



Use of Orally Ingestible Unapproved Prescription Drug Products Containing Fluoride in the Pediatric Population; Public Meeting; Establishment of a Public Docket; Request for Comments [FDA Docket No: FDA-2025-N-1557]

Comments of the American Dental Education Association

July 16, 2025

Oral fluoride supplements play an important role in supporting good oral health in children, which in turn leads to better health and lower health care costs. They are a powerful tool for disease prevention, particularly in combating dental caries, commonly known as cavities, which remain the most prevalent chronic disease among children.¹ In areas that lack community water fluoridation or where fluoride levels are suboptimal per the Centers for Disease Control and Prevention's (CDC's) recommendations, or where access to oral health care is scarce, including topically applied fluoride treatments, orally ingestible fluoride prescription products, primarily drops and tablets, have played an essential role in preventing dental caries in children. Despite the fact that these products have never been formally approved by the U.S. Food and Drug Administration (FDA), they have long been considered a standard of care in pediatric dental prevention and have a decades-long history of safe use in children when appropriately prescribed. Major dental organizations, including the American Dental Association (ADA) and the American Academy of Pediatric Dentistry, have consistently recommended the targeted use of these supplements. Their guidance is based on a substantial body of clinical and research evidence supporting the effectiveness of systemic fluoride in reducing the incidence of caries in pediatric populations.^{2,3}

The benefits of fluoride in promoting children's oral health are well established and essential during tooth development. Fluoride aids in the remineralization of enamel and enhances its resistance to acid attacks from bacteria and dietary sugars, which are key contributors to dental caries.⁴ In children whose teeth are still forming and are more susceptible to decay, fluoride can play a crucial protective role.⁵ When administered systemically, such as through tablets or drops, fluoride can become part of the tooth structure during development, enhancing resistance to future decay.⁶ This method is particularly beneficial for children living in areas without access to fluoridated community water systems or who are at increased risk of dental caries due to nutritional factors or socioeconomic status.^{7,8} When prescribed appropriately and used under professional guidance, fluoride supplements remain a safe, evidence-based, and

¹ <https://www.nidcr.nih.gov/news-events/nidcr-news/2024/big-hopes-little-teeth#:~:text=What%20is%20the%20most%20common,of%20children%20in%20the%20U.S.>

² American Dental Association. (2010). ADA Fluoride Supplement Dosage Schedule. <https://www.ada.org>.

³ American Academy of Pediatric Dentistry. (2021). *Policy on Use of Fluoride*. <https://www.aapd.org>.

⁴ *Journal of the American Dental Association*, 131(7), 887–899. <https://doi.org/10.14219/jada.archive.2000.0307>.

⁵ <https://www.aapd.org/research/oral-health-policies--recommendations/fluoride-therapy/>

⁶ Buzalaf, M. A. R., Pessan, J. P., Honório, H. M., & ten Cate, J. M. (2011). Mechanisms of action of fluoride for caries control. *Monographs in Oral Science*, 22, 97–114. <https://doi.org/10.1159/000325151>.

⁷ American Dental Association. (2018). *Fluoride supplements*. <https://www.ada.org/resources/research/science-and-research-institute/oral-health-topics/fluoride-supplements>.

⁸ Dye, et al. Trends in dental caries in children and adolescents according to poverty status in the United States from 1999 through 2004 and from 2011 through 2014. <https://pubmed.ncbi.nlm.nih.gov/28619207/>.

cost-effective tool in preventing early childhood caries and promoting long-term oral health.⁹ Their sustained availability to oral health professionals is a cornerstone of preventive oral health care that ensures preventive care reaches the populations who need it most.

In light of current scientific evidence, the American Dental Education Association (ADEA) strongly supports the easy availability of fluoride supplements to competent oral health professionals and the use of orally ingestible prescription drug products containing fluoride in the pediatric population. We believe these products remain a safe and effective means of preventing tooth decay and promoting oral health nationwide.

The FDA requested comments on the following topics:

- 1. “Please comment on the evidence supporting the current clinical uses of orally ingestible unapproved prescription drug products containing fluoride for tooth decay prevention in the pediatric population. What factors do clinicians consider when prescribing such drug products for the pediatric population?”**

Oral health clinicians who prescribe these supplements do so thoughtfully, evaluating multiple factors including a child’s risk for dental decay, access to dental services, socioeconomic status, and fluoride concentration in their local drinking water. According to dosing guidelines published by the ADA, children from 6 months to 16 years of age may receive fluoride supplements if their community water supply contains less than 0.6 parts per million (ppm) of fluoride.^{10,11} This targeted, evidence-based approach is designed to maximize the protective benefits of fluoride while minimizing the risk of adverse effects, such as dental fluorosis. Specific recommendations¹² exist for dietary fluoride supplementation in children ages 6 months through 16 years based on several factors, including the fluoride level in drinking water, other dietary sources of fluoride, use of fluoridated toothpaste, and caries risk.¹³ As such, the use of systemic and topical fluoride products, whether provided in a clinical or home setting, is determined by the individual needs of each patient.

Furthermore, a 2019 analysis of Medicaid claims data for children in this age group across states with varying levels of community water fluoridation found that prescribing patterns for fluoride supplements generally aligned with established clinical guidelines. Additionally, real-world utilization was often suboptimal: many children received only short-duration prescriptions (average ~72 days per fill) and a small proportion in already fluoridated areas received supplements unnecessarily.¹⁴ These findings suggest that while clinical guidelines are widely adopted and serve as an effective framework for fluoride supplementation, the actual use in practice tends to lean more toward underutilization than overuse.

⁹ U.S. Preventive Services Task Force. Screening and Preventive Interventions for Oral Health in Children and Adolescents Aged 5 to 17 Years. <https://jamanetwork.com/journals/jama/fullarticle/2811427>.

¹⁰ American Dental Association. (2010). ADA Fluoride Supplement Dosage Schedule. <https://www.ada.org>.

¹¹ ADA. Evidence-based clinical recommendations on the prescription of dietary fluoride supplements for caries prevention: a report of the American Dental Association Council on Scientific Affairs.

<https://pubmed.ncbi.nlm.nih.gov/21158195/> and <https://publications.aap.org/pediatrics/article/146/6/e2020034637/33536/Fluoride-Use-in-Caries-Prevention-in-the-Primary>

¹² APD. Fluoride Therapy (2023). https://www.aapd.org/media/Policies_Guidelines/BP_FluorideTherapy.pdf.

¹³ AAPD. Caries-Risk Assessment and Management for Infants, Children, and Adolescents (2022). https://www.aapd.org/globalassets/media/policies_guidelines/bp_cariesriskassessment.pdf.

¹⁴ Griffin et al. Filled dietary fluoride supplement prescriptions for Medicaid-enrolled children living in states with high and low water fluoridation coverage. <https://pmc.ncbi.nlm.nih.gov/articles/PMC7977682/>.

The effectiveness and safety of orally ingestible fluoride products is well documented in scientific literature. A Cochrane systematic review found that fluoride supplements, when taken regularly during the tooth development period, can reduce caries incidence in permanent teeth by approximately 24%.¹⁵ The benefits are particularly pronounced in children from communities who lack access to fluoridated water or regular oral health care. It is important to note that for many such children, these supplements are the only source of systemic fluoride exposure during critical periods of enamel development. In the absence of these products, the risk of early childhood caries, a condition associated with pain, infection, difficulty eating and speaking, and time lost from school, would increase significantly.

2. “Please comment on the safety concerns associated with these drug products, taking into account the amount of fluoride they provide when used as directed for prevention of tooth decay prevention in the pediatric population.”

Concerns about the use of ingested fluoride in children do exist. One of the primary issues is the risk of dental fluorosis, a condition caused by excessive fluoride intake during the years of tooth development, resulting in white spots or streaks on the enamel.¹⁶ In rare and extreme cases, more severe enamel discoloration or pitting can occur. Additionally, some groups have raised concerns about potential links between high fluoride exposure and systemic health issues, such as cognitive effects or skeletal problems, although these claims are not consistently supported by high-quality scientific evidence.¹⁷

The consensus among scientific and medical communities is that the benefits of fluoride use in children, which include the use of orally ingestible prescription drug products containing fluoride, far outweigh the risks. Most cases of fluorosis in the United States are mild and cosmetic in nature, while the damage caused by untreated dental decay can be painful, expensive to treat, and harmful to overall health and development.¹⁸

Emerging studies have raised potential questions related to thyroid hormone regulation and changes to the gut microbiome. While these findings warrant careful examination, it is essential to place them in the appropriate scientific and public health context.

Regarding thyroid function, some studies have observed associations between higher fluoride exposure and altered thyroid hormone levels. For example, a Canadian study by Malin, et al., reported that individuals exposed to higher fluoride levels, especially those with low iodine intake, had elevated thyroid-stimulating hormone (TSH) levels and lower triiodothyronine (T3).¹⁹ However, this research primarily examined populations exposed to community water fluoridation, not low-dose fluoride supplements. The fluoride doses used in prescription products in the United States are generally between 0.25 mg and 1 mg per day—doses substantially lower than those typically examined in studies reporting thyroid disruption.

¹⁵ Tubert-Jeannin, S., et al. (2011). Fluoride Supplements for Preventing Dental Caries in Children. *Cochrane Database of Systematic Reviews*.

¹⁶ Centers for Disease Control and Prevention. (2010). *Community water fluoridation: Questions and answers*. <https://www.cdc.gov/fluoridation/faqs/index.htm>.

¹⁷ National Research Council. (2006). *Fluoride in drinking water: A scientific review of EPA's standards*. Washington, DC: The National Academies Press.

¹⁸ U.S. Public Health Service. (2015). *U.S. Public Health Service recommendation for fluoride concentration in drinking water for the prevention of dental caries*. *Public Health Reports*, 130(4), 318–331. <https://doi.org/10.1177/003335491513000408>.

¹⁹ Malin, A. J., et al. (2018). Fluoride Exposure and Thyroid Function Among Adults in Canada. *Environmental International*, 121, 667–674.

Concerns about potential effects on the microbiome are also speculative. Most relevant studies have been conducted in animal models or in populations with exposure to much higher fluoride levels than those provided by prescription supplements. For instance, a study by Kumar, et al., using mice found significant changes to gut microbial composition after chronic high-dose fluoride exposure.²⁰ However, translating these findings to children receiving medically guided low-dose supplements is premature without further research. No scientific human studies have yet demonstrated clinically significant microbiome changes at these exposure levels.

The safety concerns associated with ingestible fluoride products at therapeutic doses remain inconclusive and lack definitive evidence of harm. Current data do not support discontinuation of these products based solely on potential, unproven risk, particularly when weighed against the well-established benefit of caries prevention in vulnerable populations. The total systemic fluoride burden must be monitored and considered holistically, especially since children may be exposed to fluoride from multiple sources, including toothpaste, processed foods, and dental treatments. However, targeted use of prescription fluoride supplements in nonfluoridated areas continues to offer meaningful protection with minimal risk when properly dosed by an oral health professional.

3. “Based on the totality of the data available today, please comment on the continued use of these drug products for tooth decay prevention in the pediatric population considering the additional sources of fluoride available.”

The continued availability of ingestible fluoride supplements remains vital. Despite the expansion of community water fluoridation in the United States, an estimated 27% of the U.S. population, roughly 90 million people, still rely on water sources without optimal fluoride levels.²¹ Many of these communities are rural, low-income, or geographically isolated, with limited access to professional oral health care. For children in such areas, fluoride supplements may represent the only practical method of caries prevention. Eliminating these products from the market without a feasible substitute would likely increase the burden of dental disease among the very populations already most affected.

4. “From the perspective of patients and clinicians, what are the potential products from the market? Are there alternatives to use of these ingestible drug products to achieve these ends?”

The fluoride preventive effect works differently with different delivery mechanisms. Fluoride tablets and topical fluoride varnish prevent tooth decay through distinct mechanisms. Fluoride tablets are ingested and can be incorporated into the structure of developing teeth, increasing their resistance to acid attacks. In contrast, topical fluoride—such as varnish—is applied directly to the tooth surface, where it strengthens enamel and promotes the remineralization of early decay.²²

From the perspective of oral health professionals, removing ingestible fluoride products would eliminate a critical preventive tool. Without them, dentists and allied oral health

²⁰ Kumar, A., et al. (2020). Fluoride Exposure Impacts the Gut Microbiota of Mice. *Scientific Reports*, 10, 1362.

²¹ Center for Disease control and Prevention. [2020 Water Fluoridation Statistics](#). Public Health May 15, 2024. Accessed on July 9, 2025.

²²Nassar Y and Brizuela M. The Role of Fluoride on Caries Prevention (2023). <https://www.ncbi.nlm.nih.gov/books/NBK587342/>.

professionals would have to rely more heavily on topical fluoride applications, which often require in-person dental visits every 6 months—if the child has a dental home and the family is regularly bringing the child to these 6-month checkups. Fluoridated toothpaste is helpful but depends on daily compliance and adequate adult supervision—factors that are not guaranteed in all households. Community water fluoridation remains the most effective and equitable means of fluoride delivery, but expansion efforts continue to face legislative, logistical, and political barriers.

Rather than remove these products from the market, the FDA might consider collaborating with other units within HHS to increase the number and availability of oral health professionals so their training and experience can inform the right therapeutic judgement for the pediatric population.

About ADEA: The American Dental Education Association (ADEA) is The Voice of Dental Education. Our mission is to lead and support the health professions community in preparing future-ready oral health professionals. Our members include all 79 U.S. and Canadian dental schools, more than 800 allied and advanced dental education programs, more than 50 corporations and approximately 15,000 individuals. Our activities encompass a wide range of research, advocacy, faculty development, meetings and communications, including the esteemed *Journal of Dental Education*[®], as well as the dental school application services ADEA AADSAS[®], ADEA PASS[®], ADEA DHCAS[®] and ADEA CAAPID[®]. For more information, visit adea.org.
