



JUN 13 2006

James W. Barnett, Jr., Ph.D., DABT
ACC Consulting Group
16709 French Harbour Court
Austin, Texas 78734

Dear Dr. Barnett:

This is to inform you that the notification you submitted, dated March 28, 2006, on behalf of Enzymotec, Ltd., pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on April 3, 2006. Your notification concerns the substance "CardiaBeat™" that you intend to market as a new dietary ingredient.

According to the notification, Enzymotec intends to market "CardiaBeat™" dietary supplement product in the form of capsules, liquids, and nutritional bars. Each capsule will contain 1g of "CardiaBeat™" The suggested use is to take one capsule twice a day with meals providing a total serving of 2 g CardiaBeat™ per day. Your notification further states that "CardiaBeat™" is an omega-3 phytosterol ester preparation composed of vegetable phytosterols, DHA and EPA fatty acid esters and DHA/EPA enriched fish oil.

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement that contains 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 section 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 deemed 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 present a significant or unreasonable risk of illness or injury.

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In accordance with 21 CFR 190.6(c), FDA must acknowledge its receipt of a notification for a new dietary ingredient. For 75 days after the filing date, your client must not introduce or deliver for introduction into interstate commerce any dietary supplement that contains the new dietary ingredient that is the subject of this notification.

Please note that acceptance of this notification for filing 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 April 3, 2006. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316.

If you have any questions concerning this matter, please contact Victoria Lutwak at (301) 436-1775.

Sincerely yours,

A handwritten signature in black ink that reads "Linda S. Pellicore". The signature is written in a cursive style with a large initial "L" and "P".

Linda S. Pellicore, Ph.D.
Supervisory Team Leader, Senior Toxicologist
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements,
Center for Food Safety and Applied Nutrition



4/04/2006

Ms. Vickey Lutwak
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: New Dietary Ingredient Notification (NDI) for omega-3 phytosterol esters

Dear Ms. Lutwak::

Per your request, I am providing additional contact information for myself and the manufacturer Enzymotec, Ltd. In the future, correspondence from FDA should be e-mailed and faxed to myself and Ms. Bendek at Enzymotec, Ltd.

My information:

James W. Barnett, Jr., Ph.D.
16709 French Harbour Court
Austin, TX 78734
Voice-512-26-2620
Fax-512-266-9736
jbarnett@aacgroup.com.

For Enzymotec, contact:

Iris Meiri-Bendek
Regulatory Manager
Enzymotec -LTD.
P.O.Box 6, Migdal HaEmeq
Israel 23106

Tel: 972-4-6545112 (ex. 115)

Fax: 972-4-6443799

e-mail: irisb@enzymotec.com

Should you have any questions regarding this response, feel free to call me at 512-266-2620 or e-mail to jbarnett@aacgroup.com. We will respond promptly to any questions you might have.

Best regards,

James W. Barnett, Jr., Ph.D., DABT

Authorized Agent for Enzymotec for NDI Notification