

July 16, 2025

Marty Makary, M.D., M.P.H.
Commissioner
Food and Drug Administration (FDA)
10903 New Hampshire Avenue
Silver Spring, MD 20993

Docket No. FDA– 2025–N–1557

Dear Dr. Makary,

On behalf of our 40,000 members, the Academy of General Dentistry (AGD) offers the following response to FDA’s request for comments on the use of orally ingestible prescription drug products containing fluoride in the pediatric population. AGD dentists provide a full range of dental care to patients of all ages, demographics, and socioeconomic segments throughout the country.

According to the Federal Register notice, prescription fluoride drops and tablets for ingestion were first marketed in the United States in the 1940’s to prevent dental caries, particularly for children who lived in areas with low or no water fluoridation. Although these products are prescribed today, we understand that none have been reviewed and approved by the FDA for safety, effectiveness, or quality.

As some communities are foregoing water fluoridation, it is important to ensure that alternative sources of fluoridation remain accessible to patients that may need them. Safety concerns in the scientific literature are generally attributed to fluoride levels significantly higher than those found in the prescription drug products marketed in the U.S. The AGD supports the availability of fluoride drops and tablets for the pediatric population to prevent tooth decay.

We urge the FDA to do due diligence and make a swift determination regarding the safety and effectiveness of these products, particularly at a time when parents may have few options for caries prevention due to water fluoridation being curtailed in their local community.

The Centers for Disease Control and Prevention (CDC) recognizes that community water fluoridation benefits all members of a community by preventing cavities, reducing oral health disparities, and saving money for everyone. Due to a dramatic decrease in tooth decay, the CDC named community water fluoridation one of 10 great public health achievements of the 20th century.¹

While fiscal matters are not a consideration for the FDA, they are for public health, the United States budget, and families. In a simulation eliminating fluoride, dental caries prevalence and total number

¹ Centers for Disease Control and Prevention. Achievements in public health, 1900-1999: fluoridation of drinking water to prevent dental caries. *MMWR Morb Mortal Wkly Rep.* 1999;48(41):933–940.
<https://www.cdc.gov/mmwr/preview/mmwrhtml/mm4841a1.htm>

of decayed teeth were estimated to increase by 7.5 percentage points, at a cost of \$9.8 billion over 5 years.²

In Closing

The AGD thanks the FDA for considering our comments on the use of orally ingestible prescription drug products including fluoride for the pediatric population. We look forward to the opportunity to work with federal officials. If you have questions or would like to discuss our comments in greater detail, please contact Daniel J. Buksa, JD, CAE, Executive Director, by phone at (312) 440-4328 or via email at daniel.buksa@agd.org.



Chethan Chetty, DDS, MAGD
AGD President

CC: jk

Cc:
Daniel Buksa, JD, CAE
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² Sung Eun Choi, SM, PhD, Lisa Simon, MD, DMD. Projected Outcomes of Removing Fluoride From US Public Water Systems. Projected Outcomes of Removing Fluoride From US Public Water Systems. JAMA. May 30, 2025. 6;(5):e251166. doi:10.1001/jamahealthforum.2025.1166. <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2834515?guestAccessKey=fd1c0a1d-7251-4625-84cf-571c900545f7>