



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 26 2001

John V. Kelly
36th District
Bergen-Essex-Passaic Counties
New Jersey General Assembly
371 Franklin Avenue, 2nd Floor
Nutley, New Jersey 07710

Re: Docket No. 00P-1602/CP1

Dear Mr. Kelly:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on November 6, 2000. Your petition requests that the Agency remove unapproved children's fluoride supplements from the market.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

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