DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

OCT 24 2003

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

Re: Health Claim Petition – Calcium and Essential Hypertension, Gestational Hypertension, and Pre-eclampsia

Dear Mr. Emord:

This letter concerns your health claim petition, received on October 9, 2003, 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) essential hypertension, 2) gestational hypertension, and 3) pre-eclampsia. You submitted this petition on behalf of Marine Bio USA, Inc. We are not acknowledging the receipt of your health claim petition, within the meaning of 21 CFR 101.70(j)(1), because the petition is not complete.

Under 21 CFR 101.70(j)(1), FDA is to notify the petitioner by letter (the "acknowledgment letter"), within 15 days of receipt of the petition, the date that the petition was received. This acknowledgment letter is intended to inform the petitioner that the petition is undergoing agency review and that the agency will subsequently notify the petitioner of its decision to either file the petition for comprehensive review or to deny the petition. Under 21 CFR 101.70 (f), the petition is required to include, among other attachments, copies of any computer literature searches done by the petitioner, copies of articles cited in the literature searches, and all other information that the petitioner relies upon for the support of the health claim.

FDA is not able to acknowledge the receipt of your petition and begin its review of the petition because the petition is not complete. We have found the following deficiencies in your petition:

1. You have not included in your petition the references listed below (by number of reference as cited in the petition) that you cite as support for your proposed health claims:

2004Q-0098

LET 1

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Our decision not to review your petition at this time is based on your failure to submit copies of the information on which you rely to support your petition, as required by 21 CFR 101.70. The comments in this letter cannot be considered a substantive review of your petition or a comprehensive list of all issues that may be identified in a complete review. If you wish FDA to review your petition, please resubmit it with the information required by 21 CFR 101.70.

If you have any questions please feel free to contact Dr. Julie Schrimpf in the Division of Nutrition Programs and Labeling at 301-436-1450.

Sincerely yours,

Virginia I. Wilkening

for Christine L. Taylor
Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition