VIA EMAIL

October 31, 2025

NAME
FIRM
ADDRESS
EMAIL

RE: _____

Firm:

Your firm has listed the following unapproved fluoride-containing prescription drug products in FDA's electronic Drug Registration and Listing System (eDRLS): [drug product names omitted]. FDA is notifying you of our intent to pursue compliance action against certain unapproved fluoride-containing prescription drug products, as explained below. We are providing this notice to allow your company time to assess your products and take appropriate corrective actions.

Public Input and Scientific Evaluation

In May 2025, FDA initiated a review of the evidence regarding the risks of orally ingestible fluoride prescription drug products in pediatric populations. FDA subsequently held a public meeting in July 2025 to gather scientific input on this topic, as well as collected public comments through a Federal Register Notice.[1] FDA also conducted a scientific evaluation that provided an analysis of utilization trends, a high-level examination of the benefits and risks of ingestible fluoride drug products, and a recommendation to restrict use of ingestible fluoride drug products. FDA's scientific evaluation concluded that ingestible fluoride drug products should be limited to children aged three years and older who are at high risk for tooth decay.

FDA's Intent to Take Compliance Action

Consistent with our general risk-based enforcement approach and to address potential safety concerns, FDA is providing notice that we intend to take compliance action against companies that market unapproved fluoride-containing ingestible drug products with labeling:

- for children under three years of age; or
- that does not limit use to children at high risk for dental caries, such as those who have a history of tooth decay and lack access to fluoridated drinking water.

FDA continues to review information regarding the use of ingestible fluoride drug products and may consider additional regulatory action to address emerging, serious health risks. Furthermore, FDA will continue to enforce the new drug approval requirements of the Federal Food, Drug, and Cosmetic Act, applying our risk-based enforcement approach to individual unapproved ingestible fluoride drug products.

[1] 90 FR 25329.

U.S. FOOD & DRUG ADMINISTRATION

Firm Action and Response

Within thirty (30) days of receipt of this letter, please notify FDA in writing of the specific steps you intend to take to ensure your products address the safety concerns described above. We are providing this notice to allow your company time to assess your products and implement appropriate corrective actions. If you no longer manufacture or market the above-mentioned product(s), your response should indicate this, including the date on which you ceased production.

Your response should be sent to U.S. Food and Drug Administration, CDER/OC/Office of Unapproved Drugs and Labeling Compliance by email to FDAAdvisory@fda.hhs.gov. Please include your firm name and the unique identifier "_____" in the subject line of the email.

Sincerely,

George F. Tidmarsh, M.D., PhD
Director
Center for Drug Evaluation and Research
Food and Drug Administration