



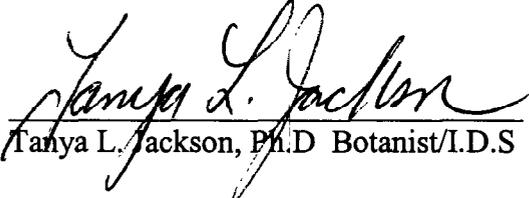
Memorandum

FEB 27 2004

Date:
From: Lead Reviewer, Division of Dietary Supplements Program, 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: Buckthorn Seed Oil
Hippophae rhamnoides L.
Firm: Conseco Sea Buckthorn Co., LTD
Date Received by FDA: September 4, 2003
90-Day Date: December 5, 2003

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.


Tanya L. Jackson, Ph.D Botanist/I.D.S

955-0316

RPT210



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, Maryland 20740

NOV 14 2003

Dr. Han Xu
Senior Researcher
Conseco Sea Buckthorn Co., Ltd
Jia 1 Fuxing Road, Haidian District
Beijing 100038
P.R. China

Dear Dr. Xu:

This is to inform you that the notification that you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on September 4, 2003. Your notification concerns the substance "Conesco Brand Sea Buckthorn Seed Oil" that you intend to market as a new dietary ingredient.

According to the notification, you intend to sell soft capsules containing 0.45g-0.5g of your new dietary ingredient, Conesco Brand Sea Buckthorn Seed Oil. You recommend taking 2-3 capsules twice daily for a total daily intake of 3 g.

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this

requirement is not met, the dietary supplement is deemed to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA has carefully considered the information in your submission, and the agency has concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing Conseco Brand Sea Buckthorn Seed Oil will reasonably be expected to be safe.

The notification does not clearly identify the new dietary ingredient, Conseco Brand Sea Buckthorn Seed Oil. The description of Conseco Brand Sea Buckthorn Seed Oil provided in the notification includes ambiguous fatty acid nomenclature. For example, the Conseco Brand Sea Buckthorn Seed Oil component identified as “sub-oleic acid” is apparently C18:2, but the component “flax acid” is not identified as a unique chemical compound. Moreover, the notification did not include a description of the manufacturing process.

Based on the notification, it is unclear how the information submitted relates qualitatively and quantitatively to the dietary supplement containing Conseco Brand Sea Buckthorn Seed Oil. The notification did not clearly characterize the test substances used in the referenced studies or how these studies are relevant to evaluating the safe use of Conseco Brand Sea Buckthorn Seed Oil under the recommended conditions of use. For example, the notification contains the results of three (3) acute and one (1) 90-day safety studies conducted with a substance called “Sea Buckthorn Seed Oil”, however, the notification does not specify that “Sea Buckthorn Seed Oil” is the same as Conseco Brand Sea Buckthorn Seed Oil. Moreover, your notification stated that “the dosage used in the 90 days long-term toxicity studies, 2 ml/kg/bw, 5 ml/kg/bw, 10 ml/kg/bw are equivalent to 12, 30, 60 times of human using dosage” however, the notification did not include an explanation of how the figures for the human dosages were derived.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that the Conseco Brand Sea Buckthorn Seed Oil product, when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of September 4, 2003. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Victoria Lutwak at (301) 436-1775.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Walker', with a stylized flourish at the end.

Susan J. Walker, M.D.
Division Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition