

Memorandum

1726 5 JUN 22 P2:16

Date:

JUN 10 2005

From:

Consumer Safety Officer, 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

Subject of the Notification: Enzyme-treated *Agaricus blazei* mycelia

Firm: Japan Applied Microbiology Research Institute, LTD

Date Received by FDA: March 29, 2005

90-Day Date: June 8, 2005

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.

Victoria Lutwak

1995S-0316

RPT 276



JUN 3 2005

Takeru Suyama, Director
Japan Applied Microbiology Research Institute, LTD
326 Otoguro, Tamaho-cho
Nakakoma-gun, Yamanashi 409-3812
Japan

Dear Mr Suyama:

This is to inform you that the notification, dated March 8, 2005, 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 March 10, 2005. Additional information that you sent, dated March 18, 2005, was received by the Agency on March 29, 2005. Your notification concerns the substance that you call "enzyme-treated *Agaricus blazei* Murill mycelia mixed with brewer's yeast" that you intend to market as a new dietary ingredient.

According to the notification, you intend to market your new dietary ingredient "enzyme-treated *Agaricus blazei* Murill mycelia mixed with brewer's yeast" in dietary supplement products consisting of tablets containing 0.25 g or packets containing 1.0 g of granules of your new dietary ingredient. According to your notification, the level of use that will be suggested or recommended will be 1-2 g/day (1-2 packets of granules or 4-8 tablets)" and that the conditions of use that will be suggested or recommended will be "[d]aily use for lifetime except pregnant women, lactating women, or infant should not take this product."

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 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 considered to be adulterated under

21U.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.

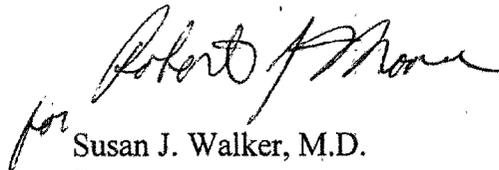
In accordance with 21 CFR 190.6(c), FDA must acknowledge its receipt of a notification for a new dietary ingredient. For 75 days after the filing date, you must not introduce or deliver for introduction into interstate commerce any dietary supplement that contains the new dietary ingredient that is the 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 March 10, 2005. After the 90-day date, the notification will be placed on public display at FDA's Division of Docket Management 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 further questions concerning this matter, please contact Linda S. Pellicore, Ph.D., at (301) 436-2375.

Sincerely yours,



Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

75-day Notification for New Dietary Ingredient

Agaricus Blazei Practical Compound (ABPC®)

Volume 1 of 3

MAR 10
d.B./FDA

Privileged and Confidential

JAPAN APPLIED MICROBIOLOGY RESEARCH INSTITUTE LTD.
326 Otoguro, Tamaho-cho
Nakakoma-gun, Yamanashi 409-3812
Japan

March 8, 2005