Use of Orally Ingestible Unapproved Prescription Drug Products Containing Fluoride in the Pediatric Population

Hybrid Public Meeting

Wednesday, July 23, 2025 | 9:30am – 4pm (eastern)

In-person: 10903 New Hampshire Ave, Bldg. 31 Conference Center, Great Room, Silver Spring, MD 20993-0002

Virtual: Link to follow

Meeting Description

This hybrid public meeting, convened by the Reagan-Udall Foundation for the FDA in collaboration with the FDA, aims to gather input on the clinical use and safety of ***orally ingestible unapproved prescription fluoride drug products*** in children, such as drops and tablets. Some of these products have been used since the 1940s to prevent tooth decay in areas with low or no water fluoridation. This meeting is ***not*** about adding fluoride to drinking water and is ***not*** a decision-making forum.

Draft Agenda

9:30am **Welcome**

- Susan C. Winckler, RPh, Esq.
  CEO, Reagan-Udall Foundation for the FDA

9:35am **Opening Remarks**

- Jacqueline Corrigan-Curay, JD, MD
  Principal Deputy Center Director, Center for Drug Evaluation and Research, FDA

9:45am **Session 1: Scope of Use of Orally Ingestible Unapproved Prescription Drug Products Containing Fluoride in Clinical Practice**

Session Description: *This session will explore the current scope and patterns of use of orally ingestible unapproved prescription drug products containing fluoride within clinical practice settings*

Presentations:

- Sally Greenberg, JD, Lived Patient Experience
- James H. Bekker, DMD, University of Utah School of Dentistry
- Bill Osmunson, DDS, MPH, Fluoride Action Network

Reactor Panel (30 min)

- Linda Birnbaum, PhD, DABT, ATS, Duke University, National Institute of Environmental Health Sciences
- David Krol, MD, MPH, FAAP, American Academy of Pediatrics
- Scott Tomar, DMD, MPH, DrPH, University of Illinois Chicago College of Dentistry

10:45am **Break**

11am **Session 2: Identifying Safety Concerns and Potential Risks Associated with the Use of Orally Ingestible Unapproved Prescription Drug Products Containing Fluoride**

Session Description: *This session will examine safety concerns and potential risks related to the use of orally ingestible unapproved prescription drug products containing fluoride*

Presentations:

- Valerie Heaton, Lived Patient Experience
- Jennifer Webster-Cyriaque, DDS, PhD, National Institutes of Health

Oral and Gut Microbiome

- Purnima Kumar, BDS, MDS, PhD, University of Michigan School of Dentistry
- Gary Moran, BA (Mod), PhD, FTCD, Trinity College Dublin

Neurocognitive

- Griffin Cole, DDS, NMD, MIAOMT, International Academy of Oral Medicine and Toxicology
- Jayanth Kumar, DDS, MPH*, formerly at* California Department of Public Health
- Susan Fisher-Owens, MD, MPH, University of California San Francisco
- Kyla Taylor, PhD, National Institutes of Health

Thyroid

- Christine Till, PhD, C.Psych, York University
- Kathleen Thiessen, PhD, Oak Ridge Center for Risk Analysis

Reactor Panel (30 min)

- Bruce Lanphear, MD, MPH, Simon Fraser University
- Charlotte W. Lewis, MD, MPH, University of Washington School of Medicine

1pm **Lunch Break**

2pm **Public Comment on 4 Topics**

- Clinical Use and Prescribing Considerations for Pediatric Tooth Decay Prevention
- Safety Concerns
- Appropriateness of Pediatric Use Considering Additional Sources of Exposure
- Impact of Removal of Orally Ingestible Unapproved Prescription Drug Products /Potential Alternatives

3:55pm **Adjourn**

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