



DEC 9 2003

Food and Drug Administration
College Park, MD 20740.8/16/04
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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 kidney stones;
(2) Calcium may reduce the risk of urinary stones; and (3) Calcium may reduce
the risk of kidney stones and urinary stones.

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 kidney stones and/or urinary stones. 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 required 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.

2004Q-0102

ACK1

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If you have any questions please feel free to contact Ms. Nancy Crane in the Nutrition Programs and Labeling Staff at 301-436-1450.

Sincerely yours,

A handwritten signature in black ink that reads "Nancy T. Crane". The signature is written in a cursive style with a long horizontal flourish at the end.

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