



DEC 9 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 cyclic severe depression associated with the menstrual cycle; (2) Calcium may reduce the risk of premenstrual dysphoric disorder; (3) Calcium may reduce the risk of the onset of symptoms of premenstrual dysphoric disorder; (4) Calcium may reduce the risk of abnormal menstrual cycles; and (5) Calcium may reduce the risk of polycystic ovary syndrome.

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) cyclic severe depression associated with the menstrual cycle, (2) premenstrual dysphoric disorder, (3) the onset of symptoms of premenstrual dysphoric disorder, (4) abnormal menstrual cycles, and (5) polycystic ovary syndrome. 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 your petition, the petition will either be filed for comprehensive review or denied. A denial may be by either FDA action within the initial 100-day period, which

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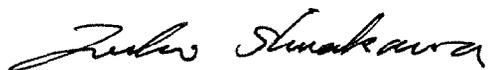
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ends on March 4, 2004, or by a lack of action by FDA within the initial 100-day period in which case the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

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

Sincerely yours,



Tomoko Shimakawa, Sc.D.
Nutrition Programs and Labeling Staff
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition