



July 16, 2025

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

Docket No. FDA-2025-N-1557

On behalf of the **Michigan Oral Health Coalition**, thank you for the opportunity to provide comments regarding the proposed rule on the use of orally ingestible unapproved prescription drug products containing fluoride in the pediatric population.

The Michigan Oral Health Coalition is a statewide network of more than 100 organizations and individuals working to improve oral health outcomes for all Michiganders, especially vulnerable populations such as children, rural residents, and low-income families. Our members include health professionals, public health agencies, insurers, educators, and advocates dedicated to promoting evidence-based policies that reduce health disparities and strengthen preventive care.

We strongly oppose any action that impacts the continued availability of orally ingestible fluoride prescription products for children. In communities without access to fluoridated water, these supplements serve as a critical and proven tool in the prevention of dental caries (cavities)—still the most common chronic childhood disease in the United States. In Michigan, many rural and underserved areas lack optimal community water fluoridation and face barriers to accessing regular dental care. Fluoride supplements help bridge that gap and reduce preventable oral disease, which is linked to school absenteeism, pain, infection, and long-term health consequences.

The safety and efficacy of these supplements are well established. Over six decades of public health data have confirmed that the use of prescription fluoride reduces the incidence of tooth decay by up to 80% in high-risk populations. When prescribed appropriately and in accordance with guidelines from the American Dental Association (ADA) and the American Academy of Pediatrics (AAP), these therapies are safe and present no credible risk of neurodevelopmental harm. The recent National Toxicology Program review and statements from the CDC and National Academies of Sciences support this conclusion.

We are also mindful of the recent spread of misinformation related to fluoride. It is essential that policy decisions remain grounded in science and public health principles. At therapeutic levels, fluoride—like many essential nutrients—is safe, effective, and beneficial. Denying children access to these preventive therapies would exacerbate existing inequities and harm those least able to afford care.

The Michigan Oral Health Coalition urges the FDA to protect access to pediatric fluoride prescription therapies. These products must remain available for healthcare providers to prescribe and for families to choose. Doing so is essential to advancing health equity, reducing disparities, and safeguarding the oral health of Michigan's children.

Thank you for your leadership and commitment to public health.

Sincerely,

A handwritten signature in blue ink that reads "Mert N. Aksu".

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