



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

3774 55 SEP 17 P1:30

JAN 29 1997

Mr. Vincent W.H. Chou
Chairman
Winsor Health Products Ltd.
Room 1008-1010, Harbour Crystal Centre
100 Granville Road
T.S.T. East
Kowloon, Hong Kong

Dear Mr. Chou:

This is in response to your letter dated December 4, 1996, concerning the marketing of ESSENCE OF MUSHROOM (YUN-ZHI) as a new dietary ingredient. Your letter is intended to be a dietary submission given in accordance with section 413 of the Federal Food, Drug, and Cosmetic Act (the act).

Section 413 of the act requires a manufacturer or distributor of a dietary supplement which contains a new dietary ingredient to submit certain information to the agency. Specifically, the act requires that at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient provide the FDA with information which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe. In your submission, you do not state that you have concluded that a dietary supplement containing ESSENCE OF MUSHROOM (YUN-ZHI) will reasonably be expected to be safe or do you provide any basis for such a conclusion. Therefore, you have not complied with section 413 of the act.

A dietary supplement that contains a new dietary ingredient (i.e., ESSENCE OF MUSHROOM) is deemed to be adulterated under section 402(f) of the act unless there is compliance with section 413 of the act. Since you have not complied with section 413 of the act, your product would be adulterated as a matter of law. Moreover,

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introduction of this product into interstate commerce is prohibited under section 301(u) of the act.

Sincerely yours,

James Tanner, Ph.D.
Acting Director,
Division of Programs and
Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

cc:
HFA-224 (w/incoming)
HFS-22 (CCO)
HFS-456 (r/f, Miles, Moore)
HFS-450 (r/f, OSN w/ control slip & cyp incoming)
r/d: 1/14/97: C:\Miles\Suppl\50406
Initial: Rmoore: 1/15/97
Derfler 1/16/97
f/d:1/16/97:C:\Miles\Suppl\50406



百 草 堂 有 限 公 司
WINSOR HEALTH PRODUCTS LTD.

RECEIVED BY THE
OFFICE OF SPECIAL
NUTRITIONAL PRODUCTS-450
香港九龍尖沙咀東部加連威老道100號港晶中心1008-1010室
Room 1008-1010, Harbour Crystal Centre, 100 Granville Road, T.S.T. East, Kowloon, Hong Kong.
Tel: 2366 3128 2721 0902 2721 8118 Fax: 27852121 2766 3760 P 2:22

December 4, 1996

Food & Drug Administration
Office of Special Nutritionals
HFS-450
200 C Street, SW
Washington D.C. 20204

Dear Sir,

We wish to export to the USA a food supplement with details as follows:

ESSENCE OF MUSHROOM (YUN-ZHI) manufactured and distributed by Winsor Health Products Ltd., Hong Kong.

Ingredients: 100% essence of Yun-zhi (*Coriolus versicolor*).

Content has been analyzed as follows:

Water content	4.2%
Ash	24.7%
Acid insoluble Ash	0.48%
Polysaccharide	36.0%
Peptide	21.3%

Attached is a supporting report that showed no toxic effect from the US Department of Agriculture, Nutritional Immunology Laboratory at Tufts University.

This is a dietary submission in accordance with Medical Section 413 of the Food, Drug and Cosmetics Act.

We are also enclosing a copy of the label for your reference.

Thank you for your kind attention.

Yours truly,

For and on behalf of
百 草 堂 有 限 公 司
WINSOR HEALTH PRODUCTS LIMITED

.....
Vincent W. H. Chou
Chairman

52406



Jean Mayer
United States Department of Agriculture
Human Nutrition Research Center on Aging
At Tufts University

NUTRITIONAL IMMUNOLOGY LABORATORY

June 27, 1996

Mr. H. King
300 Martine Avenue, Suite 2D
White Plains, NY 10601
FAX: (914) 428-4620

Dear Mr. King:

I wanted to inform that our preliminary results indicate that feeding mice essence of mushroom extract up to 1% for one month showed no toxic effects. I will keep you informed of our findings as they continue to develop. Should you have any questions about these results, please do not hesitate to contact me at (617) 556-3129. Thank you.

Sincerely,

A handwritten signature in cursive script that reads "Simin Nikbin Meydani".

Simin Nikbin Meydani, D.V.M., Ph.D.
Chief, Nutritional Immunology Laboratory
Professor of Nutrition and Immunology
Senior Scientist