



Memorandum

DOCKETS TRANSMITTAL MEMO

0426 '03 JAN 27 P2:20

Date: JAN 23 2003
From: Consumer Safety Officer, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-821
Subject: 75-Day Premarket Notification of New Dietary Ingredients
To: Dockets Management Branch, HFA-305

Subject of the Notification: Neptune LyO-Krill™ (Freeze-dried Krill)

Firm: Neptune Technologies & Bioresources

Date Received by FDA: 5-15-02

90-Day Date: 8-13-02

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Gloria Chang
Gloria Chang, R.Ph./Interdisciplinary Scientist

Attachments

95S-0316

RPT 133



OCT 4 2002

Tina Sampalis, M.D., Ph.D
Vice President of Research
Neptune Technologies & Bioresources Inc.
500 St. Martin Blvd. West
Laval, Quebec
H7W 3J8, Canada

Dear Dr. Sampalis:

This is to inform you that your notification, dated February 1st, 2002 was originally filed with the Food and Drug Administration (FDA) on February 28, 2002. Your original notification contained three separate notifications concerning three new dietary ingredients that were identified as: Neptune Krill Oil™ (Krill oil), Neptune Aquateine™ (Krill-based protein concentrate powder of the dry residue from the extraction of oil), and Neptune LyO-Krill™ (freeze-dried Krill). You indicated that the primary source of all three ingredients is Krill, a shrimp-like crustacean identified as Antarctic Krill (species known as *Euphausia superba*). In a telephone conversation with you on April 8, 2002, we informed you that your notification was incomplete in that it did not supply all of the information as required in Title 21 of the Code of Federal Regulations (21 CFR) Part 190.6.

Your amended notification, dated April 26, 2002, containing the additional information was received by FDA on May 15, 2002, which was the revised filing date for the three ingredients cited above. We note that in the amended notification you included a new notification for an ingredient described as Neptune Krill Enzyme™. Subsequently, in telephone conversations with you on June 17 and July 15, 2002, we requested additional information on this ingredient and indicated that the new filing date for Neptune Krill Enzyme™ would be the date that we receive this information. The new filing date for the notification on Neptune Krill Enzyme™ was July 19, 2002. Further, on July 18, 2002 you notified us via electronic mail that you changed the tradename from Neptune Krill Enzyme™ to Neptune Krill Euphausia™. Hence, we will be using the new tradename for the rest of this letter. FDA considered the notification for Neptune Krill Euphausia™ separately from the other three notifications. Nonetheless, this letter addresses the four notifications for the following ingredients: Neptune Krill Oil™ (Krill oil), Neptune Aquateine™ (Krill-based protein concentrate powder of the dry residue from the extraction of oil), Neptune LyO-Krill™ (freeze-dried Krill), and Neptune Krill Euphausia™ (a blend of Neptune Krill Aquateine™ and Neptune Lyo-Krill™).

In your amended notification, you indicated that the serving levels and daily servings are: Neptune Krill Oil™ (1 gram of oil per gelcap with a recommended daily serving of 1 to 3 gelcaps per day), Neptune Aquateine™ (300 mg per sac with a recommended daily serving of 1 to 3 sacs per day), Neptune LyO-Krill™ (300 mg per capsule with a recommended daily

servings of 1 to 3 capsules per day) and Neptune Krill Euphausia™ (300 mg per capsule with a recommended daily serving of 1 to 3 capsules. You also stated that there was no limitation in the duration of use for any of the four ingredients and that the only subpopulations excluded from using these ingredients are persons with seafood allergies and those taking anticoagulants.

In accordance with 21 C.F.R. 190.6 (c), FDA must acknowledge its receipt of a notification for a new dietary ingredient. For 75 days after the filing dates, you must not introduce or deliver for introduction into interstate commerce any dietary supplement that contains Neptune Krill Oil™ (Krill oil), Neptune Aquateine™ (Krill-based protein concentrate powder of the dry residue from the extraction of oil), Neptune LyO-Krill™ (freeze-dried Krill) or Neptune Krill Euphausia™ (a blend of Neptune Krill Aquateine™ and Neptune Lyo-Krill™).

Please note that acceptance of this notification for filing is a procedural matter and, thus, does not constitute a finding by FDA that the new dietary ingredient or supplement that contains the new dietary ingredient is safe or is not adulterated under 21 U.S.C. 342. Importantly, new dietary ingredients for use in dietary supplements that FDA has reviewed through the premarket notification process are not "approved" or "authorized" by the agency.

Although we are not finding at this time that the basis on which you concluded that a dietary supplement containing either Neptune Krill Oil™, Neptune Aquateine™, Neptune LyO-Krill™ and Neptune Krill Euphausia™ will reasonably be expected to be safe is inadequate, FDA is not precluded from taking action in the future against a dietary supplement containing any of these ingredients if it is found to be adulterated or misbranded. It is the manufacturer's or distributor's responsibility to ensure that any dietary ingredient or a dietary supplement marketed in the United States is safe and complies with all applicable requirements of the Federal Food, Drug and Cosmetic Act and implementing regulations in Title 21 of the Code of Federal Regulations as well as any other applicable Federal laws and regulations.

Your notifications for Neptune Krill Oil™ (Krill oil), Neptune Aquateine™ (Krill-based protein concentrate powder of the dry residue from the extraction of oil), Neptune LyO-Krill™ (freeze-dried Krill) and Neptune Krill Euphausia™ (a blend of Neptune Krill Aquateine™ and Neptune Lyo-Krill™) will be kept confidential for 90 days from the date of their receipt. Therefore, your notifications for Neptune Krill Oil™, Neptune Aquateine™, and Neptune LyO-Krill™ and your notification for Neptune Krill Euphausia™ will be placed on public display at FDA's Dockets Management Branch in docket number 95S-0316 after August 13, 2002 and October 16, 2002, respectively. However, any trade secret or otherwise confidential commercial information in the notifications will not be disclosed to the public.

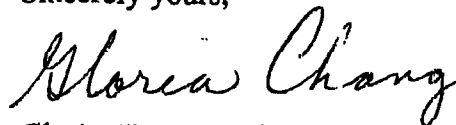
Prior to October 16, 2002, you may wish to identify in writing specifically what information you believe is proprietary in the notification for Neptune Krill Euphausia™ for FDA's consideration. Nevertheless, our Center's Freedom of Information Officer has the authority to make the final decision about what information in the notifications should be redacted before it is posted at Dockets.

For your information, the following FDA Internet sites and their corresponding links may be useful:

<http://www.cfsan.fda.gov/~dms/supplmnt.html>
<http://www.cfsan.fda.gov/~lrd/fr97923e.html> (21 CFR 190.6)
<http://www.cfsan.fda.gov/~dms/ds-info.html>
<http://www.cfsan.fda.gov/~dms/ds-ind.html>
<http://www.cfsan.fda.gov/~dms/ds-labl.html>
<http://www.cfsan.fda.gov/~lrd/fr97923b.html>
<http://www.cfsan.fda.gov/~dms/ds-labl.html#structure>
<http://www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.htm>

Please contact me at (301) 436-2371, if you have any questions concerning this matter.

Sincerely yours,



Gloria Chang, R.Ph
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HFS-821
Division of Standards
and Labeling Regulations
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and Dietary Supplements
Center for Food Safety
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