

FDA NEWS RELEASE

FDA Acts to Protect Children from Unapproved Fluoride Drug Products

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For Immediate Release:

October 31, 2025

The U.S. Food and Drug Administration today announced actions to restrict the sale of unapproved ingestible fluoride prescription drug products for children. The FDA sent [notices \(https://www.fda.gov/media/189413/download\)](https://www.fda.gov/media/189413/download) to four companies outlining the agency's intention to take enforcement action against those marketing unapproved fluoride-containing ingestible drugs labeled for use in children under age 3 or older children at low or moderate risk for tooth decay.

"This Halloween, the FDA is driving a stake through the heart of outdated science and protecting our kids from the risks associated with ingestible fluoride," **said Health and Human Services Secretary Robert F. Kennedy Jr.** "It's scary that these products have been used for decades without approval. Today's action raises public awareness, informs medical professionals, and builds on President Trump's commitment to Make Our Children Healthy Again."

The [Make Our Children Healthy Again Strategy \(https://www.whitehouse.gov/wp-content/uploads/2025/09/The-MAHA-Strategy-WH.pdf\)](https://www.whitehouse.gov/wp-content/uploads/2025/09/The-MAHA-Strategy-WH.pdf), released by President Trump's Make American Healthy Again Commission on September 9, 2025, directed the FDA to evaluate fluoride products.

"There are better ways to protect children's teeth than taking unapproved ingestible fluoride, which is now recognized to alter the gut microbiome. The microbiome is increasingly recognized to be central to a child's health and development," **said FDA Commissioner Marty Makary, M.D., M.P.H.**

This action follows months of gathering and evaluating scientific input and engaging with parents, clinicians, advocates, and federal partners through a public meeting and comment period. The FDA has published a [scientific evaluation \(https://www.fda.gov/media/189421/download\)](https://www.fda.gov/media/189421/download) of the current use of unapproved ingestible fluoride drug products and their potential benefits and risks. A [summary](#)

Feedback

(<https://reaganudall.org/news-and-events/events/use-orally-ingestible-unapproved-prescription-drug-products-fluoride>) [↗ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer) of the public meeting and comments is also available online.

The FDA has not reviewed or approved ingestible fluoride drug products for safety, effectiveness, or quality, even though they have been used since the 1940s. Based on the scientific evaluation published today, the agency concluded that such products should not be used in children under age 3 or by older children who are not at high risk of tooth decay. For the same reason fluoride may work to kill bacteria on teeth, it may also alter the gut microbiome, which may have broader health implications.

While evidence indicates fluoride reduces the risk of dental caries in older children, a Cochrane review — an independent analysis that combines results from multiple scientific studies — of the medical literature concluded that fluoride did not reduce dental caries in baby teeth. The FDA also recognizes other preliminary but potentially concerning data on risks, such as a recent meta-analysis suggesting increased fluoride exposure is associated with decreases in IQ.

To help channel this recommendation into clinical practice, the FDA also sent a [letter \(https://www.fda.gov/media/189422/download\)](https://www.fda.gov/media/189422/download) to health care professionals warning about the risks associated with these products. Additionally, the FDA, in partnership with the National Institutes of Health and the U.S. Department of Health and Human Services, is launching development of a fluoride research agenda and the first national oral health strategy. The goal is to close critical research gaps and guide efforts to better combat the most common childhood chronic disease in America.

Media:

[FDA Request for Comment \(https://www.hhs.gov/request-for-comment-form/index.html?Agency=FDA\)](https://www.hhs.gov/request-for-comment-form/index.html?Agency=FDA)
202-690-6343

Consumer:

888-INFO-FDA

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The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The

agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, radiation-emitting electronic products, and for regulating tobacco products.

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