



DEC 10 2003

Food and Drug Administration  
College Park, MD 20740

Jonathan W. Emord, Esq.  
Emord & Associates, P.C.  
5282 Lyngate Court  
Burke, VA 22015

RE: Health Claim Petition - (1) Calcium may reduce the risk of bone fractures; (2) Calcium may reduce the risk of hip fractures; (3) Calcium may reduce the risk of vertebral fractures; (4) Calcium may reduce the risk of wrist fractures; and (5) Calcium may reduce the risk of nonvertebral fractures

Dear Mr. Emord:

This letter acknowledges receipt on November 25, 2003, by the Food and Drug Administration (FDA) of your health claim petition, submitted pursuant to Section 403(r)(5)(D) of the Federal Food, Drug, and Cosmetic Act (FFD&C Act) (21 U.S.C. § 343(r)(5)(D)) with respect to certain claims about the relationship between calcium and (1) bone fractures, (2) hip fractures, (3) vertebral fractures, (4) wrist fractures and (5) nonvertebral fractures. You submitted this petition on behalf of Marine Bio USA, Inc.

Your initial petition was received on October 9, 2003. However, in a letter dated October 24, 2003, FDA stated that it could not acknowledge receipt of your petition at that time because it did not contain all of the information required under 21 CFR 101.70. In that letter the agency pointed out specific deficiencies in your petition. FDA also informed you that if you wished the agency to review your petition, you could resubmit it with the information required by 21 CFR 101.70. On November 25, 2003, FDA received your supplemental submission which contained the deficient information.

Because your petition is complete it is undergoing initial FDA review. In accordance with Section 403(r)(4)(A)(i) of the FFD&C 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, the petition will either be filed for comprehensive review or denied. A denial may be by either FDA action within the 100-day period, which ends on March 4, 2004, or by a lack of action by FDA within the initial 100-day period in which case the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

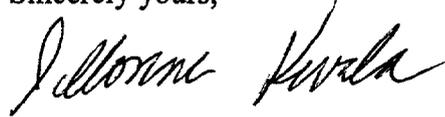
2004 Q-0100

ACK1

Page 2 - Jonathan W. Emord

If you have any questions please feel free to contact Dr. Jillonne Kevala at 301-436-1450.

Sincerely yours,

A handwritten signature in black ink that reads "Jillonne Kevala". The signature is written in a cursive, flowing style.

Jillonne Kevala, Ph.D.

Chemist

Nutrition Programs and Labeling Staff

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition