



Memorandum

MAR 03 2004

Date: _____
From: Interdisciplinary Scientist/Pharmacist , Division of Dietary Supplement Programs ,
Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810
Subject: 75-Day Premarket Notification of New Dietary Ingredients
To: Dockets Management Branch, HFA-305

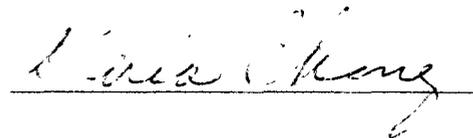
Subject of the Notification: **Sea Buckthorn Rich Flavone Extraction Substance**

Firm: Conesco Sea Buckthorn Co. LTD

Date Received by FDA: November 04, 2003

90-Day Date: 02/02/04

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.



95S-0316

RPT217



JAN 14 2004

Food and Drug Administration
College Park, Maryland 20740

Han Xu, M.D.
Pharm1 Medicine Technology INC
No: A-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 November 4, 2003. Your notification concerns the substance called "The Warmhearted Brand Sea Buckthorn Rich Flavone Extraction Substance" that you intend to market as a new dietary ingredient.

According to the notification, you intend to sell soft capsules containing 0.45 g of your new dietary ingredient, "The Warmhearted Brand Sea Buckthorn Rich Flavone Extraction Substance." You state that the substance is extracted from the botanical fruits of Sea buckthorn (*Hippophae rhamnoides* L). You recommend a dosage of "4 capsules/time, 2 times/day."

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing 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 considered 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 "The Warmhearted Brand Sea Buckthorn Rich Flavone Extraction Substance" will reasonably be expected to be safe.

The notification does not identify the new dietary ingredient called "The Warmhearted Brand Sea Buckthorn Rich Flavone Extraction Substance." The notification does not clearly describe the composition of "The Warmhearted Brand Sea Buckthorn Rich Flavone Extraction Substance," the specific part(s) of the plant structure used, and the method of obtaining the substance that is the subject of the notification. This information may have helped FDA clarify the identity of your product.

In addition, the notification did not clearly characterize the test substances used in the animal studies or how these studies are relevant to evaluating the safe use of your product. It is unclear how the test substances in the animal studies submitted relate qualitatively or quantitatively to your product containing "The Warmhearted Brand Sea Buckthorn Rich Flavone Extraction Substance." Based on the notification, FDA is unable to determine whether the scientific studies cited in your notification provide an adequate basis for your conclusion that "The Warmhearted Brand Sea Buckthorn Rich Flavone Extraction Substance" will reasonably be expected to be safe.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that your product containing "The Warmhearted Brand Sea Buckthorn Rich Flavone Extraction Substance," 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 November 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) 436-2375.

Sincerely yours,



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