



Enzymotec
Delivering Lipids

Enzymotec Ltd
Hataasia 5 St.
P.O. Box 6
Migdal HaEmeq 23106
Israel

January 17, 2005

Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD,
20740

FEB
A.B./LOA

Dear Sir or Madam:

Re: Premarket Notification for a New Dietary Ingredient

In accordance with 21 CFR, Part 190, Sec. 190.6 "Requirement for premarket notification," we are submitting this new dietary ingredient notification for the dietary ingredient carDiabeat. Please note the following:

1. Name and Address of the Manufacturer of the New Dietary Ingredient

Enzymotec Ltd
Hataasia 5 St.
P.O. Box 6
Migdal HaEmeq 23106
Israel

2. Name of the New Dietary Ingredient

CarDiabeat

3. Description of the Dietary Supplement that will contain the New Dietary Ingredient

CarDiabeat is a phytosterol ester preparation composed of vegetable phytosterols, DHA and EPA fatty acid esters and DHA/EPA enriched fish oil. CarDiabeat will be sold in the form of an oral serving (e.g., capsules, liquids, nutritional bars) providing 1.1 g of carDiabeat per serving or 2.2 g carDiabeat per day.

4. Evidence of Safety

Data supporting that carDiabeat is reasonably expected to be safe under the conditions of use indicated, are provided in the attachment.

CTS 90842



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The original and two copies of the Notification are attached. We trust that the information provided meets the requirements of a New Dietary Ingredient Notification as indicated in 21 CFR §190.6. If you have any questions or comments regarding the content of this submission, please do not hesitate to contact Iris Meiri-Bendek 972-4-6545112 extension 115.

Sincerely,

Iris Meiri-Bendek
Regulatory Affairs

ENZYMOTEC LTD.