



OCT 24 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—Calcium and Cyclic Severe Depression Associated with the Menstrual Cycle, Premenstrual Dysphoric Disorder, the Onset of Symptoms of Premenstrual Dysphoric Disorder, Abnormal Menstrual Cycles, and Polycystic Ovary Syndrome.

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 cyclic severe depression associated with the menstrual cycle, premenstrual dysphoric disorder, the onset of symptoms of premenstrual dysphoric disorder, abnormal menstrual cycles, and polycystic ovary syndrome. 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 that you cite as support for your proposed health claims:

2004Q-0099

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- Reference 3. Zhung L, Peng JB, Tou L, Takanaga H, Adam RM, Hediger MA, Freeman MR. Calcium-selective ion channel, CaT1, is apically localized in gastrointestinal tract epithelia and is aberrantly expressed in human malignancies. *Lab Invest* 2002;82:1755-1764.
- Reference 30. Bendich A. Micronutrients in women's health and immune function. *Nutrition* 2001;17:858-867.
- Reference 53. Malberti F, Surian M, Poggio F, Minoia C, Salvadeo A. Efficacy and safety of long-term treatment with calcium carbonate as a phosphate binder. *Am J Kidney Dis* 1988;12:487-491.
- Reference 54. Moriniere P, Hocine C, Boudailliez B, Belbrik S, Renaud H, Westeel PF, Solal MC, Fournier A. Long-term efficacy and safety of oral calcium as compared to Al(OH)₃ as phosphate binders. *Kidney Int* 1989;36(suppl. 27):S133-S135.
- Reference 55. Tsukamoto Y, Moriya R, Nagaba Y, Morishita T, Izumida I, Okubo M. Effect of administering calcium carbonate to treat secondary hyperparathyroidism in nondialyzed patients with chronic renal failure. *Am J Kidney Dis* 1995;25:879-886.
- Reference 56. Nolan CR, Qunibi WY. Calcium salts in the treatment of hyperphosphatemia in hemodialysis patients. *Curr Opin Nephrol Hypertens* 2003;12:373-379.
- Reference 57. Clark AGB, Oner A, Ward G, Turner C, Rigden SPA, Haycock GB, Chantler C. Safety and efficacy of calcium carbonate in children with chronic renal failure. *Nephrol Dial Transplant* 1989;4:539-544.
- Reference 58. Orwoll ES. The milk-alkali syndrome: Current concepts. *Ann Intern Med* 1982;97:242-248.
- Reference 61. Lagman R, Walsh D. Dangerous nutrition? Calcium, vitamin D, and shark cartilage nutritional supplements and cancer-related hypercalcemia. *Support Care Cancer* 2003;11:232-235.
- Reference 62. Burtis WJ, Gay L, Insogna KL, Ellison A, Broadus AE. Dietary hypercalciuria in patients with calcium oxalate kidney stones. *Am J Clin Nutr* 1994;60:424-429.

Reference 63. Anonymous. The role of calcium in peri- and postmenopausal women: Consensus opinion on The North American Menopause Society. *Menopause* 2001;8:84-95.

2. In Exhibit 7 of your petition, you provided only partial results of your literature search for the term, "calcium and premenstrual syndrome." Only the first 20 items out of 39 items found in your literature search were provided. Under 21 CFR 101.70(f), the petition must include complete copies from computer literature searches.

Please note that we have not evaluated at this time whether each claim cited in your petition represents a claim about a relationship between calcium and a disease or health-related condition. 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 Tomoko Shimakawa in the Division of Nutrition Programs and Labeling at 301-436-1450.

Sincerely yours,



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