



MAR 15 2004

1015 '04 MAR 19 01:36

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

RE: Health Claim Petition – Calcium and Essential Hypertension, Gestational Hypertension and Pre-eclampsia (Docket No. 2004Q-0098)

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/nuttftoc.html>).

Accordingly, today we are filing your qualified health claim for calcium and reduced risk of essential hypertension, gestational hypertension and pre-eclampsia. The petition is posted on Dockets web page ([Http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm](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.

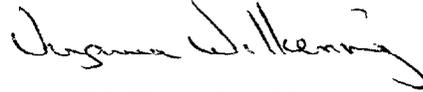
2004Q-0098

ACK 2

Page 2 - Jonathan W. Emord, Esq.

Please feel free to contact Dr. Julie Schrimpf at 301-436-2031 if you have any questions concerning this petition.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Laura M. Tarantino".

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