



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, Maryland 20740

4706 7 JAN 17 11:33

DEC 20 2006

Mr. Toshimitsu Sumiya, President  
Iwade Research Institute of Mycology Co., Ltd.  
1-9, Suehiro-Cho  
Tsu, Mie, Japan 514-0012

Dear Mr. Sumiya:

This is to inform you that the notification, dated June 21, 2006, that 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)) was filed by the Food and Drug Administration (FDA) on June 28, 2006. Your notification concerned the substance that you called "Vacuum Freeze-Dried *Agaricus blazei* Murrill extract" that you intend to market in a dietary supplement product called "ABM-FD." According to your notification, "*Agaricus blazei* Murrill extract" is derived from the fruiting body of *Agaricus blazei* Murrill.

Your notification states that "ABM-FD" will be marketed in powder form and that each glass bottle of ABM-FD contains 3.0 grams of powder. Regarding the conditions of use, your notification states that "the consumer dissolves AMB-FD [sic] in water in the marketed bottle, by filling the bottle between half to seven-tenths in the bottle, shake, and then drink on an empty stomach, prior to a meal" once a day. It further states that the product is for non-pregnant and non-lactating adults.

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 21 U.S.C. 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.

In accordance with 21 CFR 190.6(c), FDA must acknowledge its receipt of a notification for a new dietary ingredient. For 75 days after the filing date, your firm must not introduce or

19955-0316

LET 13  
(See RPT 356)

deliver for introduction into interstate commerce any dietary supplement that contains the dietary ingredient that is the subject of this notification.

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 your new dietary ingredient if it is found to be unsafe, adulterated or misbranded.

Your notification will be kept confidential for 90 days after the filing date of June 28, 2006. 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.

If you have any questions concerning this matter please contact me at (301) 436-1448.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Vasilios" followed by a stylized signature, possibly "Linda S. Pellicore".

Linda S. Pellicore, Ph.D.  
Supervisory Team Leader, Senior Toxicologist  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety and Applied Nutrition