

February 21, 2001

Acting Commissioner Bernard A. Shwetz
U.S. Food and Drug Administration
Dockets Management Branch
5630 Fischers Lane, Room 1061-HFA-305
Rockville, Maryland 20857

805 '01 FEB 27 P12:27

I am writing to urge you to support **Petition docket number 00P-1602/CP 1, dated 11/6/00**, which requests that the FDA comply with federal law by ordering the removal of fluoride supplements until such time that a proper approval process is completed .

I am the father of four young children, and, as directed by my dentist and pediatrician, have been giving fluoride tablets to my children. Upon discovering that the FDA has never approved this drug, I immediately stopped the practice of allowing my children to ingest this substance. I am particularly bothered by the Battelle study which linked fluoride ingestion to osteosarcoma in young males and by the 1996 Zhao study linking fluoride to impaired brain function .

Fluoride supplements cannot legally use a grandfather clause to escape FDA scrutiny because no form of fluoride supplements were on the market prior to 1938. Sodium fluoride, used primarily as a rat poison prior to 1938, was not even added to water supplies until the 1940's, and it certainly wasn't available in tablet or drop form before 1938. The fluorosilic acid used in most water fluoridation projects wasn't in use until much later. Likewise, FDA's Over-the-Counter OTC Drug Review does not apply to fluoride supplements because, unlike these over-the-counter products which are topical applications, fluoride supplements are intended to be ingested.

I find it shocking that the Food and Drug Administration has allowed over 50 years to elapse without bothering to look into this unapproved drug. This failure becomes especially egregious when it is taken into account that this is the only drug where it is being mandated that every citizen (in communities where water is fluoridated) eat, drink and bathe in this substance. The FDA has been remiss in its duties for far too long. I respectfully request that you support Assemblyman Kelly's petition.



2-21-01

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