



**Memorandum**

**DOCKETS TRANSMITTAL MEMO**

0641 '03 FEB 25 P1:54

Date: 2/20/03

From: Consumer Safety Officer, Division of Standards and Labeling Regulations, 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

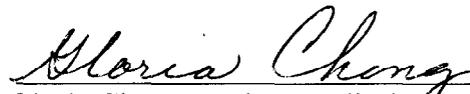
**Subject of the Notification:** Extract of *Padina pavonica* (Algae)

**Firm:** Advanced Nutratceutical Concepts

**Date Received by FDA:** November 21, 2002

90-Day Date: February 19, 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 after February 19, 2003. Thank you for your assistance.

  
Gloria Chang, R.Ph./Interdisciplinary Scientist

Attachments

95S-0316

RPT156

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Marilyn F. Booker, RN, MS  
Advanced Nutratceutical Concepts  
16 Sunnyview Drive  
Phoenix, Maryland 21131

Dear Ms. Booker:

This is in response to your notification that you submitted pursuant to 21 U.S.C. 350b(a)(2) and 21 Code of Federal Regulations (CFR) Part 190.6 and initially received by the Food and Drug Administration (FDA) on November 6, 2002. On November 21, 2002, we requested additional information in accordance with 21 CFR 190.6. We received a facsimile from you with this information on November 21, 2002 which is the new effective filing date. Your notification concerns the substance, extract of *Padina pavonica* (Algae) that you assert is a new dietary ingredient.

Your notification describes the substance as an off-white, odorless, fine powder which can be prepared in a hard gelatin capsule dosage form containing 200 mg per capsule. The recommended conditions of use is for adults to take one capsule (200 mg) daily.

Under 21 U.S.C. 350b(a)(2), the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient is required to submit certain information to FDA at least 75 days before a new dietary ingredient or a dietary supplement containing it is introduced or delivered for introduction into interstate commerce. This information must include the basis on which the manufacturer or distributor has concluded that the new dietary ingredient or a dietary supplement containing the 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 21 U.S.C. 350b(a)(2), there must be a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the product's labeling, will reasonably be expected to be safe. If this requirement is not met, the new dietary ingredient or dietary supplement containing it may be 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.

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FDA has carefully considered the information in your notification and has concerns about the evidence on which you rely to support your conclusion that the ingredient, extract of *Padina pavonica* (Algae), will be reasonably expected to be safe for the suggested or intended use.

You indicate in your notification that the ingredient is a marine extract from the *Padina pavonica* brown algae, a member of the Pheophyceae genus. The notification contains the results of three animal studies and a mutagenicity study.

In the studies, it was unclear as to whether the test substances used are the same as that of the ingredient in your notification. Moreover, your submission provides no information that the test substances used in the referenced studies are qualitatively or quantitatively similar to your ingredient or how these studies are relevant to evaluating the safe use of your ingredient under the recommended conditions of use. For example, in one of the studies there was a statement that the formulation used was not analyzed for the test article concentration and that the test substance was prepared as a 10 percent w/v suspension in water. Further, the notification contains no information describing a history of use of the extract of *Padina pavonica* that is the subject of this notification.

In conclusion, the information in your notification does not appear to provide an adequate basis to conclude that it is reasonably expected to be safe when used under the recommended or suggested conditions of use. 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 it does not present a significant or unreasonable risk of illness or injury. Introduction of such products 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 21, 2002. After February 19, 2003, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to February 19, 2003, you may wish to identify in writing specifically what information in your

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notifications you believe is proprietary, trade secret or otherwise confidential information which should not be disclosed to the public.

If you have any questions concerning this matter, please contact us at (301) 436-2371.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Walker", with a long horizontal flourish extending to the right.

Susan J. Walker, M.D.  
Acting Division Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements