DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

DEC 9 2003

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

RE: Health Claim Petition - (1) Calcium and colorectal cancer; (2) Calcium and colon cancer; (3) Calcium and rectal cancer; (4) Calcium and breast cancer; and (5) Calcium and prostate cancer; (6) Calcium and colorectal, colon, rectal, breast, and prostate cancers; (7) Calcium and breast and prostate cancers; (8) Calcium and colorectal, colon, and rectal cancers; (9) Calcium and anticarcinogenic effects in the colon, breast, and prostate; and (10) Calcium and recurrent colon polyps.

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) colorectal cancer, 2) colon cancer, 3) rectal cancer, 4) breast cancer, 5) prostate cancer, and 6) recurrent colon polyps. 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.

2004Q-0097

ACK1

If you have any questions please feel free to contact Lisa Lubin of the Nutrition Programs and Labeling Staff at 301-436-1450.

Sincerely yours,

Lisa F. Lubin, MS, RD

Lisa F. Lubin, M.S., R.D.
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and Dietary Supplements
Center for Food Safety
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