



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

OCT 29 1998
7375 '98 NOV -4 P1:45

Xuping Gu, L.Ac., OMD
Director
Institute of Alternative Medicine
P.O. Box 251504
Los Angeles, California 90025

Dear Dr. Gu:

This is in response to your letter of October 10, 1998 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 the Institute of Alternative Medicine is marketing the dietary supplement "Tinnitusaid" labeled with claims that it is intended to "...support of reducing tinnitus due to weakness, aging or other non-structural causes."

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, as well as the use of the term "Tinnitus" in the product's name, suggests that it is intended to prevent, treat, cure, or mitigate disease, namely tinnitus. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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-310, 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

LET 228

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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, Los Angeles District Office, Office of Compliance, HFR-PA240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (File)

HFS-450 (file, r/f, OSN#61919)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

Init:GCF-1:DDorsey:10/27/98

f/t:HFS-456:rjm:10/28/98:docname:61919.adv:disc32

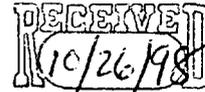
Institute of Alternative Medicine

613 S. Vecino Dr.
Covina, CA 91723

Tel: (626) 339-7668

Fax: (626) 339-7668

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



October 10, 1998

Notification Letter for Statement on Dietary Supplement

Dear FDA officers:

I am the director of the Institute of Alternative Medicine, which is, among other things, an importer and distributor of dietary supplements, mostly herbal products. I am writing as per Code of Federal Regulations, Volume 21, Part 101.93, to notify you that we have included a statement on the label or in the labeling of one of our products. The following are the information required in this notification letter:

1. Statement of Purpose:

This is a letter to provide notification of a statement of nutritional support, including the exact wording that appears on the label and labeling for a dietary supplement.

2. Vendor Information:

Name, address, telephone and fax numbers of the importer and distributor for mailing and other communication purposes, are as follows:

Institute of Alternative Medicine

P. O. Box 251504
Los Angeles, CA 90025
Tel: (626) 339-7668
Fax: (626) 339-7668

The above address is also used for consumer inquiries.

61919

3. Product Identification:

The trade name of the product:

Tinnitusaid.

The common and usual name of the product:

None.

A label copy showing all information displayed and provided to consumers is attached.

4. The text of the Structure/Function Statement:

Tinnitusaid is a botanical blend of oriental medicine formulated to maintain a healthy body, especially in support of reducing tinnitus due to weakness, aging or other non-structural causes.

5. Ingredient Statement

This product is a proprietary blend of botanicals. The following is a complete list of dietary ingredients:

Common Name	Chinese Name	Latin Binomial	Part of Plant
Rehmannia	Shou Di Huang	<i>Rehmannia glutinosa</i> Libosch	Root, steamed
Dogwood Tree	Shan Yu Rou	<i>Cornus officinalis</i> Sieb. et Zucc.	Pulp
Chinese Yam	Shan Yao	<i>Dioscorea opposita</i> Thunb.	Tuber
Water Plantain	Ze Xie	<i>Alisma orientale</i> (Sam.) Juzep.	Tuber
Tree Peony	Mu Dan Pi	<i>Paeonia suffruticosa</i> Andr.	Root skin
Tuckahoe	Fu Lin	<i>Poria cocos</i> (Schw.) Wolf	Subterranean Fungus
Bamboo	Zhu Ye	<i>Lophatherum gracile</i> Brongn.	Leaf
Hare's ear	Chai Hu	<i>Bupleurum chinense</i> DC	Root
Honey			

6. Intended Use:

This product is recommended to be used by adult over the age of 18.

Dosage: 3 ~ 5 pills (540 ~ 900 mg) each time. Twice a day, morning and evening, after meals.

Warning: Not recommended for pregnant and lactating woman..

7. Statement of Affirmation:

We, as an importer and distributor of the above mentioned product, affirm that we have substantiation that the structure/function statement (as shown in No. 4 above) made under 403(6)(r) of the Federal Food, Drug and Cosmetic Act is truthful, not misleading, and scientifically valid and that the product does not present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the label or labeling.

8. Disclaimer:

At the end of each structure/function statement, there is an asterisk that refers to another asterisk placed adjacent to another statement called disclaimer. The disclaimer is placed at the bottom of the same panel or, in adjacent with the structure/function statement. The disclaimer reads:

The statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Should there be any question or comment, please contact the Vendor through the information in No. 2 above, or contact the preparer of this letter:

George Su, Ph.D.
Crosslinks International
A Regulatory Consulting Firm to the Food Drug and Agriculture Industries
1800 Century Park East, Suite 600
Century City, CA 90067
Tel: (310) 229-5748
Fax: (310) 229-5749
E-Mail: crosslinks@aol.com

Sincerely,



Xuping Gu, L.Ac., OMD
Director

Enclosure

BRAND & LOGO

200 pills
(180 mg each)

TINNITUSAID
HERBAL SUPPLEMENT

*Tinnitusaid is a botanical blend of oriental medicine formulated to maintain a healthy body, especially in support of reducing tinnitus due to weakness, aging or other non-structural causes.**

Directions: To be used as an herbal supplement for adult. Take 3 - 5 pills (540 - 900 mg) each time; twice a day, morning and evening, after meals

WARNING: This product is intended to be used by adult over the age of 18. Not recommended for pregnant or lactating woman. Keep out of reach of children.

Distributed by: Institute of Alternative Medicine, Covina, CA 91723
Consumer Inquiry: P.O. Box 251504, Los Angeles CA 90025

* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease
Product of China

Exp:

Supplement Facts

Serving Size:	4 pills (720 mg)
Servings per Bottle:	50
Amount per serving:	%Daily Value*
Calories 0.	
Proprietary blend 0.7g	
Rehmannia (root, steamed)	†
Dogwood Tree (pulp)	†
Chinese Yam (tuber)	†
Water Plantain (tuber)	†
Tree Peony (root skin)	†
Tuckahoe (subterranean fungus)	†
Bamboo (leaf)	†
Hare's Ear (root)	†

*Percent Daily Values are based on a 2,000 calorie diet
† Daily Value not established.

Other ingredients: Honey.

Attachment

Label of TINNITUSAID.