DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

January 28, 1993

Mr. Michael Perone
Office of John V. Kelly
Assemblyman 36th District
Bergen-Essex-Passaic Counties
242.Washington Avenue, Suite D
Nutley, New Jersey 07110

Dear Mr. Perone:

This is in response to our telephone conversation of December 14, 1992 in which you asked whether there are any approved New Drug Applications (NDAs) on file with the Food and Drug Administration (FDA) covering fluoride supplements for infants. We apologize for the delay.

There are no NDAs on file with FDA covering fluoride supplements for infants. However, at a meeting of The FDA's Dental Drug Product Advisory Committee on January 22, 1975 (copy of minutes enclosed) it was unanimously decided to publish in the Federal Register (FR) the conditions under which dietary supplements of sodium fluoride or acidulated phosphate fluoride would be considered safe and effective. These conditions are described in Appendix I of the January 22, 1975 meeting minutes. Even though an FR was not published, as a matter of policy, the FDA has used, in part, the committee's recommendations to evaluate these kinds of products.

Accordingly, if these products are marketed in accordance with the conditions described in Appendix I and also meet the conditions described in Compliance Policy Guide 7132c.02, Marketed New Drugs Without Approved NDAs or ANDAs (Abbreviated New Drug Applications), the FDA does not currently object to the marketing of these products. A copy of Compliance Policy Guide 7132c.02 is enclosed for your reference.

Should you have any further questions regarding this issue, I can be contacted at (301) 295-8073.

Sincerely yours,

Frank R. Fazzari

Frank R. Fazzari
Chief
Prescription Drug Compliance Branch (HFD-313)
Division of Drug Labeling Compliance
Office of Compliance
Center for Drug Evaluation and Research

Enclosure

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