



**NEW JERSEY GENERAL ASSEMBLY**

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November 27, 2000

Commissioner Jane Henney, M.D.  
US Food and Drug Administration  
5600 Fischers Lane  
Rockville, Maryland 20857

NOV 27 9 13 AM '00

Dear Commissioner Henney:

I would like to supplement my petition of November 6, 2000, FDA docket number OOP-1602/CP 1, with the Toxicological Profile for Fluorides of US Department of Health and Human Services (TP-91/17, page 112, section 2.6 and 2.7).

Thank you for your assistance in this matter.

Sincerely,

John V. Kelly  
Assemblyman District 36

JK/ki

OOP-1602

SUP 2

**Toxicological  
Profile  
for**

**FLUORIDES, HYDROGEN  
FLUORIDE, AND FLUORINE (F)**

**U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES**  
Public Health Service  
Agency for Toxic Substances and Disease Registry

**TP-91/17**



## 2. HEALTH EFFECTS

### 2.6 INTERACTIONS WITH OTHER CHEMICALS

The absorption of fluoride from the gastrointestinal tract of humans and/or animals is affected by the presence of several minerals including calcium, magnesium, phosphorus, and aluminum (Rao 1984). These effects are discussed in Section 2.8. No reliable data on interactions that exacerbate negative effects of fluoride were located.

### 2.7 POPULATIONS THAT ARE UNUSUALLY SUSCEPTIBLE

Existing data indicate that subsets of the population may be unusually susceptible to the toxic effects of fluoride and its compounds. These populations include the elderly, people with deficiencies of calcium, magnesium, and/or vitamin C, and people with cardiovascular and kidney problems.

Because fluoride is excreted through the kidney, people with renal insufficiency would have impaired renal clearance of fluoride (Juncos and Donadio 1972). Fluoride retention on a low-protein, low-calcium, and low-phosphorus diet was 65% in patients with chronic renal failure, compared with 20% in normal subjects (Spencer et al. 1980a). Serum creatinine levels were weakly correlated ( $r=0.35-0.59$ ) with serum fluoride levels (Hanhijarvi 1982). People on kidney dialysis are particularly susceptible to the use of fluoridated water in the dialysis machine (Anderson et al. 1980). This is due to the decreased fluoride clearance combined with the intravenous exposure to large amounts of fluoride during dialysis. Impaired renal clearance of fluoride has also been found in people with diabetes mellitus and cardiac insufficiency (Hanhijarvi 1974). People over the age of 50 often have decreased renal fluoride clearance (Hanhijarvi 1974). This may be because of the decreased rate of accumulation of fluoride in bones or decreased renal function. This decreased clearance of fluoride may indicate that elderly people are more susceptible to fluoride toxicity.

Poor nutrition increases the incidence and severity of dental fluorosis (Murray and Wilson 1948; Pandit et al. 1940) and skeletal fluorosis (Pandit et al. 1940). Comparison of dietary adequacy, water fluoride levels, and the incidence of skeletal fluorosis in several villages in India suggested that vitamin C deficiency played a major role in the disease (Pandit et al. 1940). Calcium intake met minimum standards, although the source was grains and vegetables, rather than milk, and bioavailability was not determined. Because of the role of calcium in bone formation, calcium deficiency would be expected to increase susceptibility to effects of fluoride. No studies in humans supporting this hypothesis were located. Calcium deficiency was found to increase bone fluoride levels in a two-week study in rats (Guggenheim et al. 1976) but not in a 10-day study in monkeys (Reddy and Srikantia 1971). Guinea pigs administered fluoride and a low-protein diet had larger increases in bone fluoride than those given fluoride and a control diet (Parker et al. 1979).