



OCT 24 2003

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

Re: Health Claim Petition – Calcium and bone, hip, vertebral, wrist, and nonvertebral fractures

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) bone fractures, (2) hip fractures, (3) vertebral fractures, (4) wrist fractures and (5) nonvertebral fractures. 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:
  3. Zhang, L., et. al., Calcium-selective ion channel, CaT1, is apically localized in gastrointestinal tract epithelia and is aberrantly localized human malignancies. *Lab Invest* 2002;82:1755-1764.

2004Q-0100

LET 1

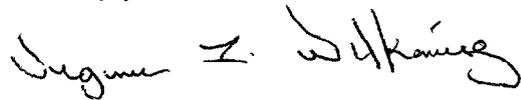
45. Heaney, RP., Thinking straight about calcium. *N Engl J Med* 1993;328:503-505.
59. Riggs, BL., et. al., Long term effects of calcium supplementation on serum parathyroid hormone levels, bone turnover and bone loss in elderly. *J Bone Miner Res* 1998;13:168-174.
86. Cummings, SR., et. al., Risk factors for hip fractures in white women. *N Engl J Med* 1995;332:767-773.
99. Paganini-Hill, A., et. al., Menopausal estrogen therapy and hip fractures. *Ann Intern Med* 1981;95:28-31.
106. Verd Vallespir, S., et. al., Association between calcium content of drinking water and fractures in children. *An Esp Pediat* 1992;37:461-465.
107. Wyshak, G., et. al., Carbonated beverages, dietary calcium, the dietary calcium/phosphate ratio, and bone fractures in boys and girls. *J Adolesc Health* 1994;15:210-215.
114. Wallace, LS., et. al., 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., et. al., 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* 2002;8:84-95.
127. Buckely, LM., et. al., A cost effective 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 Supp* 1996;103:75-78.
138. Malberti, F., et. al., 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., et. al., Long-term efficacy and safety of oral calcium as compared to Al(OH)<sub>3</sub> as phosphate binders. *Kidney Int* 1986;36(Suppl. 27):S133-S135.
140. Tsukamoto, Y., et. al., 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, C., et. al., Calcium salts in the treatment of hyperphosphatemia in hemodialysis patients. *Curr Opin Nephrol Hypertens* 2003;12:373-379.
142. Clark, AGB., et. al., Safety and efficacy of calcium in children with chronic renal failure. *Nephrol Dial Transplant* 1989;4:539-544.
143. Orwoll, ES., et. al., The milk-alkali syndrome: Current concepts. *Ann Intern Med* 1982;97:242-248.
146. Lagman, R., et. al., Dangerous nutrition? Calcium, vitamin D, and shark cartilage nutritional supplements and cancer-related hypercalcemia. *Support Care Cancer* 2003;11:232-235.
147. Burtis, WJ., et. al., Dietary hypercalciuria in patients with calcium oxalate kidney stones. *Am J Clin Nutr* 1994;60:424-429.

2. Under 21 CFR 101.70(a), all materials submitted in a foreign language must be accompanied by an accurate and complete English translation. One article that you submitted is not in English. Please submit an English translation of the following article, referenced in the Scientific Report prepared by Dr. Michael Glade: Verd Vallespir, S. et al., Association between calcium content of drinking water and fractures in children. *An Esp Pediatr* 1992;37:461-465.

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 Dr. Jillonne Kevala in the Division of Nutrition Programs and Labeling at 301-436-1450.

Sincerely yours,

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