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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,



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Miriam J. Guggenheim
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cc: Ricardo Carvajal, OCC

2006Q-0418

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