

FLUORIDATED BOTTLED WATER

SUMMARY: The recent health claim notification for fluoridated bottled water provisionally approved by the US Food and Drug Administration is shown to be scientifically unsound except for the exclusion of the use of such water by infants.

Keywords: Bottled water; Fluoride and dental caries; Fluoride hazards; Food and Drug Administration; Health claim notification; Infant formula; Water fluoridation.

Water fluoridation was introduced on a trial (or “demonstration”) basis in the 1940s and later widely promoted by health authorities as a viable dental public health measure that would significantly help prevent tooth decay. At the time, the US Food and Drug Administration (FDA) did not rule on claims for its safety or effectiveness. Instead, the FDA took the position that water fluoridation did not come under its purview but fell under the aegis of the US Public Health Service (USPHS).¹ Later, in the 1970s, the US Environmental Protection Agency (EPA) became responsible for regulating fluoridation, and afterward the US Centers for Disease Control actively encouraged and promoted it. Endorsements of fluoridation by various dental and medical officials and groups like the World Health Organization and other professional bodies are based largely on the original approvals by public health authorities.¹

Recently, the FDA, in the centennial year of its origin in 1906, reversed its previous position and, on October 14, 2006, issued a *Health Claim Notification for Fluoridated Water and Reduced Risk of Dental Caries*.² With this document the FDA approved by default after 120 days a health claim notification filed on June 16 by the law firm of Covington and Burling to allow marketing in the United States of bottled drinking water containing sodium fluoride at a level of 0.6 to 1.0 ppm total fluoride with a label claiming: “Drinking fluoridated water may reduce the risk of [dental caries or tooth decay].” In support of this action, the FDA accepted and relied on the Covington and Burling health claim notification that cited as its authority three government documents: *Recommendations for Using Fluoride to Prevent and Control Dental Caries in the U.S.* by the Centers for Disease Control (2001), *Oral Health in America: A Report of the Surgeon General* (2000), and *Review of Fluoride: Benefits and Risks* by the USPHS (1991).

However, even along with its approval, the FDA admitted that this health claim notification is open to further review and possible litigation.² Surprisingly, the notification failed to cite the recent comprehensive, 367-page March 22, 2006 report of the National Research Council of the US National Academy of Sciences, *Fluoride in Drinking Water*, prepared at the request of the EPA and which, by law, should have been consulted by the FDA. As a matter of fact, far from supporting the endorsements of fluoridation noted above, and three years in the making, with over a thousand references to the primary literature, the NRC report included a large amount of recent well-documented evidence of adverse health effects of fluoride in drinking water at or close to 1 ppm or even lower concentrations.³ Among these findings are disturbing increases in disfiguring dental fluorosis, stage I skeletal fluorosis including arthritic joint pain and stiffness, depressed thyroid function, gastrointestinal irritation, and detrimental neurological effects.

Just after the NRC report was released, a new study showing a “robust” association of fluoridated water with osteosarcoma in young boys appeared.⁴

Since the NRC report was prominently discussed in the news media and had been available online for over six months before publication of the October 14 health claim notification, the failure of the FDA even to mention the report is an inexcusable example of its failure to exercise legally required due diligence.

Also very troubling about this recent FDA action is that there apparently has never been a formal review by the FDA for any pharmaceutical use of sodium fluoride (NaF), let alone in drinking water, either for health safety or as a caries-preventive agent. The reason given by the FDA for this failure to require testing of NaF by clinical trials is that it was in use prior to the 1938 law requiring testing for human safety and was simply grandfathered in. Before 1938, NaF was used only experimentally in humans (e.g., to treat hyperthyroidism) but was marketed as a pesticide for roaches and ants and as a rodenticide. How can one take seriously an agency that deems the prior use of NaF as a rat poison is reason enough not to test it for harmful effects in humans, especially for its use in vitamin-mineral dietary supplements?

FDA acquiescence in the use of NaF and other forms of fluoride in toothpaste was similar. Only since April 7 1997, has the FDA required a printed warning on all fluoridated toothpaste sold in the USA: “Keep out of reach of children under 6 years of age.” The warning continues: “If you accidentally swallow more than used for brushing, seek professional assistance or contact a poison control center immediately.”

Since the amount of water individuals drink is variable, the amount of fluoride ingested from fluoridated bottled water also varies and can easily be in the toxic range swallowed from “more than used for brushing” the teeth. Moreover, the FDA in its health claim notification also states that fluoridated bottled water “is not intended for use on bottled water products specifically marketed for use by infants.”² The FDA therefore tacitly recognizes that fluoridated bottled water is toxic to infants, in agreement with the fact that the complete, balanced nutrition from a mother’s milk, which contains only 0.01 ppm F or less, ordinarily produces healthy, decay-free teeth.

Evidently prompted by this portion of the FDA health claim notification, and also citing the NRC report³ (but denying the existence of harm from 1-ppm fluoridated water other than dental fluorosis), the American Dental Association has recently issued an *Interim Guidance on Reconstituted Infant Formula*, November 9, 2006: *Infants, Formulas and Fluoride* (www.ADA.org) in which parents and caregivers are urged to use “water that has no fluoride or low levels of fluoride” when preparing a baby formula that needs water to be added to it.

A further concern is the fact that both recent and older dental research provides little support for government agency claims for a significant anti-caries effect of fluoride in drinking water in permanent dentition. Thus, as Mark Diesendorf points out in this issue of *Fluoride*,⁵ decay of permanent teeth where nonfluoridated water is used is *not* significantly greater than where fluoridated water is used. Earlier independent large-scale studies, especially in Japan and India, also indicate that cavity rates can actually be lower with less rather than

more natural fluoride in the drinking water.^{6,7} Adequate intake of calcium, along with other important tooth nutrients, which today are often still deficient among children, even in developed countries, is far more important for caries resistance than exposure to fluoride.^{8,9}

An inescapable cardinal principle of sound science is that pertinent research should never be disregarded,^{10,11} as the FDA has evidently done here. By ignoring a detailed, well-documented review of the relevant literature conducted by the research arm of the National Academy of Sciences, the FDA has not lived up to its mandate to make use of a review of that type in promulgating a highly disputable health claim notification. For the FDA to give a green light to very questionable health claims about fluoridated drinking water at a time when recent research shows that such water may lead to the death of young males from osteosarcoma takes its long-time failure to recognize and publicize serious adverse health effects of 1-ppm fluoride in water to a new low. This indifference flies in the face of scientific integrity and can only foster misplaced trust in faulty official thinking.¹² Unfortunately, erroneous health claims for fluoridated water have far-reaching and even devastating consequences.

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