



AUG 26 2002

Rec'd 8/27/02  
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Mr. George Su  
Crosslinks International, inc.  
1800 Century Park East, Suite 600  
Los Angeles, California 90067

Dear Mr. Su:

This is in response to your letters of June 10, 2002 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 Herbmax, Inc., Santa Fe Springs, California, is making the following claims for the following products.

The product **Yunnan Baiyao Ding** uses the claim "...for the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, as well as frostbite." This claim is a disease claim because it suggests that the product is intended to treat, prevent, or mitigate diseases, namely disorders such as arthritis and other conditions that result in pain. In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1030) FDA discussed the circumstances under which claims about pain would imply disease treatment. We stated that since pain is not a normal state, nor are there "normal pain levels," a claim about pain treatment or prevention is ordinarily a disease claim. We addressed the issue of joint pain claims in particular, noting that such claims are disease claims because joint pain is a characteristic symptom of arthritis. We added, however, that an acceptable structure/function claim could be made for pain associated with non-disease states, such as muscle pain following exercise. But, your claim includes no context that to limit the scope of the intended use of the product to non-disease states that result in pain and, in fact, the claim explicitly states that it is intended to treat pain associated with diseases such as arthritis, backache, strains, bruises, and frostbite.

You also submitted a notification for the product **Liuwei Dihuang Wan** that states that this product is "...for people with...tinnitus..."

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 suggests 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,

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you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

You also represent that the product **Yunnan Baiyao Ding** "...is used as oral administration or externally...." This product does not appear to meet the statutory definition of a dietary supplement contained in 21 U.S.C. 321(ff), and therefore, cannot be marketed as a dietary supplement. The claim to use this product externally is a claim that describes an effect of the product that is not achieved by its ingestion. Therefore, the product does not meet all of the elements of the statutory definition of a dietary supplement, namely that it be a product intended for ingestion, when it is intended to be applied to the skin. We explain the basis for our opinion below.

The term "dietary supplement" is defined in 21 U.S.C. 321(ff). 21 U.S.C. 321(ff) provides that the term means a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients. 21 U.S.C. 321(ff) further states that dietary supplements are intended for ingestion in a form described in 21 U.S.C. 350(c)(1)(B)(i) or in compliance with 21 U.S.C. 350(c)(1)(B)(ii), are not represented as conventional food or as a sole item of a meal or the diet, and are labeled as a dietary supplement.

This product is not "intended for ingestion." As stated above, the definition of dietary supplement in 21 U.S.C. 321(ff) states that a dietary supplement is a product "intended for ingestion." The term "ingestion" has been addressed by the court in United States v. Ten Cartons, Ener-B Nasal Gel, 888 F. Supp. 381, 393-94 (E.D.N.Y.), aff'd, 72 F.3d 285 (2d Cir. 1995), which states:

The ordinary and plain meaning of the term "ingestion" means to take into the stomach and gastrointestinal tract by means of enteral administration. See Stedman's Medical Dictionary (4th Lawyer's Ed. 1976) (defining ingestion as the "introduction of food and drink into the stomach."); Webster's Third New International Dictionary (1976) (defining ingestion as "the taking of material (as food) into the digestive system.")....

The interpretation of the term "ingestion" to mean enteral administration into the stomach and gastrointestinal tract is also supported by the language of the statutory sections immediately preceding and following section 350(c)(1)(B)(ii). Section 350(c)(1)(B)(i) states that the vitamin must be intended for ingestion in tablet, capsule or liquid form. Each of these forms denotes a method of ingestion that involves swallowing into the stomach. Section 350(c)(2) states that a food is intended for ingestion in liquid form under section 350(c)(1)(B)(i) "only if it is formulated in a fluid carrier and is intended for ingestion in daily quantities

Page 3 - Mr. George Su

measured in drops or similar small units of measure.” This elaboration of “liquid form” also denotes ingestion by swallowing the fluid.

Therefore, because the term “ingestion” means introduced into the gastrointestinal tract, a product that is used to deliver its ingredients into the body when applied topically to the skin is not subject to regulation as a dietary supplement because it is not “intended for ingestion” because it is intended for external or topical use.

Moreover, this product may be subject to regulation as a drug under the Act. The statements that you are making for this product, as discussed earlier in this letter, suggest that it is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B) and (C), 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).

Please contact us if we may be of further assistance.

Sincerely,



John B. Foret

Director

Division of Compliance and Enforcement

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

Copy:

Mr. Li Zhiping

President

Herbmax, Inc.

12155 Mora Drive

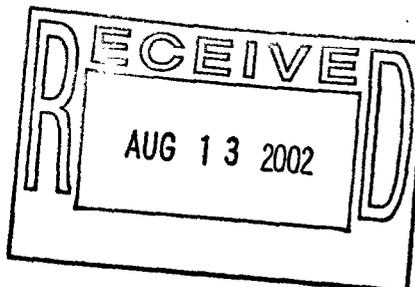
Unit 13

Santa Fe Springs, California 90670

# HERBMAX, INCORPORATED

12155 Mora Dr. Unit 13, Santa Fe Springs, CA 90670 Tel.: (562) 946-2066 Fax: (562) 946-2966

Office of Special Nutritionals (HFX-450)  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835



June 10, 2002

## Notification Letter for Statement on Dietary Supplement

Dear FDA officers:

I am the president of HERBMAX Incorporated, who is, among other things, a distributor of dietary and herbal supplements in California. I am writing as per Code of Federal Regulations, Volume 21, Part 101.93, to notify you that we have included statements on the label and 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 statements 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 manufacturer and distributor for mailing and other communication purposes, are as follows:

Manufacturer:  
Yunnan Baiyao Group Co., Ltd.  
51 Xiba Road  
Kunming, Yunnan  
People's Republic of China  
Post Code: 650032  
Tel: 011-86-800-820-0538

Distributor:  
HERBMAX, Incorporated

12155 Mora Dr., Unit 13  
Santa Fe Springs, CA 90670  
USA

Tel: 562-946-2066  
Fax: 562-946-2966

The telephone number for consumer inquiries in the US is:

866-286-2700

3. Product Identification:

The trade name of the product:

Yunnan Baiyao Ding

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:

**Dietary Supplement for temporary muscle pain relief**

**Yunnan Baiyao Ding is a liquid contains proprietary blend of natural plant extracts by isolating and purifying of effective ingredients. It is used as oral administration or externally for the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, as well as frostbite.**

5. Ingredient Statement

This product is a proprietary blend of herbs and other ingredients. The following is a complete list of ingredients:

Ingredients:

Common Name	Chinese Name	Latin Binomial	Part of Plant
Notoginseng	Tian Qi	<i>Panax pseudoginseng</i> Wall	Root
Borneol	Bing Pian	<i>Dryobalanops aromatica</i> Gaertn. f.	Crystal
Boea Clarkeana	San Yu Cao	<i>Boea clarkeana</i> Hemsl.	Entire plant
Inula Copp	Bai Niu Dan	<i>Inula coppa</i> DC.	Root
Complanatum	Chuan Shan Long	<i>Lycopodium complanatum</i> L.	Rhizome

Chinese Yam	Huai Shan Yao	<i>Dioscorea opposita</i> Thunb.	Rhizome
Galanga	Ku Liang Jiang	<i>Alpinia officinarum</i> Hance	Rhizome
Cranebill	Lao Guan Cao	<i>Erodium stephanianum</i> Wild.	Aerial parts
Alcohol			

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6. Intended Use:

This product is intended to be used as a dietary supplement for the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains.

Direction:

Take orally 1/2 to 1 teaspoon (3 to 5 mL) each time, 3 times daily. No more than 2 teaspoons (10 mL) at one time.

For external application, damp a cotton ball with Yunnan Baiyao Ding liquid, apply to the affected area for about 3 minutes, 3 to 5 times daily.

7. Statement of Affirmation:

We, as manufacture 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:

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

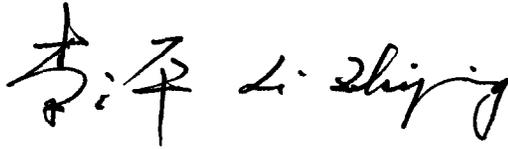
Should there be any question or comment, please contact the person as follows:

George Su  
 Crosslinks International, Inc.  
 1800 Century Park East, Suite 600  
 Los Angeles, CA 90067

Tel: (310)229-5748  
Fax: (310)229-5749  
E-mail: [crosslinks2000@cs.com](mailto:crosslinks2000@cs.com)

Sincerely,

Li Zhiping  
President

Handwritten signature of Li Zhiping, consisting of Chinese characters '李:平' followed by the English name 'Li Zhiping' in cursive script.

Enclosures

# **Yunnan Baiyao Ding**

**Dietary Supplement for temporary muscle pain relief \***

**1/5 cup (50 mL) bottle**

## **Indications:**

**This product is intended to be used as a dietary supplement for the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains.\***

**Yunnan Baiyao Ding is a liquid contains proprietary blend of natural plant extracts by isolating and purifying of effective ingredients. It is used as oral administration or externally for the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, as well as frostbite.\***

\* These statements have not been evaluated by the Food and Drug Administration.  
This product is not intended to diagnose, treat, cure, or prevent any disease.

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## **Direction:**

Take orally 1/2 to 1 teaspoon (3 to 5 mL) each time, 3 times daily. No more than 2 teaspoons (10 mL) at one time.

For external application, damp a cotton ball with Yunnan Baiyao Ding liquid, apply to the affected area for about 3 minutes, 3 to 5 times daily.

## **Ingredients:**

Notoginseng (Root), Borneol (Crystal), Boea Clarkeana (Entire plant), Inula Copp (Root), Complanatum (Rhizome), Chinese Yam (Rhizome), Galanga (Rhizome), Cranebill (Aerial parts), Alcohol

Expiration Date:

Distributed by:  
Herbmax, Inc., Santa Fe Spring, CA 90670

Product of China

## Supplement Facts

Serving Size 1 teaspoon (5 mL)

Servings per bottle 10

Amount per Serving

**Total Calorie** 10      **Fat Cal.** 0

% Daily Value\*

**Total Fat** 0 g      **0%**

**Sodium** 15 mg      **0%**

**Total Carbohydrate** 2g      **0%**

**Protein** 0 g

Proprietary Blend 1 g

Notoginseng (root) †

Borneol (crystal) †

Boea Clarkean (entire plant) †

Inula Copp (root) †

Complanatum (rhizome) †

Chinese Yam (rhizome) †

Galanga (rhizome) †

Cranebill (aerial parts) †

\*Percent Daily Values are based on a 2,000 calorie diet.

† Daily Value not established.

Label No.: 9061202

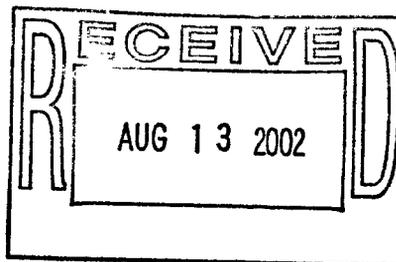
Client No.: H07

Product: Yunnan Baiyao Ding (50 mL)

# HERBMAX, INCORPORATED

12155 Mora Dr. Unit 13, Santa Fe Springs, CA 90670 Tel.: (562) 946-2066 Fax: (562) 946-2966

Office of Special Nutritionals (HFX-450)  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835



June 13, 2002

## Notification Letter for Statement on Dietary Supplement

Dear FDA officers:

I am the president of HERBMAX Incorporated, who is, among other things, a distributor of dietary and herbal supplements in California. I am writing as per Code of Federal Regulations, Volume 21, Part 101.93, to notify you that we have included statements on the label and 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 statements 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 manufacturer and distributor for mailing and other communication purposes, are as follows:

Manufacturer:

Yunnan Baiyao Group Co., Ltd.  
51 Xiba Road  
Kunming, Yunnan  
People's Republic of China  
Post Code: 650032  
Tel: 011-86-800-820-0538

Distributor:

HERBMAX, Incorporated

81488

12155 Mora Dr., Unit 13  
Santa Fe Springs, CA 90670  
USA

Tel: 562-946-2066  
Fax: 562-946-2966

The telephone number for consumer inquiries in the US is:

866-286-2700

3. Product Identification:

The trade name of the product:

Liuwei Dihuang Wan

The common and usual name of the product:

Liuwei Dihuang Wan

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

4. The text of the Structure/Function Statement:

**Dietary Supplement with tonic function for weakness**

**Liuwei Dihuang Wan is specially formulated with the best-selected natural plant extracts to be vast nourishing on the febleness of the body especially for people with dizziness, tinnitus, and weakness on kidney and knees. Using this product following the directions shall be helpful in improving night sweating; seminal emission derived from a variety of weaknesses.**

5. Ingredient Statement

This product is a proprietary blend of herbs and other ingredients. The following is a complete list of ingredients:

Ingredients:

Common Name	Chinese Name	Latin Binomial	Part of Plant
Rehmannia	Shu Di Huang	<i>Rehmannia glutinosa</i> Libosch	Root
Dogwood	Shan Zhu Yu	<i>Cornus officinalis</i> Sieb. Et Zucc.	Fruit
Paeony	Mu Dan Pi	<i>Paeonia suffruticosa</i> Andr.	Root-bark
Chinese Yam	Shan Yao	<i>Dioscorea opposita</i> Thunb.	Rhizome

Indian Bread  
Water Plantain  
Honey

Fu Ling  
Ze Xie

*Poria cocos* (Schw.) Wolf  
*Alisma plantago-aquatica* L.

Sclerotium  
Rhizome

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6. Intended Use:

This product is intended to be used as a dietary supplement in improving body weakness.

Direction: Take orally one sachet (6 g) each time, twice daily.

7. Statement of Affirmation:

We, as manufacture 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:

**These statements have 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 person as follows:

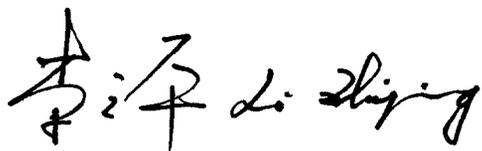
George Su  
Crosslinks International, Inc.  
1800 Century Park East, Suite 600  
Los Angeles, CA 90067

Tel: (310)229-5748  
Fax: (310)229-5749  
E-mail:[crosslinks2000@cs.com](mailto:crosslinks2000@cs.com)

Sincerely,

Li Zhiping  
President

Enclosures

Handwritten signature in cursive script, reading "Li Zhiping".

# **Liuwei Dihuang Wan**

Dietary Supplement with tonic function for weakness\*

## **Quantity:**

**6 g X 10 sachets**

## **Indications:**

**This product is intended to be used as a dietary supplement in improving body weakness\***

**Liuwei Dihuang Wan is specially formulated with the best-selected natural plant extracts to be vast nourishing on the feebleness of the body especially for people with dizziness, tinnitus, and weakness on kidney and knees. Using this product following the directions shall be helpful in improving night sweating; seminal emission derived from a variety of weaknesses. \***

\* These statements have not been evaluated by the Food and Drug Administration.  
This product is not intended to diagnose, treat, cure, or prevent any disease.

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## **Direction:**

Take orally one sachet (6 g) each time, twice daily.

## **Ingredients:**

Rehmannia (root), Dogwood (fruit), Paeony (root-bark), Chinese Yam (rhizome), Indian Bread (sclerotium), Water Plantain (rhizome), Honey.

## **Warning:**

1. Avoid pungent foods.
2. Do not take these pills when using medicine for treating common cold.
3. While taking these pills, you should consult your doctor when symptoms appear, such as poor appetite, stomachache, diarrhea, abdominal pain.
4. If the symptoms persist for more than two weeks after using this product, please see your doctor.
5. This product is not recommended for pregnant women and children under the age of 12.
6. As all drugs and medicine, keep this product out the reach of children.

## **Expiration Date:**

## **Distributed by:**

Herbmax, Inc., Santa Fe Spring, CA 90670

Product of China