



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

MAR 16 2004

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

RE: Health Claim Petition – Calcium and various cancers (Docket No. 2004Q-0097)

Dear Mr. Emord:

This letter acknowledges receipt on March 3, 2004 by the Food and Drug Administration (FDA) of your letter dated March 2, 2004 regarding the various calcium health claim petitions you submitted on November 25, 2003 on behalf of Marine Bio USA, Inc. We understand that the petitioner has elected to have their health claim petitions reviewed under the new process for qualified health claims rather than under the standard health claim review process described in Section 403(r)(5)(D) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 343(r)(5)(D)). We will follow the interim procedures for qualified health claims described in the FDA publication entitled “Consumer Health Information for Better Nutrition Initiative” Task Force Final Report (<http://www.cfsan.fda.gov/~dms/nuttfoc.html>).

Accordingly, today (March 16, 2004) we are filing your petition for qualified health claims about the relationship between calcium and (1) colorectal cancer, (2) colon cancer, (3) rectal cancer, (4) breast cancer, (5) prostate cancer, (6) colorectal, colon, rectal, breast and prostate cancers, (7) breast and prostate cancer, (8) colorectal, colon, and rectal cancers, (9) anticarcinogenic effects in the colon, breast, and prostate, and (10) recurrent colon polyps. The petition is posted at this web address: <http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm> and we are requesting comment on it for 60 days. Interested persons may submit comments until May 17, 2004. Within 225 days of the filing date we will notify you of our final decision regarding the requested qualified health claims. We have calculated that date to be October 27, 2004.

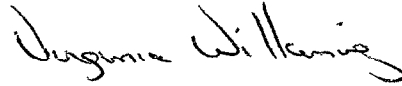
2004Q-0097

ACK 2

Page 2 - Jonathan W. Emord, Esq.

Please feel free to contact Dr. Jillonne Kevala at 301-436-1450, if you have any questions concerning this petition.

Sincerely yours,



for Laura M. Tarantino, Ph.D.  
Acting Director  
Office of Nutritional Products, Labeling,  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition