

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

- **CALCIUM AND BONE FRACTURES.**
- **CALCIUM AND HIP FRACTURES.**
- **CALCIUM AND VERTEBRAL FRACTURES.**
- **CALCIUM AND WRIST FRACTURES.**
- **CALCIUM AND NONVERTEBRAL FRACTURES.**

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

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

HQ-0100

SUP1

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

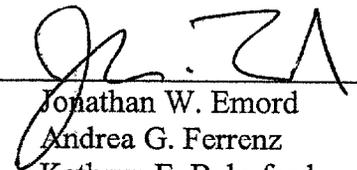
In re: Petition for Health Claims: (1) Calcium may reduce the risk of bone fractures; (2) Calcium may reduce the risk of hip fractures; (3) Calcium may reduce the risk of vertebral fractures; (4) Calcium may reduce the risk of wrist fractures; (5) Calcium may reduce the risk of nonvertebral fractures

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: 
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CALCIUM AND BONE FRACTURES 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.
45. Heaney RP. Thinking straight about calcium. *N Engl J Med* 1993;328:503-505.
59. Riggs BL, O'Fallon MW, Muhs J, O'Connor MK, Kumar R, Melton JL. Long term effects of calcium supplementation on serum parathyroid hormone levels, bone turnover, and bone loss in elderly women. *J Bone Miner Res* 1998;13:168-174.
86. Cummings SR, Nevitt MC, Browner WS, Stone K, Fox KM, Ensrud KE, Cauley J, Black D, Vogt TM. Risk factors for hip fractures in white women. Study of Osteoporotic Fractures Research Group. *N Engl J Med* 1995;332:767-773.
99. Paganini-Hill A, Ross RK, Gerkins VR, Henderson BE, Arthur M, Mack TM. Menopausal estrogen therapy and hip fractures. *Ann Intern Med* 1981;95:28-31.
106. Verd Vallespir S, Dominguez Sanchez J, Gonzalez Quintial M, Vidal Mas M, Mariano Soler AC, de Roque Company C, Sevilla Marcos JM. [Association between calcium content of drinking water and fractures in children] *An Esp Pediatr* 1992;37:461-465. **Original article and translation included.**
107. Wyshak G, Frisch RE. Carbonated beverages, dietary calcium, the dietary calcium/phosphorus ratio, and bone fractures in girls and boys. *J Adolesc Health* 1994;15:210-215.
114. Wallace LS, Ballard JE. Lifetime physical activity and calcium intake related to bone density in young women. *J Womens Health Gend Based Med* 2002;11:389-398.
115. Wooton R, Brereton PJ, Clark MB, Hesp R, Hodgkinson HM, Klenerman L, Reeve J, Slavin G, Tellez-Yudilevich M. Fractured neck of femur in the elderly: An attempt to identify patients at risk. *Clin Sci* 1979;57:93-101.
126. Anonymous. The role of calcium in peri- and postmenopausal women: Consensus opinion of The North American Menopause Society. *Menopause* 2001;8:84-95.

127. Buckley LM, Hillner BE. A cost effectiveness analysis of calcium and vitamin D supplementation, etidronate, and alendronate in the prevention of vertebral fractures in women treated with glucocorticoids. *J Rheumatol* 2003;30:132-138.
128. Meunier P. Prevention of hip fractures by correcting calcium and vitamin D insufficiencies in elderly people. *Scand J Rheumatol Suppl* 1996;103:75-78.
138. 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.
139. 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.
140. 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.
141. Nolan CR, Qunibi WY. Calcium salts in the treatment of hyperphosphatemia in hemodialysis patients. *Curr Opin Nephrol Hypertens* 2003;12:373-379.
142. 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.
143. Orwoll ES. The milk-alkali syndrome: Current concepts. *Ann Intern Med* 1982;97:242-248.
146. 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.
147. 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.

SECTION 2

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