

2762 '03 MAY 28 P2:35
MAY 23 2003

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

Dear Mr. Zhu:

This is in response to your letters 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 claims for the following products:

Joints Help Capsules

"...support joints and muscle for Arthritis Sufferers. It may help a person who has arthritis, pain in joint and muscle;"

Liyuan 2 Capsules

"...help people who have weakness and pain condition caused by illness, chemicals/radiative therapy or surgery;"

LiYuan I (For Energy)

"...help people who has [sic] a chronic fatigue...disorder sleep [sic]..."

Injury Formula

"...help people who have pain in joint and soft tissue which caused by any type of injury or arthritis."

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 statements that you are making for these products (including the product name "Injury Formula") suggest that they are intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are 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.

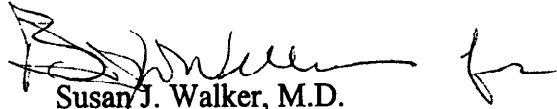
975-0163

LET701

Page 2 - Mr. Fengshan Zhu

Please contact us if we may be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "Susan J. Walker", followed by a small flourish.

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

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

Page 3 - Mr. Fengshan Zhu

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-800 (r/f, file)

HFS-810 (file)

HFS-811 (file)

HFD-40 (Behrman)

HFD-310

HFD-314

HFS-607

HFV-228 (Benz)

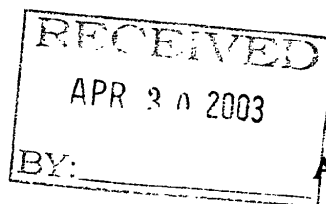
GCF-1 (Nickerson)

f/t:HFS-811:rjm:5/22/03:docname:84435.adv:disc76

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

84435

The above address is also used for consumer inquiries.

3. Product Identification:

The trade name of the product:

Joints Help Capsules

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 to support joints and muscle for Arthritis Sufferers.
It may help a person who has arthritis, pain in joint and muscle.***

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
Paud Bark	Zi Cha Pi	<i>Paudarco</i>	Bark
Lucid Ganoderma	Ling Zhi Cao	<i>Ganoderma lucidum karst.</i>	Dried fructidication of the fungus
Erythrina Bark	Hai Tong Pi	<i>Erythrina variegata L.</i>	Bark

6. Intended Use:

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

Dosage: Take 2 or 3 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

Joint Help Capsules

Herbal Supplement to support joints and muscle for Arthritis Sufferers.

It may help a person who has arthritis, pain in joint and muscle.*

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

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.	

Ingredients: Paud barks (Zi Cao Pi) , Lucid Ganoderma (Zi Mu Zhi), Erythrina Bark (Hai Tong Pi).

Directions: Take 2 or 3 capsules, 3 times a day, after meals .

Warning: Not recommended for using by pregnant woman. Keep out of reach of children. To be kept 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.

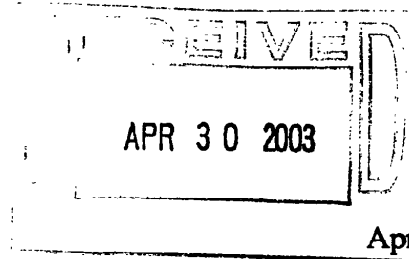
Manufactured by:
Liaoning Da Sheng pharmaceuticals Inc.
No.35 South Heping Street, Heping District,
Shenyang , China . Tel: 86-24-22856682

Expiration Date:

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



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

84435

The above address is also used for consumer inquiries.

3. Product Identification:

The trade name of the product:

Liyuan 2 Capsules

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 to restore energy and provide protection against free radical or oxidative damage to tissue cells. It can build up and strengthen the immune system .

It may help people who have weakness and pain condition caused by illness, chemicals/radiative therapy or surgery.

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
Lucid Ganoderma	Ling Zhi Cao	<i>Ganoderma lucidum karst.</i>	Dried fructification of the fungus
Paud Bark	Zi Cha Pi	<i>Paudarco</i>	Bark
Leonurus	Chong Wei Zi	<i>Leonurus heterophyllus Sweet</i>	Fruit

6. Intended Use:

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

Dosage: Take 3-4 capsules, 2-3 times a day.

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

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

Liyuan 2 Capsules

Herbal Supplement to restore energy and provide protection against free radical or oxidative damage to tissue cells. It can build up and strengthen the immune system.*

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

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.	

Ingredients: Lucid Ganoderma (Ling Zhi Cao), Paud Bark (Zi Cha Pi), Leonurus Fruit (Chong Wei Zi).

This product may help people who have weakness and pain condition caused by illness, chemicals/radiative therapy, or surgery.*

Directions: Take 3-4 capsules, 2-3 times a day.

Warning: Do not use if you have bleeding symptom or anemia. Not recommended for using by pregnant woman. Keep out of reach of children. To be kept 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

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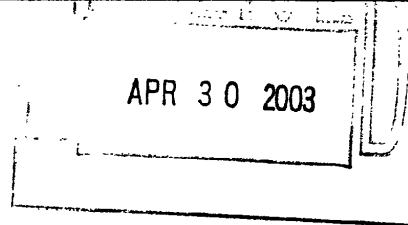
Manufactured by:
Liaoning Da Sheng pharmaceuticals Inc.
No.35 South Heping Street, Heping District,
Shenyang , China
Tel: 86-24-22856682

Expiration Date:

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:

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2. Vendor Information:

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

84435

The above address is also used for consumer inquiries.

3. Product Identification:

The trade name of the product:

LiYuan I (For Energy)

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 to provide energy and thermogenic properties.
It may help people who has a chronic fatigue, weakness, disorder sleep, poor
appetite or cold limbs.***

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
Ginseng	Ren Sheng	<i>Panax ginseng</i>	Root
Angelica Root	Dang Gui	<i>Angelica Sinensis (olive) Diels</i>	Root
Lucid Ganoderma	Zi Ling Zi	<i>Ganoderma Lucidum karst.</i>	Dried fructification of the fungus
Astragalus	Huang Qi	<i>Astragalus membranaceus (Fisch.) Bge.</i>	Root

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. (Not for people who have high blood pressure, fever.)

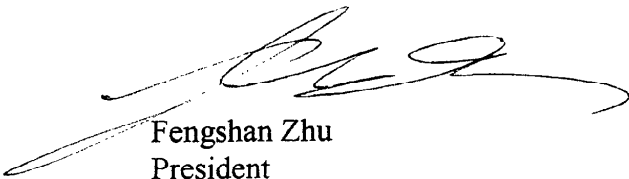
7. Statement of Affirmation:

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

LiYuan I (For Energy)

Herbal Supplement to provide energy and thermogenic properties.

It may help people who has a chronic fatigue, weakness, disorder sleep, poor appetite or cold limbs.*

**120 Capsules
(750 mg each)**

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

Ingredients: Korean Ginseng, Angelica Root (Dang Gui), Lucid Ganoderma (Zi Ling Zhi), Astragalus (Huang Qi).

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. (Not for people who have high blood pressure or fever.)

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

Expiration Date:

Amasia Acupuncture & Herbs Ltd.

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

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APR 30 2003

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Seattle, WA 98104
Tel: (206) 748-5168, Fax: (206) 748-0088

9-035

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.

It may help people who have pain in joint and soft tissue which caused by any type of injury or arthritis.

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.

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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.

It may help people who have pain in joint and soft tissue which caused by any type of injury or arthritis. *

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

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.	

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. ,
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