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OCT 22 2003

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

Dear Dr. Su:

This is in response to your letter, on behalf Beijing Tong Ren Tang (USA) Corporation, dated March 15, 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 submission states that Beijing Tong Ren Tang (USA) Corporation is making the following claims, among others, for its product **Allergine Tea**:

“Dietary Supplement for refreshing feelings during allergy season.”

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, as well as the name of the product (i.e., Allergine Tea) which incorporates a clearly recognizable transformation of the term “allergen,” suggests that it is intended to treat, prevent, or mitigate a disease, namely allergies. Moreover, in your letter, you explicitly describe that the intended use of the product “is intended to be used as a beverage by persons over the age of 12, who are allergic to pollen and other allergens.” The claim you are making for the product, as well as the stated intended use, 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.

975-0163

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Please contact us if we may be of further assistance.

Sincerely yours,



Susan J. Walker, M.D.
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, Los Angeles District Office, Office of Compliance, HFR-PA240

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

Copy:

Mr. Chuanli Zhou

Vice General Manager

Beijing Tong Ren Tang (USA) Corporation

4300 Geary Boulevard

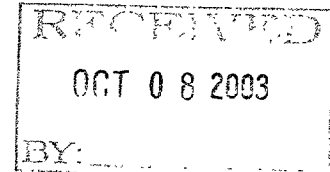
Suite 203

San Francisco, California 94118

BEIJING TONG REN TANG (USA) CORP.

4300 Geary Blvd., Suite 203, San Francisco, CA 94118 Tel: 415-876-1168 Fax: 415-876-1166

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



September 16, 2003

Notification Letter for Statement on Dietary Supplement

Dear FDA officers:

I am the vice general manager of Beijing Tong Ren Tang (USA) Corporation, who is, among other things, a manufacturer of dietary supplements in People's Republic of China and distributor of those products in the US. 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:

BEIJING TONG REN TANG (USA) CORP.
4300 Geary Blvd., Suite 203
San Francisco, CA 94118
Tel: 415-876-1168
Fax: 415-876-1166

3. Product Identification:

The trade name of the product:

Allergine Tea

The common and usual name of the product:

Huafen Guomin Cha

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

4. The text of the Structure/Function Statement:

Herbal Dietary Supplement for refreshing feeling during allergy season.

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.

Poria (*Poria cocos*) sclerotium (Fu Ling)
Perilla (*Perilla frutescens*) leaf (Bai Su Ye)
Citrus (*Citrus reticulata*) peel (Chen Pi)
Mulberry (*Morus alba*) bark (Sang Bai Pi)
Thunberg Fritillary (*Fritillaria verticillata*) bulb (Zhe Bei Mu)
Scute (*Scutellaria baicalensis*) root (Huang Qin)
Licorice (*Glycyrrhiza uralensis*) root (Gan Cao)
Loquat (*Eriobotrya japonica*) leaf (Pi Pa Ye)
Cynanchum (*Cynanchum stauntoni*) root (Bai Qian)
Hogfennel (*Peucedanum praeruptorum*) root (Bai Hua Qian Hu)
Pinellia (*Pinellia ternate*) tuber (Ban Xia)
Angelica (*Angelica dahurica*) root (Bai Zhi)
Cocklebur (*Xanthium sibiricum*) fruit (Cang Er)

6. Intended Use:

This product is intended to be used as a beverage by persons over the age of 12, who are allergic to pollen and other allergens.

Suggested use: One teabag (3 g) twice daily.

Caution: If pregnant, nursing, taking prescription medication, or children under 12, consult health professionals before use.
Store in a dry place, bellow 86⁰ F (30⁰ C), out of reach of children.

7. Statement of Affirmation:

We, as manufacturer 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:

**This statement has 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 letter:

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

Tel: (310)229-5748
Fax: (310)229-5749
E-mail:crosslinks2000@aol.com

Sincerely,



Chuanli Zhou
Vice General Manager

Enclosures

Information on Label

Allergine Tea

Dietary Supplement for refreshing feelings during allergy season*

Net Content: 3 g x 12 teabags

Suggested Use: Twice daily. Pour 2/3 cup (150 mL) of boiling water over a single teabag, and let it steep for 5 minutes. Continually add hot water to the teacup until the tea becomes tasteless and clear. If you desire higher potency, please use 2 teabags simultaneously.

Do not use if imprinted seal is broken or missing.

Caution: If pregnant, nursing, taking prescription medication, or for children under 12, consult health professionals before use.

Expiration Date:

**Manufactured by: Beijing Tong Ren Tang Nutritional and Health Products Factory,
46 Xidamochang Street, Chongwen District, Beijing 100051, People's Republic of
China**

Product of China

*** This statement has 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 1 teabag (3 g)

Servings per box 12

Amount per Serving	% Daily Value*
Proprietary Blend (3 g)	
Poria (<i>Poria cocos</i>) sclerotium	†
Parilla (<i>Parilla frutescens</i>) leaf	†
Citrus (<i>Citrus reticulata</i>) peel	†
Mulberry (<i>Morus alba</i>) bark	†
Thunberg Fritillary (<i>Fritillaria verticillata</i>) tub	†
Scute (<i>Scutellaria baicalensis</i>) root	†
Licorice (<i>Oxyrrhiza uralensis</i>) root	†
Loquat (<i>Eriobotrya japonica</i>) leaf	†
Cynanchum (<i>Cynanchum auriculatum</i>) root	†
Hogfennel (<i>Peucedanum praeruptorum</i>) root	†
Pinellia (<i>Pinellia ternata</i>) tuber	†
Angelica (<i>Angelica dahurica</i>) root	†
Coccoloba (<i>Xanthium sibiricum</i>) fruit	†

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

† Daily Value not established.