

# Defining “Candy-Like” Nonprescription Drug Products

## Hybrid Public Workshop

Location: FDA Great Room, Building 31, 10903 New Hampshire Ave., Silver Spring, MD 20993

Date: October 30, 2023

Time: 8:30 am - 4:00 pm EDT

## Agenda

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8:30 am - 8:45 am

### Welcome and Opening Remarks

Theresa Michele, Office of Nonprescription Drugs, FDA

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## Session 1: Formulation Considerations for Solid Oral Candy-Like Dosage Forms

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8:45 am – 9:05 am

### Overview of USP Monographs

Natalia Davydova, United States Pharmacopeia (USP)

9:05 am – 9:25 am

### Drug Product Palatability

David Tisi, Senopsys

9:25 am – 9:45 am

### 3D Printing Technologies for Oral Drug Delivery

Xiaoling Li, Thomas J Long School of Pharmacy, University of the Pacific

9:45 am – 10:30 am

### PANEL 1: Formulation Considerations for Solid Oral Candy-Like Dosage Forms

**Moderator:** Danae Christodoulou, Office of Pharmaceutical Quality, FDA

**Panelists:** Natalia Davydova, Jeffrey Worthington (Senopsys), Xiaoling Li, Swapan De (Office of Pharmaceutical Quality, FDA)

10:30 am – 10:40 am

### Break

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## Session 2: Exploring the Impact of Candy-Like Characteristics on Medication Adherence in Pediatric and Geriatric Populations

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<b>10:40 am – 11:00 am</b>	<b>Impact of Candy-Like Characteristics on Medication Adherence in Pediatric Populations</b>  Rachel Meyers, Ernest Mario School of Pharmacy, Rutgers University
<b>11:00 am – 11:20 am</b>	<b>International Perspectives: Appropriate Pharmaceutical Design of Oral Medicines in Pediatric and Geriatric Populations</b>  Catherine Tuleu, University College London School of Pharmacy
<b>11:20 am – 11:40 am</b>	<b>Use of Sedative Gummy Bears Compared to Oral Syrups in Pediatric Dental Patients</b>  Judith Chin, Department of Pediatric Dentistry Nova Southeastern College of Dental Medicine
<b>11:40 am – 12:25 pm</b>	<b>PANEL 2: Exploring Candy Market Trends and Implications for Medication Adherence in Pediatric and Geriatric Populations</b>  <b>Moderator:</b> Gilbert Burckart, Office of Clinical Pharmacology, Pediatrics, FDA  <b>Panelists:</b> Rachel Meyers, Catherine Tuleu, Judith Chin
<b>12:25 pm – 1:30 pm</b>	<b>Lunch</b>

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## Session 3: Assessment of Accidental Pediatric Exposure to Candy-like Nonprescription Medications and Potential Overdose Mitigation Strategies

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<b>1:30 pm – 1:50 pm</b>	<b>A Case Study of Unintended Consequences: Children and “Candy” Aspirin in Twentieth Century America</b>  Cynthia Connolly, University of Pennsylvania, School of Nursing
<b>1:50 pm – 2:10 pm</b>	<b>Preventing Pediatric Medication Overdose: Strategies, Challenges, and Innovations</b>  Jennifer Lind and Maribeth Sivilus, The Prevention of Overdoses and Treatment Errors in Children Taskforce (PROTECT) Initiative and Centers for Disease Control and Prevention (CDC)
<b>2:10 pm – 2:30 pm</b>	<b>Poison Control Guidelines for Overdoses</b>

Christopher Hoyte, Rocky Mountain Poison and Drug Safety (RMPDS)

**2:30 pm – 2:50 pm**

**Pediatric Ingestions of Gummy-Formulated Medications**

Suzanne Doyon, Connecticut Poison Control Center, UConn Health

**2:50 pm – 3:00 pm**

**Break**

**3:00 pm – 3:50 pm**

**PANEL 3: Assessment of Accidental Pediatric Exposure to Candy-like Nonprescription Medications and Potential Overdose Mitigation Strategies**

**Moderator:** Kristine Parbuoni, University of Maryland, School of Pharmacy

**Panelists:** Cynthia Connolly, Jennifer Lind, Maribeth Sivilus, Christopher Hoyte, Suzanne Doyon

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**3:50 pm – 4:00 pm**

**Closing Remarks and Next Steps**

Theresa Michele, Office of Nonprescription Drugs, FDA

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