



SEP 28 1999

67 17 '99 11:00 AM '99

Ms. Ann J. Liou  
President  
Maxi-Health Herb Products, Inc.  
43094 Christy Street  
Fremont, California 9453 8

Dear Ms. Liou:

This is in response to your letter of September 17, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Maxi-Health Herb Products, Inc. is making the following claim, among others, for the product "100% Mycelia (Cloud Mushroom Extract):"

"...alleviate the negative side effects associated with chemotherapy and/or radiotherapy"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, cure, or mitigate disease, in that the product is represented as an adjunct to mitigate the side effects of recognized disease therapies (i.e., chemotherapy and radiation therapy). This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-3 10, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.  
Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

975-0163

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, San Francisco District Office, Office of Compliance, HFR-PA140

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0 163)

HFS-22 (CCO)

HFS-456 (r/f, File)

HFS-450 (r/f, File)

HFD-3 10 (B Williams)

HFD-3 14 (Aronson)

HFS-605 (Bowers)

GCF- 1 (Dorsey, Nickerson, Barnett)

HFV-228 (SBenz)

f/t:HFS-456:rjm:9/27/99:docname:67313.adv:disc40



43094 Christy St./Fremont, CA 94538 /510-440-9107/9181 /www.Maxi-Health.com

September 17, 1999

10733



Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 c St. SW  
Washington, DC 20204

To Whom It May Concern:

In accordance with Sec. 101.93 of the Notification Procedures, I respectfully submit the following information:

We are about to start marketing a Dietary Supplement named "Cloud Mushroom Extract (PSP)". We, Maxi-Health, are the manufacturer. Our address is:

Maxi-Health Herb Products, Inc.  
43094 Christy Street  
Fremont, CA 94538  
510-440-9107

The statement that is being placed on the label reads:

"\*In clinical studies, Cloud Mushroom (PSP) has been shown to alleviate the negative side effects associated with chemotherapy and/or radiotherapy."

The "\*" is defined below the statement as "\*This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease."

This product is 100% Mycelia (Cloud Mushroom Extract) -- there are no other ingredients added.

Although we believe clinical studies have also shown this ingredient to be effective in fighting cancer/tumors, we did not make any such claim to avoid the necessity of having this product classified as a drug. We are convinced that the many clinical studies that have been performed on this product over the years support our claim. We believe that we have complied with all requirements for this product.

I certify that the information contained in this notice is complete and accurate and that there have been enough clinical studies to substantiate that the statement is truthful and not misleading.

Sincerely, /

Ann J. Liou  
President  
Maxi-Health Herb Products, Inc.

43094 Christy St. / Fremont, CA 94538 / 510-440-9107/9181 / www.Maxi-Health.com