ЗR



ORIGINAL SUBMISSION



Specializing in FDA Regulatory Matters

102-19-17 PC2 59 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

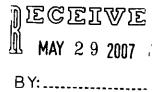
Enclosures



000004



Specializing in FDA Regulatory Matters



- I **GRAS Exemption Claim**
- Claim of Exemption From the Requirement for Premarket Approval Pursuant to A. 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

5/26/67

Agent for:

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

Krill-based lecithin GRAS notification



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 Notifi d 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.



2

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

Krill-based lecithin GRAS notification



3

DOCKET

Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.

