



NEW JERSEY GENERAL ASSEMBLY

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VIA FACSIMILE

June 7, 1993

Mr. Frank Fazzari
Chief
Prescription Drug Compliance Branch
Food and Drug Administration
Rockville, MD 20857

Dear Mr. Fazzari:

My office is preparing an Assembly Resolution and would appreciate the answer to the following three questions:

- 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?
- 2.) Since what year has the law required new drug applications to file evidence demonstrating effectiveness?
- 3.) Are there any new drug applications or abbreviated new drug applications on file with the Food and Drug Administration for childrens fluoride supplements?

Your reply by fax today would be greatly appreciated.

Sincerely,

A handwritten signature in cursive script that reads "John V. Kelly".

JVK:mp