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Mr. Fengshan Zhu
President
Amasia Acupuncture & Herbs Ltd.
621 S. Weller Street
Seattle, Washington 98104

Dear Mr. Zhu:

This is in response to your letter of April 17, 2003 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 submissions state that Amasia Acupuncture & Herbs Ltd. is making the following claim, among others, for the product **Injury Formula**:

“...joint and soft tissue support for injury...”

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 (including the product name “Injury Formula”) suggest that it is intended to treat, prevent, or mitigate diseases, namely, injuries. 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-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

Please contact us if we may be of further assistance.

Sincerely yours,

Susan J. Walker, M.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
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

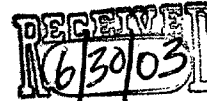
FDA, Seattle District Office, Office of Compliance, HFR-PA340

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Amasia Acupuncture & Herbs Ltd.

621 S. Weller St.
Seattle, WA 98104
Tel: (206) 748-5168 Fax: (206) 748-0088

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



April 17th, 2003

Notification letter for Statement on Dietary Supplement

Dear FDA officers:

I am the president of Amasia Acupuncture & Herbs Ltd., who is, among other things, a distributor of dietary supplements, mostly herbal products in the United States. 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 distributor for mailing and other communication purposes, are as follows:

Amasia Acupuncture & Herbs Ltd.
621 S. Weller St.
Seattle, WA 98104
Tel: (206) 748-5168, Fax: (206) 748-0088

The above address is also used for consumer inquiries.

3. Product Identification:

The trade name of the product:

Injury Formula

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:

Herbal Supplement provides joint and soft tissue support for injury and also promote blood circulation. *

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
Angelica	Bai Zhi	<i>Angelica dahuria</i>	Root
Gleditsia Spine	Zao Jiao Ci	<i>Gleditsia Sinensis lam.</i>	Spine or thorn
Corydalis Tuber	Yan Hu Suo	<i>Corydalis yanhusuo w.t. Wang</i>	Tubers
Sophora Flower	Huai Hua	<i>Sophoria japonica L.</i>	Flower
Calamus Gum	Xue Jie	<i>Calamus draco willd</i>	Red resinous secretion from the fruit and stem
Sanguisorba Root	Di Yu	<i>Sanguisorba officinalis L.</i>	Root
Mastic	Ru Xiang	<i>Boswellia carterii Birdw</i>	Gum-resin
Phellodendron Bark	Huang Bai	<i>Phellodendron amurense Rupr.</i>	Bark

6. Intended Use:

This product is intended to be used by adult over the age of 15.

Dosage: Take 3-4 capsules, 3 times a day, after meals.

Warning: Not recommended for use by pregnant woman. Keep out of reach of children. To be kept in a dry and cool place.

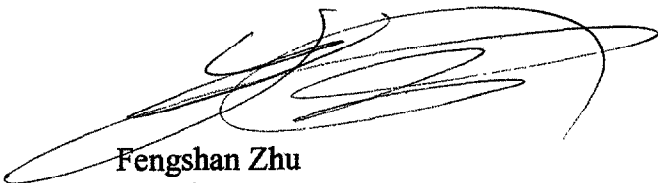
7. Statement of Affirmation:

We, as a 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.

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:

Annie Wang
Knature Corporation
10655 NE 4th St. #400
Redmond, WA 98004
Tel: (425)649-2075
Fax: (425)649-1784

Sincerely,



Fengshan Zhu
President

Enclosure

Injury Formula

Herbal Supplement provides joint and soft tissue support for injury and also promote blood circulation. *

**120 Capsules
(750 mg/ each)**

Ingredients: Angelica (Bai Zhi), Gleditsia Spine (Zao Jiao Ci), Corydalis Tuber (Yan Hu Suo), Sophora Flower (Huai Hua), Calamus Gum (Xue Jie), Sanguisorba Root (Di Yu), Mastic (Ru Xiang), Phellodendron Bark (Huang Bai).

Directions: Take 3-4 capsules, 3 times a day, after meals.

Warning: Not recommended for using by pregnant woman. Keep out of reach of children. To be kept it in a dry and cool place. If you have any questions, please contact your acupuncturist or call (206)748-5168.

Distributor: Amasia herbs Ltd.
621 S. Weller St. ,
Seattle, WA 98104
Tel: (206)748-5168

* These statements have not been evaluated by the FDA. This product is not intended to diagnose, prevent, treat, or cure any disease.

Manufactured by:

Liaoning Da Sheng Pharmaceuticals Inc.
No.35 South Heping Street, Heping District,
Shenyang, China.
Tel: 86-24-22856682

Supplement Facts	
Serving Size: 10 capsules (7500 mg)	
Servings per bottle 12	
Amount per Serving	% Daily Value
Calories	
Total Carbohydrates	
Proprietary blend	
Not a significant source of other nutrients.	
* Percent Daily Values are based on a 2,000 calorie diet.	
+ Daily Value not established.	

Expiration Date: