

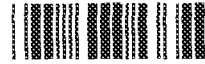
Links on this page:

1. <http://wcms.fda.gov/FDAgov/ICECI/inspections/InspectionGuides/default.htm>

## Appendix C

GRAS Notice for Aker Biomarine Antarctic  
AS, December 14, 2010.

GR



ORIGINAL SUBMISSION

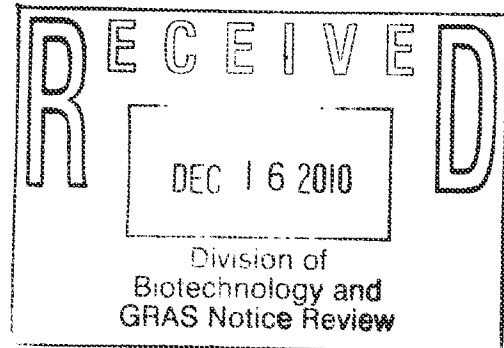
nnnn001

# Soni & Associates Inc.

749 46<sup>th</sup> Square  
Vero Beach, FL 32968, USA  
Telephone: 772-299-0746  
Facsimile: 772-299-5381  
E-mail: sonim@bellsouth.net

December 14, 2010

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



## Subject: Notification of GRAS Determination for Krill Oil

Dear Sir/Madam:

In accordance with proposed 21 CFR 170.36 (Notice of a claim for exemption based on a GRAS determination) published in Federal Register (62 FR 18938-18964; April 17, 1997), I am submitting in triplicate, as the agent of the notifier, Aker Biomarine Antarctic AS, Norway, a Generally Recognized As Safe (GRAS) notification for Superba® Krill Oil.

Superba™ Krill Oil extracted from Antarctic krill, *Euphausia superba* is intended for use as a food ingredient in non-alcoholic beverages; breakfast cereals; cheeses; frozen dairy desserts; milk whole and skim; processed fruit and fruit juices; and medical foods, at use levels ranging from 0.05 to 0.50 g per serving (reference amounts customarily consumed, 21 CFR 101.12). The intended use of Superba® Krill Oil is estimated to result in a maximum daily intake of 8.28 g/person.

If you have any questions or require additional information, please feel free to contact me by phone at 772-299-0746 or by email at sonim@bellsouth.net.

Sincerely,  
(b) (6)

Madhu G. Soni, Ph.D.

Enclosures:

# Soni & Associates Inc.

749 46<sup>th</sup> Square  
Vero Beach, FL 32968, USA  
Telephone: 772-299-0746  
Facsimile: 772-299-5381  
E-mail: sonim@bellsouth.net

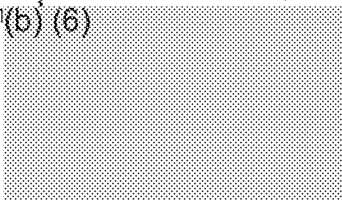
## GRAS NOTIFICATION

### I. Claim of GRAS Status

#### A. Claim of Exemption from the Requirement for Premarket Approval Requirements Pursuant to Proposed 21 CFR § 170.36(c)(1)

Aker Biomarine Antarctic AS, Norway, has determined that high phospholipid krill oil is Generally Recognized As Safe, and therefore, exempt from the requirement of premarket approval, under the conditions of its intended use. This determination is based on scientific procedures as described in the following sections, under the conditions of krill oil's intended use in food, among experts qualified by scientific training and expertise.

Signature (b) (6)



Date 12/14/10

Madhu G. Soni, Ph.D., FACN

Agent for:

Aker Biomarine Antarctic AS  
Fjordalléen 16, 0115 Oslo  
Norway

0 0 0 0 0 0

# 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.