

# COVINGTON & BURLING LLP

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October 3, 2006

BY FEDERAL EXPRESS

Dr. Kathleen Ellwood  
Director, Division of Nutrition Programs and Labeling  
Office of Nutritional Products, Labeling  
and Dietary Supplements (HFS-830)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
Harvey W. Wiley Federal Building  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

Re: Notification for a Health Claim Based on an Authoritative  
Statement: Drinking Fluoridated Water Reduces the Risk of  
Dental Caries (Tooth Decay)

Dear Dr. Ellwood:

This letter is in follow up to our June 14, 2006 Notification for a Health Claim Based on an Authoritative Statement: Drinking Fluoridated Water Reduces the Risk of Dental Caries (Tooth Decay) ("June 14 Notification"). In the June 14 Notification, pursuant to section 403(r)(3)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 343(r)(3)(C)), we notified the Food and Drug Administration of the following health claim for use on bottled water products: "Drinking fluoridated water reduces the risk of [dental caries or tooth decay]." By this letter, we hereby revise the health claim language stated in the June 14 Notification to the following: "Drinking fluoridated water may reduce the risk of [dental caries or tooth decay]." This letter also confirms that the food eligible to bear this health claim is bottled water meeting the standards of identity and quality as set forth in 21 C.F.R. § 165.110, and containing greater than 0.6 and up to 1.0 mg/L *total* fluoride. In addition, this health claim is not intended for use on bottled water products specifically marketed for use by infants.

Respectfully submitted,



Sarah Taylor Roller, JD, RD, MPH  
Clausen Ely, Jr.  
Miriam J. Guggenheim  
Heather D. Bañuelos

cc: Ricardo Carvajal, OCC

2006Q-0418

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JUN 30 2006

Sarah Taylor Roller, JD, RD, MPH  
Covington & Burling  
1201 Pennsylvania Ave. NW  
Washington, DC 20001-2401

Re: Notification for a health claim based on an authoritative statement

Dear Ms. Roller:

This letter acknowledges receipt on June 16, 2006 by the Food and Drug Administration (FDA) of the health claim notification you submitted pursuant to Section 403(r)(3)(C) of the Federal Food, Drug and Cosmetic Act (the Act) (21 U.S.C. 343(r)(3)(C)). The notification is informing FDA of a health claim characterizing the relationship between the consumption of fluoridated water and a reduced risk of dental caries. The health claim is based on authoritative statements from 1) an Institute of Medicine (1997) report entitled, "Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride," 2) a Morbidity and Mortality Weekly Report from the Centers for Disease Control and Prevention (2001) entitled, "Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States," 3) a Surgeon General's report (2000) entitled, "Oral Health in America: A Report of the Surgeon General," and 4) a Public Health Service (1991) report entitled, "Public Health Service Report on Fluoride Benefits and Risks."

The notification is undergoing FDA review. In accordance with Section 403(r)(3)(C) of the Act, within 120 days (ending on October 14, 2006) of receipt of your health claim notification, you will be informed by FDA if the notification does not comply with Section 403(r)(3) of the Act. A lack of action by FDA within the 120-day period will deem the proposed health claim approved and will allow a food with a label containing the claim to be introduced into interstate commerce.

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If you have any questions concerning this notification, please feel free to contact me at (301) 436-2031 or [Julie.Moss@fda.hhs.gov](mailto:Julie.Moss@fda.hhs.gov).

Sincerely,

A handwritten signature in cursive script that reads "Julie Moss".

Julie Moss, PhD, RD  
Consumer Safety Officer  
Office of Nutritional Products, Labeling  
and Dietary Supplements