

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

In re:

Petition for Health Claims: (1) Calcium may reduce the risk of colorectal cancer; (2) Calcium may reduce the risk of colon cancer; (3) Calcium may reduce the risk of rectal cancer; (4) Calcium may reduce the risk of breast cancer; (5) Calcium may reduce the risk of prostate cancer; (6) Calcium may reduce the risk of colorectal, colon, rectal, breast, and prostate cancers; (7) Calcium may reduce the risk of breast and prostate cancers; (8) Calcium may reduce the risk of colorectal, colon, and rectal cancers; (9) Calcium may have anticarcinogenic effects in the colon, breast, and prostate; (10) Calcium may reduce the risk of recurrent colon polyps

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.,

Bv

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

Date submitted: November 21, 2003

SUPI

CALCIUM AND CANCER 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.
- 171. Bostick RM, Potter JD, Fosdick L, Grambsch P, Lampe JW, Wood JR, Louis TA, Ganz R, Grandits G. Calcium and colorectal epithelial cell proliferation: A preliminary randomized, double-blinded, placebo-controlled clinical trial. *J Natl Cancer Inst* 1993;85:132-141.
- 228. Wargovich MJ, Stephens LC, Gray K. Effect of two "human" nutrient density levels of calcium on the promotional phase of colon tumorigenesis in the F344 rat (abstract). *Proc Am Assoc Cancer Res* 1989;30:196.
- 234. Adell-Carceller R, Segarra-Soria M, Gibert-Jerez J, Salvador Sanchis JL, Lazaro-Santander R, Escrig-Sos J, Ruiz-Castillo J. Inhibitory effect of calcium on carcinogenesis at the site of colonic anastomosis: An experimental study. *Dis Colon Rectum* 1997;40:1376-1381.
- 235. Arlow FL, Walczak SM, Luk GD, Majumdar AP. Attenuation of azoxymethane-induced colonic mucosal ornithine decarboxylase and tyrosine kinase activity by calcium in rats. *Cancer Res* 1989;49:5884-5888.
- 238. Hambly RJ, Rumney CJ, Cunninghame M, Fletcher JM, Rijken PJ, Rowland IR. Influence of diets containing high and low risk factors for colon cancer on early stages of carcinogenesis in human flora-associated (HFA) rats. *Carcinogenesis* 1997;18:1535-1539.
- 261. Appleton GV, Owen RW, Wheeler EE, Challacombe DN, Williamson RC. Effect of dietary calcium on the colonic luminal environment. *Gut* 1991;32:1374-1377.
- 282. Pence BC. Role of calcium in colon cancer prevention: Experimental and clinical studies. *Mutat Res* 1993;290:87-95.
- 287. Barthold SW, Beck D. Modification of early dimethylhydrazine carcinogenesis by colonic mucosa hyperplasia. *Cancer Res* 1980;40:4451-4455.

- 288. Yu B, Wu J, Zhou X. [Interference of selenium germanium and calcium in carcinogenesis of colon cancer.] Zhonghua Wai Ke Za Zhi 1995;33:167-169. Original article and translation included.
- 289. Ahnen J. Are animal models of colon cancer relevant to human diseases? Dig Dis Sci 1985;30:103S-106S.
- 292. Potten CS, Loeffler M. Stem cells: Attributes, cycles, spirals, pitfalls and uncertainties. Lessons for and from the crypt. *Development* 1990;110:1001-1020.
- 350. Biasco G, Zannoni U, Paganelli GM, Santucci R, Gionchetti P, Rivolta G, Miniero R, Pironi L, Calabrese C, Di Febo G, Miglioli M. Folic acid supplementation and cell kinetics of rectal mucosa in patients with ulcerative colitis. *Cancer Epidemiol Biomarkers Prev* 1997;6:469-471.
- 381. Almendingen K, Hofstad B, Vatn MH. Lifestyle-related factors and colorectal polyps: Preliminary results from a Norwegian follow-up and intervention study. *Eur J Cancer Prev* 2002;11:153-158.
- 382. Baron JA, Beach M, Mandel JS, van Stolk RU, Haile RW, Sandler RS, Rothstein R, Summers RW, Snover DC, Beck GJ, Frankl H, Pearson L, Bond JH, Greenberg ER. Calcium supplements and colorectal adenomas. Polyp Prevention Study Group. *Ann NY Acad Sci* 1999;889:138-145.
- 399. Yang G. [Relationship between colorectal cancer and ten inorganic elements.] Zhonghua Yu Fang Yi Xue Za Zhi 1993;27:282-285. Original article and translation included.
- 400. Yang G, Gao Y-T, Ji B-T. [A case-control study on colorectal cancer and dietary fiber and calcium of various sources.] Zhonghua Yu Fang Yi Xue Za Zhi 1994;28:195-198. Original article and translation included.
- 403. Kampman E, Giovannucci E, van 't Veer P, Rimm E, Stampfer MJ, Colditz GA, Kok FJ, Willett WC. Calcium, vitamin D, dairy foods, and the occurrence of colorectal adenomas among men and women in two prospective studies. *Am J Epidemiol* 1994;139:16-29.
- 471. Anonymous. The role of calcium in peri- and postmenopausal women: Consensus opinion of The North American Menopause Society. *Menopause* 2001;8:84-95.
- 511. Vlajinac HD, Marinkovic JM, Ilic MD, Kocev NI. Diet and prostate cancer: A case-control study. *Eur J Cancer* 1997;33:101-107.

- 512. Berndt SI, Carter HB, Landis PK, Tucker KL, Hsieh LJ, Metter EJ, Platz EA. Calcium intake and prostate cancer risk in a long-term aging study: The Baltimore Longitudinal Study of Aging. *Urology* 2002;60:1118-1123.
- 513. Chan JM, Pietinen P, Virtanen M, Malila N, Tangrea J, Albanes D, Virtamo J. Diet and prostate cancer risk in a cohort of smokers, with a specific focus on calcium and phosphorus (Finland). Cancer Causes Control 2000;11:859-867.
- 514. Schuurman AG, van den Brandt PA, Dorant E, Goldbohm RA. Animal products, calcium, and protein and prostate cancer risk in the Netherlands Cohort Study. *Br J Cancer* 1999;80:1107-1113.
- 516. Tavani A, Gallus S, Franceschi S, La Vecchia C. Calcium, dairy products, and the risk of prostate cancer. *Prostate* 2001;48:118-121.
- 519. Ohno Y, Yoshida O, Oishi K, Okada K, Yamabe H, Schroeder FH. Dietary beta-carotene and cancer of the prostate: A case-control study in Kyoto, Japan. *Cancer Res* 1988;48:1331-1336.
- 520. Tzonou A, Signorello LB, Lagiou P, Wuu J, Trichopoulos D, Trichopoulou A. Diet and cancer of the prostate: A case-control study in Greece. *Int J Cancer* 1999;80:704-708.
- 521. Zhang Y, Kiel DP, Ellison RC, Schatzkin A, Dorgan JF, Kreger BE, Cupples LA, Felson DT. Bone mass and the risk of prostate cancer: The Framingham Study. *Am J Med* 2002;113:734-739.
- 523. Giovannucci E, Rimm EB, Wolk A, Ascherio A, Stampfer MJ, Colditz GA, Willett WC. Calcium and fructose intake in relation to risk of prostate cancer. *Cancer Res* 1998;58:442-447.
- 524. Chan JM, Giovannucci E, Anderson S-O, Yuen J, Adami H-O, Wolk A. Dairy products, calcium, phosphorus, vitamin D, and risk of prostate cancer. *Cancer Causes Control* 1998;9:559-566.
- 525. Chan JM, Giovannucci EL. Dairy products, calcium, and vitamin D and risk of prostate cancer. *Epidemiol Rev* 2001;23:87-92.
- 533. 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.
- 534. 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 A1(OH)₃ as phosphate binders. *Kidney Int* 1989;36(Suppl. 27):S133-S135.

- 535. 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.
- 536. Nolan CR, Qunibi WY. Calcium salts in the treatment of hyperphosphatemia in hemodialysis patients. Curr Opin Nephrol Hypertens 2003;12:373-379.
- 537. 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.
- 538. Orwoll ES. The milk-alkali syndrome: Current concepts. *Ann Intern Med* 1982;97:242-248.
- 541. 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.
- 542. 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.