

**MAY 28 2004**

Mr. Marc S. Ullman  
Ullman, Shapiro & Ullman, LLP  
Counselors at Law  
299 Broadway, Suite 1700  
New York, New York 10007

Dear Mr. Ullman:

This is to inform you that the notification, dated March 5, 2004, 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)) on behalf of your client, Fuji Chemical Industry Co., Ltd, was filed by the Food and Drug Administration (FDA) on March 15, 2004. Your notification concerns the substance called, Astaxanthin, extracted from the algae, *Haematococcus pulvialis* (Flotow em. Wille), that you intend to market as a new dietary ingredient.

You state that your client intends to market Astaxanthin under the trade names AstaREAL™ and AstaCarox®. You also state that AstaREAL™ will initially be marketed in tablet and softgel capsule form. Each tablet/softgel will contain 5-6 mg of Astaxanthin extract and the recommended dose of AstaREAL™ will be 2-12 mg 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 notification and has significant concerns about the evidence on which you rely to support your conclusion that the ingredient, Astaxanthin, will be reasonably expected to be safe for the suggested or intended uses.

Although you stated in your notification the recommended dose and conditions of use of AstaREAL™, you didn't provide information regarding the composition and conditions of use of for AstaCarox®. This information should be provided in any subsequent notification.

Your notification does not contain any information about the actual preparation of your Astaxanthin extracted from the algal source. A description of the method of manufacture or process of obtaining your product, Astaxanthin, may have helped FDA clarify the identity of your product. It is unclear to FDA whether the test substances used in the referenced studies are the same as the Astaxanthin, in your notification. It is not evident that the test substances used in the referenced studies are qualitatively or quantitatively similar to your Astaxanthin, or how these studies are relevant to evaluating the safe use of your new dietary ingredient under the recommended conditions of use.

Your notification will be kept confidential for 90 days after the filing date of March 15, 2004. After the 90-day date, the notification will be placed on public display at FDA's Division of Dockets 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 Victoria Lutwak at (301) 436-2375.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Walker', with a long horizontal line 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