DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

0428 '03 JAN 27 P2:21

Memorandum

DOCKETS TRANSMITTAL MEMO

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 Krill Euphausia (Krill Aquateine/LyO-Krill Blend)

Firm: Neptune Technologies & Bioressources

Date Received by FDA: 7/19/02

90-Day Date: 10/17/02

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, R.Ph./Interdisciplinary Scientist

Attachments

95S-0316

RPT145

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

OCT 4 2002

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

Dear Dr. Sampalis:

This is to inform you that your notification, dated February 1[illegible], 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

serving 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/conline/pubs/buspubs/dietsupp.htm

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

Sincerely yours,

Gloria Chang

Gloria Chang, R.Ph
Interdisciplinary Scientist
HFS-821
Division of Standards
and Labeling Regulations
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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Ms. Gloria Chang
Acting Team Leader
Dietary Supplement Team
Division of Standards and Labeling
HFS-821,
CFSAN, FDA
200 C Street, SW
Washington, DC 20204
Telephone No. 301-436-1853

April 26, 2002

Re: ITPN 79419
Dear Ms. Chang,

Please find enclosed the supplementary information requested.

Please contact me if further information is required at:
tel.: 450-972-6291
cell: 514-865-9917
e-mail: tinas@neptunebiotech.com

Best Regards

Tina Sampalis M.D., Ph.D.
Vice President Research

RECEIVED
5/15/02
AM

APPENDIX A: Photostatic copies or reprints of the full-published references,

APPENDIX B: Neptune Krill Oil TM serving and daily dose

APPENDIX C: Neptune Aquateine TM serving and daily dose

APPENDIX D: LyO-Krill daily serving and dose

APPENDIX E: Neptune Krill Enzymes TM serving and daily dose

APPENDIX F: Scientific Report

APPENDIX G: processing techniques used

APPENDIX H: Krill additive by Nippon Suisan

Neptune Technologies & Bioressources Inc.
Information Package

Table of Contents

SUPPLEMENTARY INFORMATION

- The references included abstracts. I informed her that we needed photostatic copies or reprints of the full-published references, citations, and articles in English.
    - Please refer to "Appendix A"

- The specific species of Krill was not identified in the notification. I ask if there was a specific species that was to be marketed. Dr. Sampalis stated that there was, and that she would provide that information to us.
    - The krill species used is: Antarctic Krill *Euphasia superba* fished in the Antarctic ocean near the South Georgia and Sandwich Islands

- The notification was unclear as to what form of the Krill was to be orally ingested, there were 3 forms: the oil extract, the dry fraction, and the freeze-dried form. Dr. Sampalis stated that all three forms were to be marketed for oral ingestion. I asked her to indicate this in her response.
    - All three forms are meant for oral ingestion:
        - Neptune Krill Oil™ : gel caps (1 gram of oil per gel cap)
        - Aquateine™ (dry fraction): powder
        - LyO-Krill (freeze dried): capsules (300mg per capsule)

- **The notification was unclear as to the specific levels or concentration of Krill per serving dose for each form (i.e., the oil extract, the dry fraction, and the freeze-dried Krill) and the total daily serving intake and I asked Dr. Sampalis to provide information for all three forms. I also requested if there was any limitation or duration of use and frequency of serving doses (e.g., how many times a day it is taken), if so, to please indicate, if not to also state this.**
    - Neptune Krill Oil™ : gel caps
        - 1 gram of oil per gel cap
        - recommended dose = 1 – 3 gel caps per day
        - Daily dose: Appendix B

    - Aquateine™ (dry fraction): powder
        - 300mg per sac
        - recommended dose = 1 – 3 sacs per day
        - Daily dose: Appendix C

    - LyO-Krill (freeze dried): capsules
        - 300mg per capsule
        - recommended dose = 1 – 3 capsules per day
        - Daily dose: Appendix D

    - Limitations:
        - No limitation in the duration of use

- **Because the target population was not clear or missing, to provide the target population that the NDI would be used. If there is no target population, to please indicate that. To also provide information if there is any excluded populations such as pregnant/lactating women, the elderly, children or infants (state age range if any) or other populations with specific disease or medical conditions. If so, to specify, if not also state this.**
    - There is no target population
    - Excluded populations:
        - Seafood allergy
        - Anticoagulant use

- **I also asked Dr. Sampalis to submit the requested complete information in triplicate.**
    - Three copies enclosed

- **Also please make sure that the complete processing information for all three forms, if not in original submission notification, are included in the submission, (i.e., the processing technique used, the chemicals, compounds, or other ingredients used in processing if any, the drying and freezing techniques, etc.)**
    - Please refer to "Appendix E"

- **If there are any other ingredients in the various serving (dosage) forms such as excipients, flavors, coloring, preservatives, stabilizers, etc, also please identify and indicate levels.**
    - The company that fishes the raw material (krill) in the Antarctic add "sodium hydrogen sulfite (NaHSO3)" as an additive upon freezing. The amount of NaHSO3 in krill is approximately 100 ppm.
    - There are no other ingredients included in any of the serving forms