



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

Memorandum

Date:

SEP 08 2004

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: \_\_\_ Sang-Hwang Mushroom Tea \_\_\_

Firm: \_\_\_ Herbal Cure USA LLC

Date Received by FDA: \_\_\_ June 8, 2004 \_\_\_

90-Day Date: \_\_\_ September 6, 2004 \_\_\_

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, IDS

955-0316

RPT247



Young H. Lee  
Herbal Cure USA LLC  
1165 Hillcrest Glenn Circle  
Sugar Hill, Georgia 30518

AUG 27 2004

Dear Mr. Lee:

This is to inform you that the notification, dated June 1, 2004, 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 8, 2004. Your notification concerns the substance called "Sang-Hwang Mushroom Tea," *Phellinus linteus* (Berk.& Curtis.) Teng, that you intend to market as a new dietary ingredient.

Your notification states that, "Sang-Hwang Mushroom Tea" is prepared and used as follows: "Put a 5 gram bag and 2,000 cc water in a glass pot, and boil it with high heat. When it starts to boil, simmer it with medium heat until it reduces as 1,000 cc which is 2 days portion. Pour the tea into the glass bottle, keep it in the refrigerator, and drink one small cup (250 cc) in the morning and evening."

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.

FDA has carefully considered the information in your submission, and the agency has significant concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing "Sang-Hwang Mushroom Tea" will reasonably be expected to be safe.

The notification does not name the new dietary ingredient that is the subject of the notification in "Sang- Hwang Mushroom Tea" (see 21 CFR 190.6(b)(2)). The notification does not characterize the new dietary ingredient in "Sang-Hwang Mushroom Tea". The notification describes the ingredient as a "brown powder". It is unclear to us what part of the mushroom is used to prepare your new dietary ingredient or whether the ingredient is dried plant material or an extract. A description of the method of preparation might have helped FDA clarify the identity of the ingredient.

This notification contains an acute oral toxicity study in rats using "Natural Sanghwang Mushroom", a brown powder. It is not evident that the test material used in the acute oral toxicity study in rats is qualitatively and quantitatively the same as your new dietary ingredient. Thus it is unclear how this study is relevant to evaluating the safety of the dietary ingredient "Sang-Hwang Mushroom Powder" in "Sang-Hwang Mushroom Tea". Moreover, there is no information indicating a history of use of *Phellinus linteus* (Berk. & Curtis.).

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that "Sang-Hwang Mushroom Tea", 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 June 8, 2004. After the 90-day date, the notification will be placed on public display at FDA's Division of Dockets 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 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

# NOTIFICATION FOR NEW DIETARY INGREDIENT

RECEIVED  
JUN 08 2004  
BY: *LB/FOA*

RECEIVED  
JUN 07 2004  
BY: *LB/FOA*

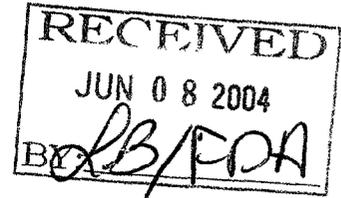
## SUBMITTING TO:

Division of Standards and Labeling Regulations  
Office of Nutritional Products, Labeling, and Dietary Supplements  
(HFS-820)  
Center for Food Safety and Applied Nutrition  
FOOD AND DRUG ADMINISTRATION  
5100 Paint Branch Parkway  
College Park, MD, 20740-3835  
Telephone Number: (301) 436-2371

*88581*

Attention: Mrs. Vickey Lutwak

**Latin Binomial Name: Phellinus Linteus**  
**Author: (Berk. & M. A. Curtis) Teng**



From Young Lee

# Bio-Science Research Institute, Inc.

4813 Cheyenne Way  
Chino, California 91710  
Phone (909) 628-3007  
Fax (909) 590-8948

Director: Tae W. Kang, Ph.D  
FDA Registration No.: 2022038  
DEA Registration No.: RB0177887  
www.bio-science-research.com

TEST: Acute Oral Toxicity, ( 5g\* ) per ( Kg ) body weight  
CLIENT: Herbal Cure USA  
SAMPLE: Natural Sanghwang Mushroom  
Sample Description: brown powder  
date received: 4-20-04 date reported: 5-19-04  
our work No.: Res042004 your PO No.: Prepaid  
Method: OECD #401-1993 Raw Data Page: Res-12

## Results

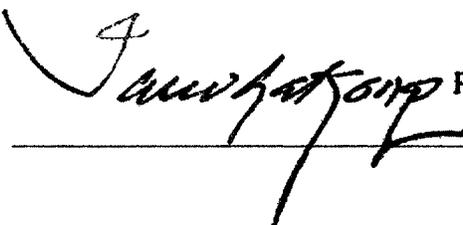
*The Sprague-Dawley rats were chosen for experimental animals. The animals were fasted 24 hours and the test substance was administered orally by gavage. The observation period was 14 days under the artificial lights, 12 hours light and 12 hours dark. The temperature was maintained at ca 20 C. The animals were provided with an unlimited supply of conventional food and drinking water during the post-dosing period. Cageside observations included changes in skin and fur, respiratory, circulatory and nervous systems, convulsions, salivations, diarrhoea, sleep and coma, and behaviour pattern.*

| <u>Animals</u> | <u>Sex</u> | <u>Initial Wt</u> | <u>Dose</u> | <u>Final Wt</u> | <u>Signs of Toxicity</u> |
|----------------|------------|-------------------|-------------|-----------------|--------------------------|
| #1             | M          | 202g              | 1.0g        | 212g            | None                     |
| #2             | M          | 211g              | 1.1g        | 214g            | None                     |
| #3             | M          | 209g              | 1.1g        | 217g            | None                     |
| #4             | M          | 200g              | 1.0g        | 208g            | None                     |
| #5             | M          | 207g              | 1.0g        | 215g            | None                     |
| #6             | F          | 206g              | 1.0g        | 216g            | None                     |
| #7             | F          | 212g              | 1.1g        | 223g            | None                     |
| #8             | F          | 210g              | 1.1g        | 216g            | None                     |
| #9             | F          | 202g              | 1.0g        | 210g            | None                     |
| #10            | F          | 200g              | 1.0g        | 211g            | None                     |

\*2g/10ml aqueous extract at 40C for 4 hours.

Conclusion: The sample is adjudged to be free from acute oral toxicants.

Authorized Signature

 Ph. D

*100% Natural*  
**Sang-Hwang Mushroom Tea**  
自然産 桑黄 / 자연산 상황버섯 / 메시마코브  
**Phellinus Linteus (Latin)**

**100% pure powder - 25 gram  
(5 x 5 gram bag)  
(For 10 days use in making tea)**

**Ordinary Conditions of use**

**Herbal Cure USA 678-546-4937**

Web site: [www.herbalcureusa.com](http://www.herbalcureusa.com) E-mail: [herbalcureusa@aol.com](mailto:herbalcureusa@aol.com)

## **Instruction**

**(For powder only)**

Put a 5 gram bag and 2,000 cc water in a glass pot, and boil it with high heat. When it starts to boil, simmer it with medium heat until it reduces as 1,000 cc which is 2 days portion.

Pour the tea into the glass bottle, keep it in the refrigerator, and drink one small cup (250 cc) in the morning and evening.

**SUBMITTING DATE:**

June 1, 2004

**APPLICANT:**



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Young H. Lee

**Owner of Herbal Cure USA LLC**

**1165 Hillcrest Glenn Circle**

**Sugar Hill, GA 30518**

**(Phone) 678-546-4937**

**1. APPLICANT:**

Young H. Lee  
Owner of Herbal Cure USA LLC  
1165 Hillcrest Glenn Circle  
Sugar Hill, GA 30518  
(Phone) 678-546-4937

**2. THE NAME OF THE NEW DIETARY INGREDIENT**

**Sang-Hwang Mushroom Tea**  
桑黃 (in China); 상황버섯 (in Korea);  
メシマコブ (in Japan);  
Phellinus Linteus (in Latin)

**3. A DESCRIPTION**

(1) Level of the new dietary ingredient in the product:

100 % pure powder 25 gram

(5 x 5 gram bag)

(For 10 days use in making tea)

(2) Condition of use of the product stated in the labeling:

The ordinary conditions of use.

(3) History of use or other evidence of safety:

N/A

**4. INFORMATIONS**

(1) The Test Result of the "Acute Oral Toxicity"

(2) The Test Result of the "Nutrition Facts"

(3) Label

(4) Instruction