DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: JAN 23 2003 0418 '03 JAN 27 P2:12

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:	dried cultured mycelia of *Cordyceps sinensis* (Berk.) Sacc.
Firm:	HOMEGI BIOTECH INTERNATIONAL CORP.
Date Received by FDA:	June 18, 2002
90-Day Date:	September 16, 2002

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.

Rhonda R. Kane

Rhonda R. Kane, M.S., R.D.

Attachments

95S-0316

RPT 136

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

AUG 29 2002

Yuan Lin, Ph.D.
Marco Polo Technologies, Inc.
5900 Conway Road
Bethesda, Maryland 20817

Dear Dr. Lin:

This letter is sent in follow up to our letter dated August 21, 2002, acknowledging receipt of a new dietary ingredient premarket notification you sent the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 350b(a)(2). On June 18, 2002, FDA received and filed the notification that concerns dried "cultured mycelia of *Cordyceps sinensis* (Berk.) Sacc." that you assert is a new dietary ingredient. You informed us that you submitted the notification on behalf of the distributor, HOMEGI BIOTECH INTERNATIONAL CORP. (Homegi).

The law at 21 U.S.C. 350b(a)(2) requires that a manufacturer or distributor of a dietary supplement that contains a new dietary ingredient submit certain information to FDA at least 75 days before the dietary ingredient is introduced or delivered for introduction into commerce. This information must include 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 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 new dietary ingredient 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 and injury.

FDA has carefully reviewed Homegi's notification and does not have any comments germane to the new dietary ingredient itself. Your notification identified several other ingredients in addition to cultured mycelia of *Cordyceps sinensis* (Berk.) Sacc. that are contained in Sustotrong. Please be advised that it is the manufacturer's or distributor's responsibility to ensure that a dietary supplement product marketed in the United States complies with all applicable requirements of the Federal Food, Drug and Cosmetic Act and implementing regulations in Title 21 of the Code of Federal Regulations as well as any other applicable Federal laws and regulations.

For 75 days after the filing date of this notification (i.e., until after September 1, 2002), the manufacturer or distributor must not introduce or deliver for introduction into interstate commerce any dietary supplement that contains dried cultured mycelia of *Cordyceps sinensis* (Berk.) Sacc. Homegi's notification will be kept confidential for 90 days after the filing date. After September 16, 2002, the notification and related FDA responses will be placed on public display at FDA's Dockets Management Branch in docket number 95S-0316. However, any trade secret or otherwise confidential commercial information that is in the notification will not be disclosed to the public.

Prior to September 16, 2002, you may wish to identify for FDA in writing the specific information in the notification that Homegi believes is proprietary. Nevertheless, our Center's Freedom of Information Officer has the authority to make the final decision about what information in the notification should be redacted before it is posted at Dockets.

Please contact me at (301) 436-2371 if you have any questions concerning this matter.

Sincerely yours,

Felicia B. Satchell

Felicia B. Satchell
Director
Division of Standards
and Labeling Regulations
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

AUG 21 2002

Yuan Lin, Ph.D.
Marco Polo Technologies, Inc.
5900 Conway Road
Bethesda, Maryland 20817

Dear Dr. Lin:

This responds to a new dietary ingredient premarket notification, dated March 31, 2002, you submitted on behalf of the distributor, HOMEGI BIOTECH INTERNATIONAL CORP. (Homegi), to the Food and Drug Administration pursuant to 21 U.S.C. 350b(a)(2). You delivered an amendment dated June 18, 2002 to FDA that same day, which is the filing date of the amended notification. Your notification concerns dried "cultured mycelia of *Cordyceps sinensis* (Berk.) Sacc." that you assert is a new dietary ingredient.

The notification further explains that this fungus represents the same genus and species as that used in traditional Chinese medicine. However, it is produced by fermentation in a biotechnological aseptic environment that does not involve the use of the caterpillar larvae *Hepialus carians* Staudinger for its cultivation. Homegi intends to market in the United States a dietary supplement capsule called "Sustotrong" that contains several ingredients, including 225 mg of dried cultured mycelia of *Cordyceps sinensis* (Berk.) Sacc.

You identify the intended consumers of Sustotrong as adults 19 years of age and older. The product will include a statement that Sustotrong should not be taken by pregnant and lactating women without consulting a physician and that persons experiencing flu-like symptoms should stop taking this product. No other contraindications are noted.

As a procedural matter in accordance with 21 CFR 190.6(c), this letter confirms FDA receipt of your notification for a new dietary ingredient. For 75 days after the filing date (i.e., until after September 1, 2002), the manufacturer or distributor must not introduce or deliver for introduction into interstate commerce any dietary supplement that contains dried cultured mycelia of *Cordyceps sinensis* (Berk.) Sacc.

The lack of any follow-up FDA response during this 75-day period does not constitute a finding by the agency that a dietary supplement containing dried cultured mycelia of *Cordyceps sinensis* (Berk.) Sacc. is safe or is not adulterated under 21 U.S.C. 342. Further, FDA is not precluded from taking action in the future against a dietary supplement containing dried cultured mycelia of *Cordyceps sinensis* (Berk.) Sacc." if it is found to be unsafe, adulterated or misbranded. It is the responsibility of the manufacturer or distributor of a dietary supplement to ensure that it is safe, properly labeled and complies with all applicable

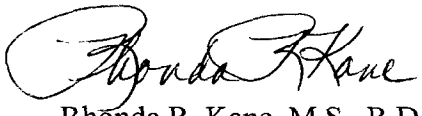
requirements of the Federal Food, Drug and Cosmetic Act and other Federal, State or local statutes or regulations. Importantly, any new dietary ingredient for use in a dietary supplement that FDA has reviewed through the premarket notification process is not "approved" or "authorized" by the agency.

As another procedural matter, your notification will be kept confidential for 90 days after the filing date. Therefore, after September 16, 2002, the notification and this response will be placed on public display at FDA's Dockets Management Branch in docket number 95S-0316. However, any trade secret or otherwise confidential commercial information that is in the notification will not be disclosed to the public.

Prior to September 16, 2002, you may wish to identify for FDA in writing the specific information in the notification that Homegi believes is proprietary. Nevertheless, our Center's Freedom of Information Officer has the authority to make the final decision about what information in the notification should be redacted before it is posted at Dockets.

Please contact me at (301) 436-2371 if you have any questions concerning this matter.

Sincerely yours,



Rhonda R. Kane, M.S., R.D.
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