



Memorandum

Date: SEP 01 2004

From: Consumer Safety Officer, Division of Dietary Supplement Programs, 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: Conseco Brand Sea Buckthorn Fruit Oil

Firm: Conseco Sea Buckthorn Co., Ltd.

Date Received by FDA: 6/7/04

90-Day Date: 9/5/04

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.

Yanya L. Jackson Botanist

95S-0316

RPT245



Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

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

AUG 19 2004

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 June 7, 2004. Your notification concerns the substance "Conseco Brand Sea Buckthorn Fruit Oil", extracted from *Hippophae rhamnoides* L., that you intend to market as a new dietary ingredient.

According to the notification, you intend to sell 100 ml bottles of your new ingredient "Conseco Brand Sea Buckthorn Fruit Oil". You recommend taking 5 ml-10 ml twice daily for a total daily intake of 20 ml per 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 "Conseco Brand Sea Buckthorn Fruit Oil" will reasonably be expected to be safe.

Although your notification included a general description of a manufacturing process for "Fruit Oil" from Sea Buckthorn (*Hippophae rhamnoides* L.), your notification does not contain any information about the actual preparation, lipid composition, product specification, methods of analysis, and purity of "Conseco Brand Sea Buckthorn Fruit Oil". There is inadequate information presented in the notification to characterize and identify your specific "new dietary ingredient". A quality standard HB/QS 001-94 is cited but no information regarding this is included in the notification. A description of the method of manufacture or process of obtaining your product, "Conseco Brand Sea Buckthorn Fruit Oil", may have helped FDA clarify the identity of your product.

Moreover, it is unclear to FDA whether the test substances used in the referenced studies are the same as the "Conseco Brand Sea Buckthorn Fruit Oil", in your notification. The test material was stated to be "Conseco Brand Sea Buckthorn Fruit Oil" and was described as a "brown red" transparent oil. It is not evident that the test substances used in the referenced studies are qualitatively or quantitatively similar to your "Conseco Brand Sea Buckthorn Fruit Oil", or how these studies are relevant to evaluating the safe use of your new dietary ingredient under the recommended conditions of use.

FDA would also like to take this opportunity to comment that this is the third "Conseco Brand Sea Buckthorn Fruit Oil" submission from Conseco Sea Buckthorn Co., Ltd. within one calendar year. The two previous submissions contained the same information as the current submission. Each time we reviewed the information, we came to the same conclusion that there was inadequate information to provide reasonable assurance of safety for "Conseco Brand Fruit Buckthorn Fruit Oil" to be used as a new dietary ingredient in a dietary supplement. Therefore, it is important to address these deficiencies before you submit another new dietary ingredient notification for "Conseco Brand Sea Buckthorn Fruit Oil" to FDA.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that the "Conseco Brand Sea Buckthorn Fruit 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 June 7, 2004. After the 90-day date, the notification will be placed on public display at FDA's Division of Docket Management 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 Linda Pellicore, Ph.D., at (301) 436-2375.

Sincerely yours,

A handwritten signature in black ink that reads "Linda S. Pellicore". The signature is written in a cursive style with a large initial "L".

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