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FDA calls fluoride "an unapproved new drug"

FDA - no research on fluoride safety

June 3, 1993

Dr. David Kessler, M.D., Commiss
United States Food and Drug Admi
Rockville, Maryland 20857

Dear Commissioner Kessler:

My office has been reviewing the i f fluoride supplem hildren since last August. My concern ori d from a report th ew Jersey Department of Health had conducted dy and found the ce of osteosarcoma to be significantly hi in fluoridated c ties versus non-fluoridated ones. The New Jers indings, release November, supported similar findings, by larger nationa udies and by the ional Toxicology Program.

The Food and Drug Administration Off e of Prescription Drug Compliance has confirmed, to my surprise, that there are no studies to demonstrate either the safety or effectiveness of these drugs, which FDA classifies as unapproved new drugs.

The presence of these drugs on the market at this time appears to be contrary to the 1962 amendment to the Food, Drug, and Cosmetic Act, which requires prescription drug applications to provide evidence of effectiveness and the 1938 amendment requiring evidence of safety. There does not appear to be any scientific or legal reason for these products to be on the market at this time.

With the mounting volume of evidence suggesting fluoride's harmful effects it is irresponsible to permit these products to be prescribed to the most vulnerable segment of our population--children.

I am therefore requesting that the public interest be served and the products be removed from the market immediately.

Sincerely,

John V. Kelly

John V. Kelly
Assemblyman 36th District

JVK:knb

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