TBD</i>
2:00 PM – 2:15 PM	<i>TBD</i>
2:15 PM – 2:25 PM	BREAK
2:25 PM – 3:25 PM	Panel Discussion
3:25 PM – 3:40 PM	Closing Remarks and Next Steps
