July 15, 2025

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2025-N-1557 Use of Orally Ingestible Unapproved Prescription Drug Products Containing Fluoride in the Pediatric Population

On behalf of the California Dental Association (CDA), representing 27,000 member dentists throughout the state, we write to express strong concern over FDA's proposal to remove orally ingestible fluoride prescription drug products for children from the market.

Prescription drug products containing fluoride are an important tool for preventing tooth decay in children, especially those living in areas without access to fluoridated drinking water, those or who have limited access to topical fluoride, and children with high dental caries risk. These prescription products are safe to use and supported by decades of clinical best practices as recommended by the American Dental Association and the U.S. Preventive Services Task Force (USPSTF). Although the FDA has cited emerging safety concerns, studies that found associations between thyroid hormones, changes to the microbiome, and decreased IQ were all at fluoride levels significantly higher than U.S. prescription products, lack methodological rigor, or have inconclusive findings. The 2021 systematic review by the USPSTF recommends that primary care clinicians prescribe oral fluoride supplementation starting at age 6 months for children whose water supply is deficient of fluoride. The USPSTF is considered the gold standard for clinical prevention, and their review found appropriate use of ingestible fluoride prescriptions to have significant reduction in caries incidence without other side effects. Appropriate prescription practices result in the well-established public health benefits of optimal fluoride exposure in preventing early childhood caries and lifelong oral health benefits.

The currently proposed action would remove a valuable clinical option and limit the shared decision-making ability between healthcare providers and family members to choose these evidence-based preventive products for the children trusted in their care. While FDA and HHS officials have publicly emphasized the importance of respecting parental freedom in health care decisions, this proposal effectively eliminates a choice, despite its safety, affordability, and long-standing public health value. CDA urges the FDA to preserve access to prescription fluoride supplements and ensure that any regulatory decision is guided by high-quality scientific evidence and a commitment to preserving clinician and parent choice in pediatric care.

Sincerely,

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