DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 14 1995

Mr. Walter Miller
5505 Big Oak Drive
San Jose, California 95129

Dear Mr. Miller:

This is in response to your letter of September 12, 1994, to Senator Barbara Boxer, regarding fluoride supplements. Your letter referenced a June 3, 1993, statement released from Assemblyman John V. Kelly (NJ) about a study undertaken by the New Jersey Department of Health exploring the relationship of osteosarcoma with the use of fluoridated water. Mr. Kelly's statement also referenced other studies conducted by the National Toxicology Program (NTP). Additionally, along with the statement by Mr. Kelly, your requested the removal of fluoride supplement products from the market. We apologize for the delay in responding to your letter.

The New Jersey study cited was a small epidemiological study[1] that compared drinking water fluoridation with the occurrence of osteosarcoma in males under 20 years of age. In the final study report, the authors concluded that there is no causal link between fluoridation and the incidence of osteosarcoma in the study population.

Studies reviewed by the National Toxicology Program (NTP), a research and testing program within the U.S. Public Health Service, did not reveal any statistically significant increase in carcinogenicity or in osteosarcoma. This final report was published in February 1991[2]. In this regard, the extensive

---

[1] Cohn, Perry D. A brief report on the association between the New Jersey Department of Environmental Protection and Energy and the New Jersey Department of Health. New Jersey Department of Health, Environmental Health Service. November 8, 1992. In a seven county area, ten cases of osteosarcoma were found in fluoridated areas and seven cases in nonfluoridated areas (males, 10-19 years of age). No interviews were conducted, nor were data collected on individual residential history, use of fluoridated products, average amount of water ingested, exposure to other carcinogens, or familial cancer history.

[2] Report of the Ad Hoc Subcommittee on Fluoride of the Committee to Coordinate Environmental Health and Related Programs of the Public Health Service. Public Health Service, Dept. of Health and Human Services: February 1991.

analysis reported in the NTP study reveals this is unrelated to the introduction and duration of fluoridation (page 82). Further, a human control study of osteosarcoma fluoridation in drinking water conducted between 1989 and 1992 of 147 cases and 248 controls, did not establish any relationship between these two variables. This study was reported in an abstract of the American Association of Dental Research, "A National-Case Control Study of Osteosarcoma and Fluoridation" (AADR Abstracts, 1995: Journal of Dental Research, 74, p. 98).

The NTP findings, together with other animal studies that were reviewed, failed to establish an association between fluoride and cancer. This has been evidenced from the 50 or more epidemiological studies attempting to identify an association between cancer rates and municipal patterns of water fluoridation. The review concluded that these studies did not provide credible evidence of an association between fluoride or adjusted fluoride levels in water and human cancer[3].

The regulation of fluoride in drinking water is under the purview of the U.S. Environmental Protection Agency (EPA). Under the Safe Drinking Water Act of 1974, the EPA sets primary and secondary maximum contaminant levels for fluoride in drinking water. Please contact that agency for further information regarding these matters.

With regard to the regulatory basis for the marketing of fluoride supplements, FDA's Dental Drug Products Advisory Committee evaluated these vitamin/fluoride supplements in January 1975. The Committee concluded that the regular use of vitamin/fluoride supplements will reduce the incidence of dental caries (copy of minutes attached - Appendix I). As a matter of policy, the FDA has used, in part, the committee's recommendations to evaluate such products.

Accordingly, if these products are marketed pursuant to the conditions described in Appendix I, and also meet the conditions described in the Compliance Policy Guide 7132c.02, Marketed New Drugs Drugs Without Approved NDAs or ANDAs (Abbreviated New Drug Applications), the FDA does not currently object to the marketing of these products. A copy of Compliance Policy Guide 7132c.02 is enclosed for your reference. If, however, additional information becomes available that questions the safety and efficacy of these products, the FDA will take the appropriate regulatory action. A number of fluoride products also are marketed as over-the-

---

[3] Ibid., p. 85

counter drugs and are regulated under FDA's over-the-counter drug monograph system.

Since the prescription of fluoride supplements to individual patients is a matter of professional practice, the American Dental Association (ADA), working together with the American Academy of Pediatrics (AAP) has recently adopted a new fluoride supplement dosage schedule. The Council on Dental Therapeutics of the ADA has recommended a lower dosage schedule for the prescription of fluoride supplements in their May 16, 1994, issue of ADA News "New Fluoride Schedule Adopted". This new dosage indicates that supplements are not needed when the level of water fluoride content is greater than 0.6 parts per million (instead of the previous content of 0.7 parts per million). This new policy supersedes the 1986 AAP policy statement entitled "Fluoride Supplementation" which reflected the previous higher dosage schedule.

We appreciate your concern for these issues and hope this information is helpful. Please be assured that whenever new data are submitted to FDA, we review this information so that any appropriate policy changes can be made to protect the public health. In addition, because fluoride is regulated and/or studied by several agencies, any final decision may involve several government orginizations.

We hope this information is helpful.

Sincerely,

for JoAnne C. Barrone

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

2 Enclosures
Appendix I
Compliance Policy Guides Chapter 32c

cc: The Honorable Barbara Boxer
United States Senator
Washington, D.C. 20510-0505