CareQuest Institute for Oral Health®

Dockets Management Staff (HFA-305)
Food and Drug Administration
530 Fishers Lane, Room 1601
Rockville, Maryland 20852

July 16, 2025

**Re: FDA Advisory Committee Meeting – Use of Orally Ingestible Prescription Drug Products Containing Fluoride for the Pediatric Population**

Docket No. FDA-2025-N-1557

On behalf of CareQuest Institute for Oral Health, we thank the U.S. Food and Drug Administration for convening this important discussion regarding the safety and efficacy of orally ingestible prescription fluoride drug products for the pediatric population.

As a national nonprofit championing better oral health for all, CareQuest Institute advances systems change through grantmaking, research, policy and advocacy, health improvement programs, and education. Central to our mission is the promotion of evidence-based strategies to prevent oral disease and increase healthcare access, particularly for underserved and vulnerable communities, including children.

Fluoride supplements are widely proven to be safe to overall health and a valuable tool to improving overall health. The United States Preventive Services Task Force recommends that primary care clinicians prescribe oral fluoride supplementation starting at age 6 months for children who are at increased risk for dental caries and whose water supply is deficient in fluoride.[1] This recommendation is supported by strong clinical evidence. A 2011 Cochrane Review found that fluoride supplements taken daily reduced decayed, missing, and filled tooth surfaces in permanent teeth by 24% compared to placebo or no treatment.[2]

The safety profile of systemic fluoride supplementation, when used appropriately, is also well established. Adverse effects are rare and primarily limited to mild dental fluorosis when dosages exceed recommended levels during early tooth development. Systematic reviews, including one by the National Toxicology Program, have found no association between fluoride exposure at recommended levels (below 1.5 ppm F) and adverse neurodevelopmental outcomes in children.[3] The American Academy of Pediatrics and the American Dental Association both emphasize that when used under professional supervision, fluoride supplementation is safe and effective.[4] [5]

Fluoride supplements remain a critical preventive healthcare strategy as millions of Americans, especially in rural or low-income communities, do not have access to local, affordable dental care. In these areas, ingestible fluoride plays a critical role in preventing dental caries, and families should continue to have the right to choose for their children to receive fluoride supplements. Dental caries remains the most common chronic disease of childhood in the United States. More than half (52%) of children aged 6–8 have experienced tooth decay in their primary teeth, with higher prevalence among children from low-income families and communities of color.[6] For these families, orally ingested fluoride therapy prescribed by health professionals can help bridge the gap and protect vulnerable children from the preventable consequences of tooth decay, including pain, infection, missed school days, and costly treatment.

In alignment with our mission to create a more accessible and integrated oral health system, we strongly urge the FDA to keep pediatric fluoride prescription therapies on the market and available to children and families who choose to use it. Ensuring these products remain available for pediatricians and dentists to prescribe is critical to improving our nation's oral health.

We appreciate the FDA's thoughtful consideration of the evidence and its ongoing commitment to protecting children's health. If you have any questions or need additional information, please feel free to contact me at msteele@carequest.org.

Sincerely,

Matthew Steele

Matthew Steele
Director of State and Local Advocacy
CareQuest Institute for Oral Health

**Endnotes**

1. U.S. Preventive Services Task Force. Prevention of Dental Caries in Children Younger Than Age 5 Years: Screening and Interventions. 2011. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-dental-caries-in-children-younger-than-age-5-years-screening-and-interventions1

2. Cochrane Oral Health Group. Tubert-Jeannin et al. Fluoride supplements (for preventing dental caries in children). Cochrane Database of Systematic Reviews. 2011. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD007592.pub2/full

3. National Toxicology Program. NTP Monograph on the State of the Science Concerning Fluoride Exposure and Neurodevelopment and Cognition: A Systematic Review. NTP Monograph 8. 2024. https://ntp.niehs.nih.gov/sites/default/files/ntp/ohat/fluoride/neurodev/monograph_fluoride_508.pdf

4. American Academy of Pediatrics. AAP reiterates support for fluoride as FDA plans to pull some supplements from the market. 2025. https://publications.aap.org/aapnews/news/32182/AAP-reiterates-support-for-fluoride-as-FDA-plans?_gl=1*kyc807*_ga*MTgxMTA2NDUxNi4xNzQyOTIzMTM2*_ga_FD9D3XZVQQ*czE3NTIyNTM5NzUkbzYkZzEkdDE3NTIyNTQwMzIkajMkbDAkaDA.*_gcl_au*NDI1MTkwMDE2LjE3NTIyNTM5NzY.*_ga_GMZCQS1K47*czE3NTIyNTM5NzYkbzUkZzEkdDE3NTIyNTQwMjIkajE0JGwwJGgw

5. American Dental Association. Fluoride – Topical and Systemic Supplements. 2023. https://www.ada.org/resources/ada-library/oral-health-topics/fluoride-topical-and-systemic-supplements

6. Centers for Disease Control and Prevention. Children's Oral Health Fast Facts. 2022. https://www.cdc.gov/oral-health/data-research/facts-stats/index.html