



JUL 22 2004

Food and Drug Administration
College Park, MD 20740

7255 04 OCT 13 22 25

Guy H. Johnson, Ph.D.
Johnson Nutrition Solutions LLC
8711 Swan Street
Kalamazoo, MI 49009

RE: Health Claim Petition - Vitamin D and/or Calcium and Osteoporosis

Dear Dr. Johnson:

This letter acknowledges receipt on July 12, 2004 by the Food and Drug Administration (FDA) of your health claim petition submitted on behalf of The Beverage Institute for Health & Wellness, LLC pursuant to section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(4)). You requested that the FDA authorize a health claim with respect to the ability of vitamin D and calcium to reduce the risk of osteoporosis.

The petition is undergoing initial FDA review as an unqualified health claim petition. In accordance with Section 403(r)(4)(A)(i) of the act (21 U.S.C. 343(r)(4)(A)(i)) and 21 CFR 101.70(j)(2), within 100 days of receipt of a petition, it will be either filed for comprehensive review or denied. A health claim petition may be denied by action taken by FDA or by a lack of action by FDA, in which case the petition will be deemed to be denied unless an extension is mutually agreed upon by the petitioner and FDA. The 100-day period ends on October 20, 2004 and FDA will notify you by letter on or before that date of the disposition of the health claim petition.

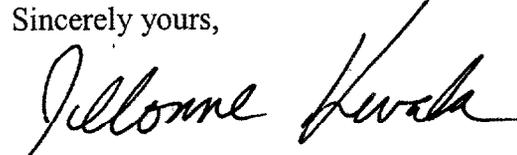
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Please feel free to contact me at 301-436-1848 if you have any questions concerning this petition.

Sincerely yours,

A handwritten signature in black ink that reads "Jilanne Kevala". The signature is written in a cursive style with a large initial "J" and a long, sweeping underline.

Jilanne Kevala, Ph.D.

Nutrition Programs and Labeling Staff
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition