DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

0420 '03 JAN 27 P2:13

Date: January 16, 2003

From: Chemist, 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:	*Corcyceps sinenis* mycelia (resubmission)
Firm:	Premiere Towa, Inc.
Date Received by FDA:	July 9, 2002
90-Day Date:	October 7, 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.

Kenneth M. P. Taylor, Ph.D.

Attachments

95S-0316

RPT 138

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD

SEP 20 2002

Yasuhiro Matsumura, D.M.D.
President
Premiere Towa, Inc.
21243 Ventura Boulevard
Suite 131
Woodland Hills, California 91364

Dear Dr. Matsumura:

This is to inform you that the notification, dated July 3, 2002, which you submitted pursuant to 21 U.S.C. 350b(a)(2) was received and filed by the Food and Drug Administration (FDA) on July 9, 2002. Your notification concerns the substance *Cordyceps sinensis* [(Berk.) Saccardo] *mycelia* that you assert is a new dietary ingredient. Your notification states that *Cordyceps sinensis mycelia* is produced by Taiwan Sugar Corporation (TSC) by fermentation, and would be marketed under the trade name *Taisugar Cordyceps sinensis mycelia* This notification represents a resubmission of an earlier notification dated February 25, 2002, that was received by FDA on March 13, 2002. FDA responded to this notification on May 2, 2002, indicating that your notification did not comply with the requirements of 21 Code of Federal Regulations (CFR) 190.6 because it was incomplete. You were further advised that because your prior notification did not satisfy regulatory requirements, you could not legally market a dietary supplement containing *Cordyceps sinensis mycelia.*

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.

Your present notification includes history of use for one strain of *Cordyceps mycelia*, CS-4, which is produced by fermentation. However, it does not identify the strain of *Cordyceps*

mycelia that you intend to market as the new dietary ingredient, or provide information that the submitted literature on the CS-4 strain can be used to provide a reasonable assurance of safety for your particular strain of *Cordyceps*. Accordingly, there is inadequate information in your notification for FDA to determine whether there is an adequate basis to conclude that the use of a dietary supplement that contains *Cordyceps mycelia* 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 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. Therefore, after October 7, 2002, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. However, any trade secret or otherwise confidential commercial information in the notification will not be disclosed to the public. Prior to October 7, 2002, you may wish to identify in writing specifically what information you believe 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

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

AUG 28 2002

Yasuhiro Matsumura, D.M.D.
President
Premiere Towa, Inc.
21243 Ventura Boulevard
Suite 131
Woodland Hills, California 91364

Dear Dr. Matsumura:

This is to inform you that the notification, dated July 3, 2002, which you submitted pursuant to 21 U.S.C. 350b(a)(2) was received and filed by the Food and Drug Administration (FDA) on July 9, 2002. Your notification concerns the substance *Cordyceps sinensis* [(Berk.) Saccardo] *mycelia* that you assert is a new dietary ingredient.

This notification represents a resubmission of an earlier notification dated February 25, 2002, that was received by FDA on March 13, 2002. FDA responded to this notification on May 2, 2002 indicating that your submission did not comply with the requirements of 21 C.F.R. § 190.6 because it was incomplete. You were further advised that because your prior notification did not satisfy regulatory requirements, you could not legally market a dietary supplement containing *Cordyceps sinensis mycelia*.

Your present notification states that *Cordyceps sinensis mycelia* is manufactured by Taiwan Sugar Corporation and distributed under the trade name *Taisugar Cordyceps sinensis mycelia* in the form of 480 mg capsules. The expected recommended daily intake of *Taisugar Cordyceps sinensis mycelia* is a maximum of 960 mg or 2 capsules, taken up to three times per day. You have identified a target population of adults as consumers of this product.

In accordance with 21 C.F.R § 190.6(c), FDA must acknowledge its receipt of a notification for a new dietary ingredient. For 75 days after the filing date (i.e., after September 22, 2002), you must not introduce or deliver for introduction into interstate commerce any dietary supplement that contains *Cordyceps sinensis mycelia*.

Please note that acceptance of this notification for filing is a procedural matter and, thus, does not constitute a finding by FDA that the new dietary ingredient or supplement that contains the new dietary ingredient is safe or is not adulterated under 21 U.S.C. 342. FDA is not precluded from taking action in the future against any dietary supplement containing *Cordyceps sinensis mycelia* if it is found to be unsafe, adulterated, or misbranded. As another procedural matter, your notification will be kept confidential for 90 days after the filing date.

- After October 7, 2002, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. However, any trade secret or otherwise confidential commercial information in the notification will not be disclosed to the public.

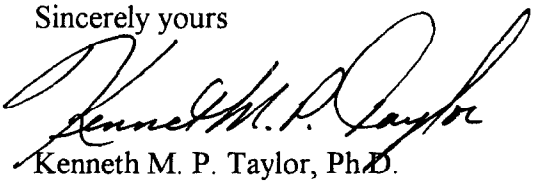
The FDA Internet site http://www.cfsan.fda.gov/~dms/ds-labl.html#structure provides details on the types of claims that are allowed for dietary supplements, including structure/function, health and nutrient content claims. Federal regulations at 21 CFR § 101.36 address the general labeling requirements of all dietary supplements whether or not claims are made.

For claims that are permitted under 21 U.S.C. 343(r)(6) (e.g., those related to the structure or function of the human body or one's general well-being), a dietary supplement's labeling must include a specific disclaimer. In addition, no later than 30 days post marketing, you must notify FDA in writing about any structure/function claim that you make pertaining to *Cordyceps sinensis mycelia*. Federal regulations at 21 CFR § 101.93 specify the notification requirements for such claims. Label claim notification requirements are separate from those for the new dietary ingredient premarket notification program.

The Federal Trade Commission Internet site http://www.ftc.gov/bcp/conline/pubs/buspubs/dietsupp.htm provides details on Federal requirements concerning the advertising of dietary supplements. All dietary supplement claims made in both product labeling and advertising must be substantiated with scientific evidence, be truthful, and not be misleading.

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

Sincerely yours



Kenneth M. P. Taylor, Ph.D.
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