

YU SHEN TANG CHINESE HERBAL MEDICINE, LLC.

8855 E. Valley Blvd, #B1, Rosemead, CA 91770 Tel: 626-286-0171 Fax: 626-286-0172

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

SEP 9 0 2004

September 6, 2004

**Notification Letter for Statement on
Dietary Supplement**

Dear FDA officers.

I am the president of Yu Shen Tang Chinese Herbal Medicine, LLC, who is, among other things, a manufacturer and distributor of dietary 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 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 manufacturer and distributor for mailing and other communication purposes, are as follows:

YU SHEN TANG CHINESE HERBAL MEDICINE, LLC
8855 E. Valley Blvd #B1
Rosemead, CA 91770
Tel: 626-286-0171
Fax: 626-286-0172

3 Product Identification:

The trade name of the product:

975 0162

LET

14627

89599

Ba Bao Dan Capsules

The common and usual name of the product:

Ba Bao Dan

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

4. The text of the Structure/Function Statement:

Dietary Supplement for the nourishment and enhancement of male sexuality*.

5. Ingredient Statement

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

The ingredients are listed in the order of Common Name, Scientific Name in Brackets, Part used, Traditional Chinese Medicine Name in phonetic alphabet.

White atractylodes (*Atractylodes macrocephala*) rhizome (Bai Zhu)
Hoelen (*Poria cocos*) sclerotium (Fu Shen)
Astragalus (*Astragalus membranaceus*) root (Huang Qi)
Wild jujube (*Zizyphus jujuba*) seed (Suan Zao Ren)
Ginseng (*Panax ginseng*) root (Ren Shen)
Licorice (*Glycyrrhiza uralensis*) root (Gan Cao)
Chinese angelica (*Angelica sinensis*) root (Dang Gui)
Polygala (*Polygala tenuifolia*) root (Yuan Zhi)
Jujube (*Zizyphus jujuba*) fruit (Da Zao)
Ginger (*Zingiber officinale*) rhizome (Sheng Jiang)
Cardamon (*Amomum villosum*) fruit (Sha Ren)
Epimedium (*Epimedium macranthum*) aerial part (Yin Yang Huo)

6. Intended Use

This product is intended to be used for male over the age of 18 who would like to have a recovery from their weakness and to improve their sexual life*.

Suggested use: Three capsules (1 5g) per dose, twice daily.

Caution: If taking prescription medication, consult your health professionals before use. Store at a dry place below 86° F (30° C), Keep this product 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 the 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 Vendor through the information in No 2 above, or contact the preparer of this notification letter:

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

Tel (310)229-5748
Fax: (310)388-1067
E-mail: crosslinks2000@aol.com

Sincerely,



Zou Jianhua
President

Enclosures

Information on Label

Ba Bao Dan Capsules

Dietary Supplement for the nourishment and enhancement of male sexuality*

Net Content: 500 mg x 90 capsules

This product is intended to be used for male over the age of 18 who would like to have a recovery from their weakness and to improve their sexual life.*

Suggested Use: Three capsules (1.5g) per dose, twice daily.

Do not use if imprinted seal is broken or missing.

Caution: If taking prescription medication, consult your health professionals before use. Store at a dry place bellow 86⁰ F (30⁰ C), Keep this product and all drugs out of reach of children.

Expiration Date:

Manufactured by:

**Yu Shen Tang Chinese Herbal Medicine, LLC
8855 E. Valley Blvd. #B1, Rosemead, CA 91770**

Product of the USA

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

Supplement Facts

Serving Size 3 capsules (1.5 g)

Servings per box 30

Amount per Serving	% Daily Value*
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Calories, Total 5

Total Carbohydrate 0.5 g **0%**

Proprietary Blend (1.5 g)

White atractylodes (<i>Atractylodes macrocephala</i>) rhizome (Bai Zhu)	†
Hoelen (<i>Poria cocos</i>) sclerotium (Fu Shen)	†
Astragalus (<i>Astragalus membranaceus</i>) root (Huang Qi)	†
Wild jujube (<i>Zizyphus jujuba</i>) seed (Suan Zao Ren)	†
Ginseng (<i>Panax ginseng</i>) root (Ren Shen)	†
Licorice (<i>Glycyrrhiza uralensis</i>) root (Gan Cao)	†
Chinese angelica (<i>Angelica sinensis</i>) root (Dang Gui)	†
Polygala (<i>Polygala tenuifolia</i>) root (Yuan Zhi)	†
Jujube (<i>Zizyphus jujuba</i>) fruit (Da Zao)	†
Ginger (<i>Zingiber officinale</i>) rhizome (Sheng Jiang)	†
Cardamon (<i>Amomum villosum</i>) fruit (Sha Ren)	†
Epimedium (<i>Epimedium macranthum</i>) aerial part (Yin Yang Huo)	†

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

† Daily Value not established

Label No.: 1081901

Client No.: C07

Product: Ba Bao Dan Capsules (90 x 500 mg)