

**SUPPLEMENTAL SUBMISSION TO  
PETITION FOR HEALTH CLAIMS:**

- **CALCIUM AND CYCLIC SEVERE DEPRESSION ASSOCIATED WITH THE MENSTRUAL CYCLE.**
- **CALCIUM AND PREMENSTRUAL DYSPHORIC DISORDER.**
- **CALCIUM AND THE ONSET OF SYMPTOMS OF PREMENSTRUAL DYSPHORIC DISORDER.**
- **CALCIUM AND ABNORMAL MENSTRUAL CYCLES.**
- **CALCIUM AND POLYCYSTIC OVARY SYNDROME.**

**SUBMITTED TO THE FOOD AND DRUG ADMINISTRATION  
NOVEMBER 24, 2003**

**PETITIONER:  
MARINE BIO USA, INC.**

2004Q-0099

SUPI

**Before the  
FOOD AND DRUG ADMINISTRATION  
Washington, D.C.**

In re: Petition for Health Claims: (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; (5) Calcium may reduce the risk of polycystic ovary syndrome

Filed on: November 21, 2003

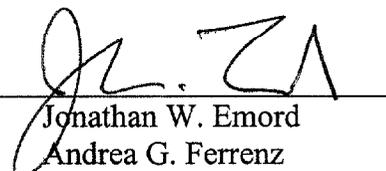
**SUPPLEMENTAL SUBMISSION**

Marine Bio USA, Inc. ("Petitioner") hereby supplements the record in the above-referenced health claim proceeding with the attached scientific references, consisting of the scientific articles cited by Michael John Glade, Ph.D., CNS, FACN in his report that were not available at the time of the initial filing with FDA on October 9, 2003, and the PubMed search results requested by the agency. With those documents before you, petition processing should commence forthwith.

Respectfully submitted,

MARINE BIO USA, INC.,

By: \_\_\_\_\_

  
Jonathan W. Emord  
Andrea G. Ferrenz  
Kathryn E. Balmford

Their Counsel

**Emord & Associates, P.C.**  
5282 Lyngate Court  
Burke, VA 22015  
P: (202) 466-6937  
F: (202) 466-4938  
Email: [jemord@emord.com](mailto:jemord@emord.com)  
Date submitted: November 21, 2003

**CALCIUM AND MENSTRUAL DISORDERS CLAIMS SUPPLEMENT  
TABLE OF CONTENTS**

**SECTION 1**

**Reference Number and Article Citation**

3. Zhuang 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.
30. Bendich A. Micronutrients in women's health and immune function. *Nutrition* 2001;17:858-867.
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.
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)<sub>3</sub> as phosphate binders. *Kidney Int* 1989;36(Suppl. 27):S133-S135.
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.
56. Nolan CR, Qunibi WY. Calcium salts in the treatment of hyperphosphatemia in hemodialysis patients. *Curr Opin Nephrol Hypertens* 2003;12:373-379.
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.
58. Orwoll ES. The milk-alkali syndrome: Current concepts. *Ann Intern Med* 1982;97:242-248.
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.
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.

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

**SECTION 2**

PubMed search results for all search terms cited in Glade Report for this petition.