DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

AlgaeCal, Inc.
2805-1323 Homer Street
Vancouver, British Columbia
V6B 5T1
Canada

SEP 0 1 2009

Dear Mr.Neuls:

This is to inform you that the notification, dated May 22, 2009, which you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was received and filed by the Food and Drug Administration (FDA) on June 17, 2009. Additional information was received on September 1, 2009. Your notification concerned "Calcium carbonate and Magnesium carbonate derived from marine algae" which you identify as a new dietary ingredient that you intend to market under the proprietary name "AlgaeCal" in a dietary supplement product.

According to your notification, "AlgaeCal is a bulk ingredient which will be used in supplements to promote maintenance of bone health. The maximum amount that will be recommended is 2,500 mg of AlgaeCal *per* day", which will provide 750 mg of calcium and 350 mg magnesium per day.

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21 U.S.C. 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not prese significant or unreasonable risk of illness or injury.

Please note that acknowledgement of this notification is a procedural matter, and thus, does not constitute a finding by FDA that the new dietary ingredient or supplement that contains the new dietary ingredient is safe or is not adulterated under 21 U.S.C. 342. FDA is not precluded from taking action in the future against any dietary supplement containing your new dietary ingredient if it is found to be unsafe, adulterated or misbranded.

Your notification will be kept confidential for 90 days after the filing date of June 17, 2009. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number FDA-1995S-0039 (formerly docket number 95S-036). Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration

If you have any questions concerning this matter please contact Dr. Fred Hines, Consumer Safety Officer, New Dietary Ingredients Review Team, at (301) 436-1756.

Sincerely yours,

Dan D. Levy, Ph.D.
Senior Microbiologist, Acting Supervisor
New Dietary Ingredient Review Team
Division of Dietary Supplement Programs
Office of Nutrition, Labeling and Dietary Supplements