DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

John V. Kelly
Assemblyman, 36th District
Bergen-Essex-Passie Countries
242 Washington Avenue, Suite D
Nutley, New Jersey 07110

JUN - 8 1993

Dear Mr. Kelly:

This is in response to the questions raised in your June 7, 1993 letter.

1.) Since what year has the Food and Drug Act required that new drug applications be filed with evidence demonstrating the safety of prescription drugs?

On June 7, 1938, the Food, Drug, and Cosmetic Act (FD&C Act) became effective and required that new drug applications be filed with the Agency, with scientific evidence demonstrating the safety of certain drugs.

2.) Since what year has the law required new drug applications to file evidence demonstrating effectiveness?

On October 10, 1962 the FD&C Act was amended to require that new drug applications be file with the Agency, with scientific evidence demonstrating effectiveness in addition to safety. This requirement (effectiveness) was applied retroactively to 1938, when the FD&C Act was passed.

3.) Are there any new drug applications or abbreviated new drug applications on file with the Food and Drug Administration for children's fluoride supplements?

At the present time, there are no approved new drug applications or abbreviated new drug applications on file with FDA for children's fluoride supplements. They can, nonetheless, be marketed in accordance with the conditions described in the package of information forwarded to your office dated January 29, 1993. For your convenience, we have attached a copy of this information.

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

Frank R. Fazzari

Frank R. Fazzari
Chief, Prescription Drug Compliance
Division of Drug Labeling Compliance
Office of Compliance

enclosure