



JAN 27 2004

Memorandum

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

5094 04 FEB -3 11:00

Subject of the Notification: **Extract of *Padina pavonica***

Firm: **Sunnybrook Consulting**

Date Received by FDA: May 19, 2003

90-Day Date: August 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 as soon possible since it is past the 90-day date. Thank you for your assistance.

*Gloria Cheney*

95S-0316

RPT 194



JUL 18 2003

Marilyn F. Booker, RN, MS  
Authorized Agent for  
Institute of Benthique Algae Limited  
Sunnybrook Consulting  
16 Sunnyview Drive  
Phoenix, MD 21131

Dear Ms. Booker:

This is to inform you that the notification, dated May 9, 2003, you submitted on behalf of your client, The Institute of Benthique Algae Limited, 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 May 19, 2003. You describe the substance as extract of *Padina pavonica* (EPP), that you intend to market as a new dietary ingredient. Your notification is a new submission for the same substance that was the subject of your previous notification filed with FDA on November 21, 2002.

You state that EPP is a natural whole marine extract from *Padina pavonica* brown algae, a member of the Pheophyceae genus. You further state that EPP is an off-white to tan, odorless, fine powder that will be prepared in a hard-gel capsule dosage form. Each hard-gel capsule will contain 200 mg of dry EPP. The daily recommended intake for adults is 1 capsule.

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement that contains 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 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.

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 extract of *Padina pavonica* will reasonably be expected to be safe.

Aside from an unreferenced statement that people in Mediterranean countries have consumed *Padina pavonica* for a generation, no history of use of the algae by humans is documented in the notification. There is no documented history of use by humans of the acetone extract of *Padina pavonica*. The animal studies included in the notification do not provide information useful for a safety assessment of the extract. One study used a brown powder, another study used a white powder, and the third study did not provide a description of the tested material. It is not known whether these powders had the same compositions as EPP. The acetone extract of *Padina pavonica* is described as a dark green to dark brown powder and EPP is described as an off-white to tan powder. All three animal studies were acute in nature, involving only a single exposure of the animals to the tested materials. In all of the studies, the dosages were provided in water or methylcellulose, despite the fact that the active components were said to be extracted from the algae with acetone. A letter from a pharmacist of the Institute of Benthique Algae stated that all of the studies cited in the notification were carried out with the same *Padina pavonica* extract that is the subject of the notification. This does not seem to be the case since the physical descriptions of the tested materials, when provided, were not the same for all of the acute studies, and did not always match the physical description of EPP or of the extract of *Padina pavonica*. Taken together, the information provided in the notification does not provide evidence supporting the safe use of the acetone extract of *Padina pavonica*.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that extract of *Padina pavonica*, 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 May 19, 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.

Page -3- Marilyn F. Booker, RN, MS

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

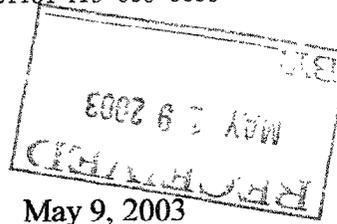
Sincerely yours,

A handwritten signature in black ink, appearing to read 'SJW', 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  
Center for Food Safety  
and Applied Nutrition

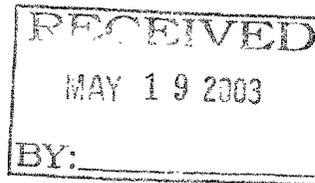
# SUNNYBROOK CONSULTING

16 Sunnyview Drive Phoenix, MD 21131 410-666-5599



May 9, 2003

Division of Standards and Labeling Regulations  
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-820)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD, 20740-3835  
Telephone Number: (301) 436-2371



Dear Sir or Madam:

Enclosed, please find, an original and three copies of the pre-market notification for the new dietary ingredient, extract of *Padina pavonica* (EPP), submitted pursuant to section 413 of the Federal Food, Drug and Cosmetic Act.

Please note that pursuant to 21 CFR 20.61, we designate Exhibit A, the *Padina pavonica* Extraction Process as confidential and request that this not be made public.

We believe that this document will provide sufficient scientific laboratory and history of use evidence to meet the expectation of safety standard as outlined in the Dietary Supplement Health and Education Act.

Should you have any questions regarding this submission, please contact:

Marilyn F. Booker, RN, MS  
16 Sunnyview Drive  
Phoenix, MD 21131  
410-666-5599  
[mbooker@comcast.net](mailto:mbooker@comcast.net)

Sincerely,

Marilyn F. Booker, RN, MS

**Extract of *Padina pavonica***  
**Dietary Supplement**  
**Premarket Notification**  
**May 9, 2003**

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