

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

8:30 am - 8:45 am

Welcome and Opening Remarks

Theresa Michele, Office of Nonprescription Drugs, FDA

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

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

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

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

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

1:30 pm – 1:50 pm	A Case Study of Unintended Consequences: Children and “Candy” Aspirin in Twentieth Century America Cynthia Connolly, University of Pennsylvania, School of Nursing
1:50 pm – 2:10 pm	Preventing Pediatric Medication Overdose: Strategies, Challenges, and Innovations 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)
2:10 pm – 2:30 pm	Poison Control Guidelines for Overdoses

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

3:50 pm – 4:00 pm

Closing Remarks and Next Steps

Theresa Michele, Office of Nonprescription Drugs, FDA
