EMORD & ASSOCIATES P.C.

BURKE PROFESSIONAL CENTER
5282 LYNGATE COURT
BURKE, VIRGINIA 22015

1050 SEVENTEENTH STREET, N.W.
SUITE 600
WASHINGTON, D.C. 20036

PHONE: (202) 466-6937 • FAX: (202) 466-6938
WEB SITE: www.emord.com
E-MAIL: aferrenz@emord.com

3/16/04

March 2, 2004

VIA EMAIL *Kathy.ellwood@cfsan.fda.gov*
AND UPS GROUND
Dr. Kathy Ellwood
Assistant Director for Nutrition Science
FDA, CFSAN
CPK 1, Room 4A026
HFS-800
College Park MD 20740

Re: Calcium Health Claim Petitions

Dear Dr. Ellwood:

Our client, Petitioner Marine Bio USA, Inc., has chosen to seek FDA review, under the qualified claims process, of the five health claim petitions (containing a total of 26 proposed health claims) concerning calcium and its relationship to various diseases. We understand that with the switch to the qualified claims process FDA is proceeding as if 45 days have passed since the receipt of the petitions, leaving 225 days remaining for the agency to complete its review and issue a decision. As per your discussion with Ms. Lewis-Eng of our office, we understand the petitions will be posted on the agency's website for public comment within the next two weeks.

Sincerely,

Jonathan W. Emord
Andrea G. Ferrenz

Cc: Marine Bio USA Inc.

2004Q-0102

LET2