



## U.S. FOOD AND DRUG ADMINISTRATION

### HEALTH CLAIM NOTIFICATION FOR FLUORIDATED WATER AND REDUCED RISK OF DENTAL CARIES

#### OVERVIEW

*Source: Food and Drug Administration website, 2006*

[\[http://www.fda.gov/Food/LabelingNutrition/LabelClaims/FDAModernizationActFDAMAClaims/ucm073602.htm\]](http://www.fda.gov/Food/LabelingNutrition/LabelClaims/FDAModernizationActFDAMAClaims/ucm073602.htm)

**Overview:** States that the FDA received a notification regarding a health claim for the relationship between fluoridated water and a reduced risk of dental caries. The notification cites authoritative statements by the CDC, Surgeon General, and Public Health Service—all supporting the claim.

Under section 403(r)(3)(C) (21 U.S.C. §343(r)(3)(C)) of the Federal Food, Drug, and Cosmetic Act (Act), a manufacturer may submit to the Food and Drug Administration (FDA) a notification of a health claim based on an authoritative statement from an appropriate scientific body of the United States Government or the National Academy of Sciences (NAS) or any of its subdivisions. The notification must be submitted to FDA at least 120 days before the food is introduced into interstate commerce. The claim may be made after 120 days from the date of submission of the notification until such time as 1) FDA issues a regulation prohibiting or modifying the claim or finding that the requirements for making the claim have not been met, or 2) a district court in an enforcement proceeding has determined that the requirements for making the claim have not been met.

On June 16, 2006, the FDA received a notification (the June 16 notification) from the law firm of Covington and Burling regarding a health claim for the relationship between fluoridated water and a reduced risk of dental caries. The 120-day period from the date of submission of the June 16 notification was October 14, 2006. Therefore, after October 14, 2006, manufacturers may use the claim specified in the notification, as modified by the notifier in a letter to FDA dated October 13, on the label and in labeling of any food product that meets the eligibility criteria described below, unless or until FDA or a court acts to prohibit the claim.

The June 16 notification cites statements from several sources as authoritative statements for the claim. FDA reviewed the sources and cited statements in their context and in light of existing authorized health claims and current science. The following three statements are considered authoritative for purposes of this notification.

*Recommendation for Using Fluoride to Prevent and Control Dental Caries in the U.S. (Centers for Disease Control, 2001):*

"Widespread use of fluoride has been a major factor in the decline in the prevalence and severity of dental caries (i.e., tooth decay) in the United States and other economically developed countries. When used appropriately, fluoride is both safe and effective in preventing and controlling dental caries. All U.S. residents are likely exposed to some degree of fluoride, which is available from multiple sources." (Summary section, page 1)

"Continue and extend fluoridation of community drinking water: Community water fluoridation is a safe, effective, and inexpensive way to prevent dental caries. This modality benefits persons in all age groups and of all SES, ...." (Recommendation section, page 24)

*Oral Health in America: A Report of the Surgeon General (2000):*

"Community water fluoridation is safe and effective in preventing dental caries in both children and adults. Water fluoridation benefits all residents served by community water supplies regardless of their social or economic status. Professional and individual measures, including the use of fluoride mouth rinses, gels, dentifrices, and dietary supplements and the application of dental sealants, are additional means of preventing dental caries." (Executive summary)

*Review of Fluoride: Benefits and Risks (Public Health Service, 1991):*

"Extensive studies over the past 50 years have established that individuals whose drinking water is fluoridated show a reduction in dental caries. Although the comparative degree of measurable benefit has been reduced recently as other fluoride sources have become available in non-fluoride areas, the benefits of water fluoridation are still clearly evident." (Conclusions section, page 87)

According to the June 16 notification and the letter to FDA dated October 13, the food eligible to bear the claim is bottled water meeting the standards of identity and quality set forth in 21 CFR 165.110, containing greater than 0.6 and up to 1.0 mg/L *total* fluoride, and meeting all general requirements for health claims (21 CFR 101.14) with the exception of minimum nutrient contribution (21 CFR 101.14 (e)(6)). The claim language is: "Drinking fluoridated water may reduce the risk of [dental caries or tooth decay]." In addition, the health claim is not intended for use on bottled water products specifically marketed for use by infants.

The notification and materials regarding the claim are publicly available from the FDA Division of Dockets Management (Docket No.2006Q-0418). Persons interested in these documents may view them at the Division of Dockets Management from 9am to 4pm, Monday through Friday at 5630 Fishers Lane, room 1061, Rockville, MD 20852. The Division of Dockets Management may be contacted at 301-827-6860. FDA also intends to make the documents available on the [Dockets web site](#), under Docket No. 2006Q-0418.