



OCT 24 2003

Food and Drug Administration
College Park, MD 20740

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

Re: Health Claim Petition – Calcium and kidney stones and/or urinary stones

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 kidney stones and/or urinary stones. 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 reference number as cited in Exhibit 1 of the petition – i.e., the bibliography of the Glade Report) that you cite as support for your proposed health claims:

2004Q-0102

LET 1

- Ref 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.
- Ref 30 Martini LA, Wood RJ. Should dietary calcium and protein be restricted in patients with nephrolithiasis? *Nutr Rev* 2000;58:111-117.
- Ref 31 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.
- Ref 34 Heller HJ. The role of calcium in the prevention of kidney stones. *J Am Coll Nutr* 1999;18(5 Suppl.):373S-378S.
- Ref 36 Baggio B, Plebani M, Gambaro G. Pathogenesis of idiopathic calcium nephrolithiasis: Update 1997. *Crit Rev Clin Lab Sci* 1998;35:153-187.
- Ref 37 Madore F, Stampfer MJ, Willet WC, Speizer FE, Curhan GC. Nephrolithiasis and risk of hypertension in women. *Am J Kidney Dis* 1998;32:802-807.
- Ref 38 Madore F, Stampfer MJ, Rimm EB, Curhan GC. Nephrolithiasis and risk of hypertension. *Am J Hypertens* 1998;11:46-53.
- Ref 39 Ramello A, Vitale C, Marangella M. Epidemiology of nephrolithiasis. *J Nephrol* 2000;13(Suppl. 3):S45-S50.
- Ref 40 Serio A, Fraioli A. Epidemiology of nephrolithiasis. *Nephron* 1999;81(Suppl. 1):26-30.
- Ref 41 Strazzullo P, Mancini M. Hypertension, calcium metabolism, and nephrolithiasis. *Am J Med Sci* 1994;307(Suppl. 1):S102-S106.
- Ref 42 Curhan GC. Dietary calcium, dietary protein, and kidney stone formation. *Miner Electrolyte Metab* 1997;23:261-264.
- Ref 43 Iguchi M, Kataoka K, Kohri K, Yachiku S, Kurita T. Nutritional risk factors in calcium stone disease in Japan. *Urol Int* 1984;39:32-35.
- Ref 44 Hess B. Low calcium diet in hypercalciuric calcium nephrolithiasis: First do no harm. *Scanning Microsc* 1996;10:547-556.
- Ref 62 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.

Ref 63 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.

Ref 64 Tsukamoto Y, Moriya R, Nagaa 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.

Ref 65 Nolan CR, Qunibi WY. Calcium salts in the treatment of hyperphosphatemia in hemodialysis patients. *Curr Opin Nephrol Hypertens* 2003;12:373-379.

Ref 66 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.

Ref 67 Orwoll ES. The milk-alkali syndrome: Current concepts. *Ann Intern Med* 1982;97:242-248.

Ref 70 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.

Ref 71 Anonymous. The role of calcium in peri- and postmenopausal women: Consensus opinion of The North American Menopause Society. *Menopause* 2001;8:84-95.

Ref 72 Unknown because this citation is not listed in the bibliography. Page 8 of the Glade Report, however, indicates that there is a reference 72.

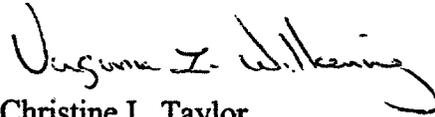
2. Under 21 CFR 101.70(f), a health claim petition shall include copies of any computer literature searches done by the petitioner. Exhibit 5 of the petition includes the results of an incomplete PubMed search (i.e., only 20 of the 937 items were included) on calcium and nephrolithiasis. While the Glade Report states that literature searches on calcium and nephrolithiasis, and on calcium and safety were performed on August 26, 2003, neither of these searches were included in the petition.

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.

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If you have any questions please feel free to contact Dr. Paulette Gaynor 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