



5169 '02 MAY 29 P2:38

MAY 16 2002

Mr. Li Zhiping
President
Herbmax, Inc.
12155 Mora Drive
Unit 13
Santa Fe Springs, California 90670

Dear Mr. Zhiping:

This is in response to your letter of April 24, 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 submission states that Herbmax, Inc. is marketing the product **BestRelief**, which you believe is a product that is a dietary supplement. The product is described as an "Herbal Supplement as External Pain Relieving Patch" and is represented "for the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains."

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. Among other claims for the product, the notification states that the product is a "...External Pain Relieving Patch." This claim 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 for the transdermal administrative of its ingredients. 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.

975-0163

LET 603

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 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 using a transdermal patch delivery system 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 suggests 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), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Page 3 - Mr. Li Zhiping

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

80376 9/16/02

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

RECEIVED
MAY 03 2002
BY:

April 24, 2002

Notification Letter for Statement on Herbal 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 an herbal 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:

BESTRELIEF

The common and usual name of the product:

Yunnan Bai Yao Gao.

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

4. The text of the Structure/Function Statement:

Bestrelief
Herbal Supplement as External Pain Relieving Patch

Indications: For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains.

5. Ingredient Statement

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

Active 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 Clarkean	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

Camphor
Peppermint

Zhang Nao
Bo He

Cinnamomum camphora (L.) Presl.
Mentha haplocalyx Briq.

Crystal extracts
Leaves

Other Ingredients

Zinc Oxide
Rubber
Rosin
Lanolin
Vaseline
Methyl Salicylate

6. Intended Use:

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

Direction: External use only. One patch on affected area daily.

Warning: This product is for external use only. Not recommended for persons under the age of 12. Discontinue use of this product and consult your doctor if condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days. Avoid contact with eyes. Do not apply to wounds or damaged skin. Not recommended for people with sensitive skin. This may cause a rash or festering. Do not apply on extremely hairy surface of skin. Highly adhesive patch may hurt skin upon removal of the product. Keep this and all drugs out of reach of children.

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:

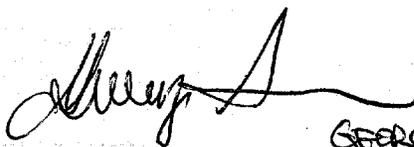
George Su
Crosslinks International, Inc.
1800 Century Park East, Suite 600
Los Angeles, CA 90067

Tel: (310)229-5748

Fax: (419)715-4365

E-mail: crosslinks2000@cs.com

Sincerely,



GEORGE Su, Authorized Rep.

Li Zhiping
President

Enclosures

BESTRELIEF

Herbal Supplement as External Pain Relieving Patch*

Quantity:

5 Patches

Size:

2 5/8" x 4"

(6.5cm x 10 cm)

Indications: For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains. *

* 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.

Direction: External use only. One patch on affected area daily.

Warning: This product is for external use only. Not recommended for persons under the age of 12. Discontinue use of this product and consult your doctor if condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days. Avoid contact with eyes. Do not apply to wounds or damaged skin. Not recommended for people with sensitive skin. This may cause a rash or festering. Do not apply on extremely hairy surface of skin. Highly adhesive patch may hurt skin upon removal of the product. Keep this and all drugs out of reach of children.

Active Ingredients:

Notoginseng, Borneol, Boea Clarkeana, Inula Copp, Complanatum, Chinese Yam, Galanga, Cranebill, Camphor, Peppermint

Other Ingredients

Zinc Oxide, Rubber, Rosin, Lanolin, Vaseline, Methyl Salicylate

Expiration Date:

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

Product of China