DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 2 1 2000

John V. Kelly
Assemblyman, 36th District
Bergen-Essex-Passaic Counties
371 Franklin Avenue, 2ND Floor
Nutley, NJ 07110

This is in response to your fax dated July 27, 2000, addressed to Lana Orgam, Director, requesting the Office of Compliance to provide an update to the previous communications that your office had with the Food and Drug Administration (FDA) on February 24, 1999, regarding any recent approval of new drug applications for fluoride containing drug products available as tablets for children or fluoride drops for infants. Your fax also referred to regulatory letters issued in 1975 by FDA to thirty-five companies regarding enziflur lozenges, a combination drug product containing fluoride and vitamins. You asked how many of these companies ceased marketing these combination drugs consisting of fluoride and vitamins in 1975.

The fluoride tablet and drop drug products you identified in your fax are not subject to the new drug requirements since they are identical to fluoride drug products marketed prior to 1938. Therefore, the FDA has not reviewed any new drug applications for the fluoride tablets or drops. Drug products marketed now that are identical to drug products marketed prior to the new drug requirements of 1938 and 1962 are presently allowed to be marketed without new drug applications.

Although the fluoride tablets and drops are marketed without new drug applications, FDA has evaluated the safety and effectiveness of other fluoride containing drug products through FDA's Over-the-Counter (OTC) Drug Review. This review has examined drug ingredients that have historically been marketed OTC in the United States. Through the OTC Drug Review, experts identify the ingredients that are generally recognized as safe and effective for their intended use and establish monographs for classes of OTC drug ingredients. Each completed OTC drug monograph considers a particular class of drugs and describes the active ingredients that have been determined to be safe and effective, with specifications for the amount of drug per dose, formulation, labeling, and other general requirements.

The Agency has established a monograph for the OTC use of topical fluoride in anticaries drug products. The monograph recognizes the topical administration of fluoride containing dental anticaries drug products to be generally safe and effective (21 CFR 355). This monograph, published as a final rule, established the safe use of fluoride for the prevention of dental caries under specific recommendation for dosage, formulation, packaging and labeling requirements.

During 1997, FDA reviewed and approved a new drug application for a dental paste containing fluoride. The approval of the new drug application is based on the FDA's evaluation that the submitted data adequately demonstrated the safety and efficacy of the drug (NDA-20231).

In addition to the FDA's reviews, there are other authoritative sources that can provide information on the use of fluoride and fluoridation. The web sites for these sources are: HTPP: //www.cdc.gov and HTPP: //www.ada.org

With respect to the companies previously marketing combination fluoride and vitamin drug products, a search of current information revealed none of these companies to be presently marketing these products. The regulatory letters that were issued in the early 1970's were based on the lack of evidence that the inclusion of a vitamin to a fluoride drug product enhances the effectiveness of fluoride. These fluoride and vitamin combination drug products did not meet the regulatory requirements for fixed combination prescription drugs, Title 21 Code of Federal Regulations, part 300.50, and had to be removed from the market.

Please feel free to contact me at 301-594-0101 with any questions.

Sincerely,

Sakineh M. Walther

Sakineh Walther, Consumer Safety Officer
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