

Memorandum

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Date:

JUL 10 2006

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: Extract of *Phellinus linteus* Mycelium (PL.Yoo)

Firm: Health World, Inc

Date Received by FDA: 4/12/2006

90-Day Date: 7/11/2006

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

19955-0316

RPT347



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

JUN 13 2006

Victor Kim, President
Health World, Inc.
3200 Wilshire Boulevard, Suite 303
Los Angeles, California 90010

Dear Mr. Kim:

This is to inform you that the notification, dated April 4, 2006, you submitted pursuant to 21 U.S.C. 3501b(a)(2) (section 413 of the Federal Food, Drug, and Cosmetic Act (the Act)) was received by the Food and Drug Administration (FDA) on April 12, 2006. Your notification concerns the new dietary ingredient "Extract of *Phellinus Linetus* [sic] Mycelium" that you intend to market as a dietary supplement product called "Mesima Extract Powder".

According to your notice the conditions for use for the mycelium extract contained in "Mesima Extract Powder" are the following: "Use one sachet with water, one to three times a day."

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 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.

The notification you sent us concerning "Mesima Extract Powder" does not comply with the requirements of 21 CFR 190.6 and is incomplete. Submissions must contain three copies of the notification. Your notification fails to correctly identify the fungus which is the subject of the notification. The notification erroneously uses the name *Phellinus Linetus* [sic] to describe the fungus *Phellinus linteus* (Berk. & Curt.) Teng which is the subject of the new dietary ingredient

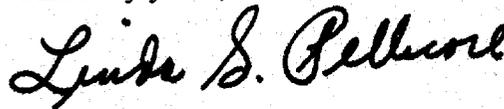
notification. No description is given for the product beyond the name and there is no description for serving levels or total daily serving levels for the ingredient. In addition, your notification fails to provide a history of use except for the statement "Use as boost for the immune system."

For the reasons discussed above, the information in your submission is incomplete and does not provide an adequate basis to conclude that "Mesima Extract Powder," 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 April 12, 2006. 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 questions concerning this matter, please contact Victoria Lutwak at (301) 436-1775.

Sincerely yours,

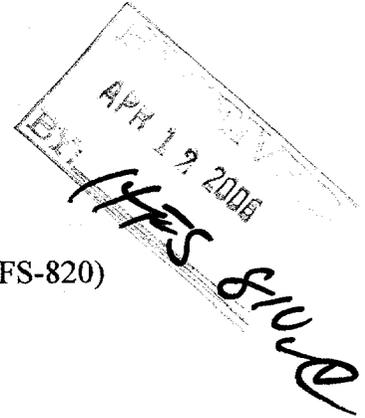


Linda S. Pellicore, Ph.D.
Supervisory Team Leader, Senior Toxicologist
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements,
Center for Food Safety and Applied Nutrition

2006 - 3224

April 4, 2006

Division of Standards & Labeling Regulations
 Office of Nutritional Products, Labeling & Dietary Supplements (HFS-820)
 Center for Food Safety & Applied Nutrition
 5100 Paint Branch Parkway
 College Park, MD 20740-3835

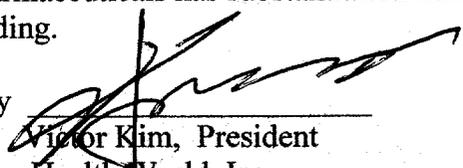


RE: PREMARKET NOTIFICATION OF A NEW DIETARY INGREDIENT

As required in 21 CFR 190.6, I am submitting pre-market notification on behalf Health World, Inc. 3200 Wilshire Blvd. Suite 303, Los Angeles, California, 90010. My firm intends to market the following product:

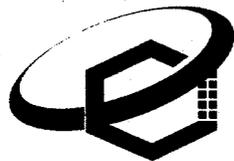
Description of Product	Dietary Ingredient & level	History of Use for Traditional Korean Herb	Recommended Use	Manufacturer
Mesima Extract Powder	Extract of Phellinus Linetus Mycelium (PL.Yoo)	Use as boost for the immune system	Use one sachet with water, one to three times daily	Han Kook Sin Yak Pharmaceutical Co, Ltd., Korea

I, Victor Kim, President of Health World, Inc. am authorized to certify this Notification on behalf of Hon Kook Sin Yak Pharmaceutical Co., Ltd. of Korea. I certify that the information presented and contained in this Notification is complete and accurate, and that Han Kook Sin Yak Pharmaceuticals has substantiation that the function statement is truthful and not misleading.

Dated: April 4, 2006 by 
 Victor Kim, President
 Health World, Inc.

FINAL REPORT

Acute Oral Toxicity Study of Mesima
in Sprague-Dawley Rats
(Study No.: G01080)



KRICT

TOXICOLOGY RESEARCH CENTER
KOREA RESEARCH INSTITUTE OF CHEMICAL TECHNOLOGY

STATEMENT

Study No.: G01080

Title: Acute Oral Toxicity Study of Mesima in Sprague-Dawley Rats.

This study was carried out according to the Testing Guidelines for Toxicity Studies of Drugs "Single Oral Toxicity Study" (Notification No. 88 issued by Japan Ministry of Health and Welfare on August 10, 1993), the Good Laboratory Practice Regulations for Nonclinical Laboratory Studies (Notification No. 2000-63 issued by Korea Food and Drug Administration on December 12, 2000) and OECD Principles on Good Laboratory Practice(1997).

Sang Seop Han

OCT. 8. 2001

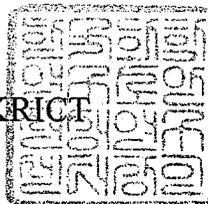
Sang-Seop Han, Ph.D.

Date

Management

Toxicology Research Center, KRICT

Daejeon, Korea



1. SUMMARY

The test item, Mesima, was administered to five male and five female rats for the evaluation of acute oral toxicity at the dose level of 0 and 2000 mg/kg body weight. Mortality, clinical findings, body weight changes, and gross findings were monitored for the 14 days following the administration.

The results were as follows:

- (1) No dead animal caused by the test item was found in 0 and 2000 mg/kg body weight during the study.
- (2) No treatment-related clinical signs were observed in all groups.
- (3) Body weight changes of all animals were within normal ranges during the study.
- (4) No treatment-related gross findings were observed in all treatment groups at necropsy on day 14 after administration.

Based on the results, there was no toxicity related to Mesima at the study of acute oral toxicity in Sprague-Dawley rats. Therefore, it was concluded that the lethal dose for male and female was over 2000 mg/kg.