

July 11, 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

To Whom It May Concern:

As the leading authority on oral health in the United States, the American Dental Association (ADA), representing more than 159,000 dentists nationwide, submits the following comments in response to the request for input on the use of orally ingestible unapproved prescription drug products containing fluoride in the pediatric population, as outlined in the Federal Register notice of June 16, 2025 (90 FR 25329).

The FDA has empaneled the Reagan-Udall Foundation to develop a report on the many perspectives about the safety of prescription-strength fluoride supplements, with an emphasis on neurodevelopment and IQ scores, the gut microbiome, and thyroid function. These perspectives will be debated by researchers and advocates at a July 23 meeting.

Our detailed comments are provided in six parts, based on the above-mentioned *Federal Register* notice and the FDA's press release of May 13, 2025. You will find that the plurality of generally accepted scientific evidence does not support the hypothesis that fluoride ingestion is harmful, certainly not at recommended levels of exposure.

[Attachment A](#)—Are fluoride supplements effective in helping to prevent tooth decay?
[Attachment B](#)—When and how do dentists prescribe fluoride supplements?
[Attachment C](#)—Does fluoride ingestion affect neurodevelopment and IQ scores?
[Attachment D](#)—Does fluoride ingestion affect the gut microbiome?
[Attachment E](#)—Does fluoride ingestion affect thyroid function?
[Attachment F](#)—Are other health claims about fluoride ingestion justified?

The ADA welcomes the opportunity to assist the Reagan-Udall Foundation and the FDA with its review of scientific evidence, which includes sharing the best available scientific literature examining the safety of all fluoride-containing oral health products. It also includes providing access to independent peer reviewers with intimate knowledge about the strengths and weaknesses of the current literature.

Additionally, we would be pleased to share the latest edition of our compendium of answers to frequently asked questions about the safety, health benefits, and cost-effectiveness of not only community water fluoridation, but all sources of fluoride. Our goal in developing this

document, *Fluoridation Facts*, is to provide clear, well-cited answers to help policy makers and the public navigate the many myths and misperceptions about fluoride exposure(s).

Fluoridation Facts explores the symbiotic relationship between all fluoride-containing sources, including community water fluoridation; fluoride toothpastes and rinses; professionally applied fluoride foams, gels, and varnish; and prescription-strength supplements. You will find that use of these products is not an either/or proposition. Rather, they work in concert to prevent tooth decay and improve oral health in a safe, comprehensive, and time-tested manner.

Again, we would welcome the opportunity to explore how the ADA can partner with FDA on a review of prescription-strength fluoride supplements. In the meantime, we urge you to prioritize high-quality studies that are consistent with the review standards of the National Academies of Science, Engineering and Medicine, and other reputable scientific organizations—and discount literature that does not meet that standard.

Thank you for providing the opportunity to comment. If you have any questions, comments or require additional information, please contact Mr. Robert J. Burns at 202-789-5176 or burnsr@ada.org.

Sincerely,

/s/

Brett Kessler, D.D.S.
President

BHK:EAS:rjb
Enclosures (6)

/s/

Elizabeth Shapiro, D.D.S., J.D., C.A.E.
Interim Executive Director