



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 21 1997

John V. Kelly
Assemblyman, 36th District
Bergen-Essex-Passaic Counties
371 Franklin Avenue, 2nd Floor
Nutely, New Jersey 07110

Dear Assemblyman Kelly:

This responds to your February 5, 1997, letter asking whether there have been any drug applications approved by the Food and Drug Administration for fluoride tablets for children or fluoride drops for infants since 1992.

At this time there are no approved new drug applications on file with the Agency for these products. If you have any further questions on this issue I can be contacted at (301) 594-0101.

Sincerely yours,

Frank R. Fazzari
Prescription Drug Strategy Development & PDMA
Division of Prescription Drug Compliance and
Surveillance
Office of Compliance
Center for Drug Evaluation and Research