



John Geier
Altai, LLC
13500 Orchard Road
Minnetonka, Minnesota 55305

MAR 19 2004

Dear Mr. Geier:

This is to inform you that the notification, dated December 25, 2003, 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 January 5, 2004. Your notification concerns the substance called "Sea Buckthorn extract," derived from the leaves of the Sea Buckthorn plant that you intend to market as a new dietary ingredient.

According to the notification, each 0.6 gram (g) tablet contains 0.02 g of a dry purified extract of the polyphenol complex of gallo-ellagi-tannins produced from *Hippophae rhamnoides* L. (Sea Buckthorn). The suggested use is "[a]s a dietary supplement, one to two tablets daily, when needed." You state that the inactive ingredients are sugar, cocoa, vanilla, and stearic acid.

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 "Sea Buckthorn extract" will reasonably be expected to be safe.

The notification does not identify the new dietary ingredient "Sea Buckthorn extract" derived from the leaves of the Sea Buckthorn plant. The notification does not clearly describe the composition of the "Sea Buckthorn extract." For example, on page one of your notification, you state that your product contains as the "active ingredient," 0.02 gram of a dry purified extract of the polyphenol complex of gallo-ellagi-tannins, produced from *Hippophae rhamnoides* (Sea Buckthorn). However, on the same page, you describe the new dietary ingredient as "Sea Buckthorn extract," derived from the leaves of the Sea Buckthorn plant (*Hippophae rhamnoides* L.). Thus, it is unclear to us whether your "Sea Buckthorn extract" is derived from the leaves of the Sea Buckthorn plant or from the dry purified extract of the polyphenol complex of gallo-ellagi-tannins, produced from *Hippophae rhamnoides* (Sea Buckthorn). The method of preparation and the solvents used for extraction may have helped FDA clarify the identity of your product.

In addition, the notification did not clearly characterize the test substances used in the abstracts submitted. It is unclear how the test substances used in the abstracts of the studies relate qualitatively or quantitatively to your substance "Sea Buckthorn extract." The four abstracts submitted do not provide sufficient information to determine reasonable expectation of safety.

Further, any reference to published information offered in support of the notification must be accompanied by reprints or legible photostatic copies of such references. If any of the material is written in a foreign language, it must be accompanied by accurate and complete English translation.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that your product containing "Sea Buckthorn extract" 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 January 5, 2004. 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.

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If you have any questions concerning this matter, please contact Victoria Lutwak at (301) 436-2375.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Walker". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

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