



OCT 20 2004

Food and Drug Administration  
College Park, MD 20740

1170 04 3 25 2210

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

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

Dear Dr. Johnson:

This letter is in reference to the subject health claim petition received by the Food and Drug Administration on July 12, 2004, in which you requested that the agency authorize a health claim with respect to the ability of vitamin D and calcium to reduce the risk of osteoporosis. The petition was submitted pursuant to section 403(r)(4)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(4)(i)) on behalf of the Beverage Institute for Health & Wellness, LLC. On July 22, 2004, we informed you that the petition was undergoing initial FDA review.

We have completed our initial review of the petition and are filing it as specified in section 403(r)(4)(i) of the act (21 U.S.C. 343(r)(4)(i)), on October 20, 2004. Within 90 days of the filing date FDA will either publish a proposed regulation authorizing use of the health claim or deny the petition. We have calculated that date to be January 18, 2005. Denial may be made by FDA action or by lack of FDA action, in which case the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

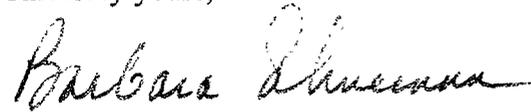
2004P-0464

LET 1

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Please feel free to contact Dr. Jillonne Kevala at 301-436-1450 if you have questions concerning this petition.

Sincerely yours,

A handwritten signature in cursive script that reads "Barbara O. Schneeman". The signature is written in black ink and is positioned above the printed name.

Barbara O. Schneeman, Ph.D.

Director

Office of Nutritional Products, Labeling,  
and Dietary Supplements

Center for Food Safety  
and Applied Nutrition



Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

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October 21, 2004

Ms. Jennie Butler  
Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane, Room 1061 (HFA-305)  
Rockville, MD 20852

RE: Health Claim Petition – Vitamin D and Calcium and Reduced Risk of Osteoporosis  
(Docket Numbers 2004P-0464)

Dear Ms Butler:

Would you please add the enclosed filing letter to Docket # 2004P-0464 for vitamin D/calcium and reduced risk of osteoporosis? Thanks

Sincerely,

Jillonne Kevala, Ph.D.  
Nutrition Programs and Labeling Staff  
Office on Nutritional Products, Labeling and Dietary Supplements  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration

5100 Paint Branch Parkway, HFS-832  
College Park, MD 20740-3835  
Telephone (301) 436-1848  
jkevala@cfsan.fda.gov

Enclosures (1)

- 1) October 20, 2004 filing letter from Barbra Schneeman, Ph.D., HFS-800, FDA to Guy Johnson, Ph.D., Johnson Nutrition Solutions.