

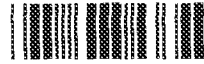
Links on this page:

1. <http://wcms.fda.gov/PDAgov/ICECI/inspections/inspectionGuides/default.htm>

## Appendix C

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

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ORIGINAL SUBMISSION

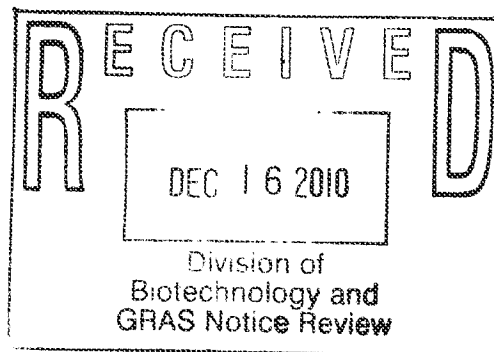
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# Soni & Associates Inc.

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.

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Vero Beach, FL 32968, USA  
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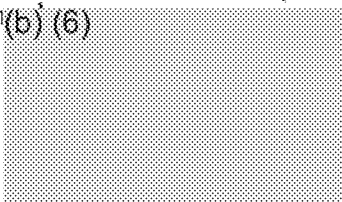
## GRAS NOTIFICATION

### 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

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