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05-19-07 PC2 50 RCVD

May 26, 2007

Office of Food Additive Safety (HFS-255)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

RE: Notification of GRAS Determination for Krill-based Lecithin in Food

Dear Sir/Madame:

In accordance with proposed 21 CFR § 170.36 (Notice of a claim for exemption based on a GRAS determination) published in the Federal Register (62 FR 18939-18964), I am submitting in triplicate, as the agent to the notifier, Enzymotec, a GRAS Notification for krill-based lecithin under the conditions of its intended use in food.

Please let me know if you have any questions.

Sincerely,

Edward A. Steele  
President

Enclosures

EAS Consulting Group, LLC  
1940 Duke Street, Suite 200, Alexandria, Virginia 22314  
(877) 327-9808 Toll Free • (703) 684-4408 Local • (703) 684-4428 Fax

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BY:.....

**I GRAS Exemption Claim**

**A. Claim of Exemption From the Requirement for Premarket Approval Pursuant to Proposed 21 CFR §170.36(c)(1) [62 FR 18938 (17 April 1997)]**

Krill-based lecithin has been determined to be Generally Recognized As Safe (GRAS), consistent with Section 201(s) of the *Federal Food, Drug, and Cosmetic Act*. This determination is based on scientific procedures as described in the following sections, under the conditions of its intended use in food. Therefore, the use of krill-based lecithin in food, as described below, is exempt from the requirement of premarket approval.

Signed,

\_\_\_\_\_  
Edward A. Steele

5/26/07  
\_\_\_\_\_  
Date

Agent for:

Enzymotec, Ltd  
P.O. Box 6, Migdal HaEmeq  
Israel 23106

Krill-based lecithin GRAS notification

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**B. Name and Address of Notifier**

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

**C. Common Name of the Notified Substance**

The substance is commonly known as lecithin. Commercial lecithin is a complex mixture obtained from edible food sources that is characterized by the principle component phosphatidyl choline. The composition of both the phosphatidyl choline and the lecithin mixture may vary depending on the source from which it is obtained, as described below. Because the fatty acid composition of marine-derived substances differs from that of plants in a way significant for nutrition, a unique name is appropriate. In this notice, we are describing the product as krill-based lecithin although we have described it in previous correspondence as marine-derived phosphatidyl choline, or MD-PC.

**D. Conditions of Intended Use in Food**

The lecithin derived from krill is intended for use as a nutrient in those foods, at levels listed below in Table I, that do not contain other significant sources of docosahexaenoic acid (DHA) or eicosapentaenoic acid (EPA) as ingredients.

**Table I**

Food	% Krill-based Lecithin
Breakfast bars	3.8
Dairy product analogs (soy products)	0.6
Fat spreads	10.0
Milk-based beverages	0.6
Yogurt	0.7
Soft candy	3.3

**E. Basis for the GRAS Determination**

Pursuant to 21 CFR § 170.30, krill-based lecithin has been determined to be GRAS on the basis of scientific procedures.

**F. Availability of Information**

The data and information that serve as the basis for this GRAS Notification will be sent to the U.S. Food and Drug Administration (FDA) upon request, or will be available for review and copying at reasonable times at the offices of:

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

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