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JUL 29 2005

Mr. Billy Jang  
President  
Greenchung (USA), Inc.  
5482 Wilshire Boulevard  
Suite 204  
Los Angeles, California 90036

Dear Mr. Jang:

This is in response to your letter of July 5, 2005 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 letter states that Greenchung (USA), Inc. intends to make the following statement, among others, for the product Greenchungkook Dietary Supplement: "Help to increase the resistance to infection."

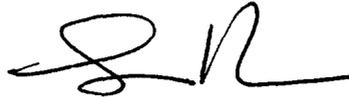
21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate diseases, namely, infectious diseases. This claim 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 20855.

975 0163 LET 835

Page 2 - Mr. Billy Jang

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'SJW', written in a cursive style.

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-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

**GREENCHUNG (USA), Inc.**

5482 Wilshire Blvd, Suite 204, Los Angeles, CA 90036 Tel: 866-371-0330 Fax: 323-634-0309

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

JUL 13 2005

July 5, 2005

**Notification Letter for Statement on  
Dietary Supplement**

Dear FDA officers:

I am the president of Greenchung (USA), Inc., 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:

GREENCHUNG (USA), Inc.  
5482 Wilshire Blvd. Suite 204  
Los Angeles, CA 90036  
Tel: 866-371-0330  
Fax: 323-634-0309

3. Product Identification:

The trade name of the product:

AIMS  
2005-4360

#1287

## Greenchungkook, Dietary Supplement

The common and usual name of the product:

Greenchungkook

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 overall health of men and women.**

- 1. Assist the promotion of better digestion**
- 2. Support the boosting of immune function**
- 3. Help to increase the resistance to infection**

### 5. Ingredient Statement

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

Beneficial Bacteria Mix 13.5%  
*Bifidobacterium longum*  
*Bifidobacterium bifidum*  
*Lacto-bacillus acidophilus*  
Fermented Soybean Powder 78%  
Turmeric (*Curcuma longa*) root 3%  
Magnesium Stearate 2%  
Green Tea 2%  
Warmwood (*Artemisis cappilaries Thunberg*) entire plant extract 1.5%

### 6. Intended Use:

This product is intended to be used for persons over the age of 16.

Suggested use: 2 capsules (about 1000 mg) Three times daily.

#### **Caution:**

1. Avoid direct light;
2. Keep at cool and dry place;
3. Keep out the 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:

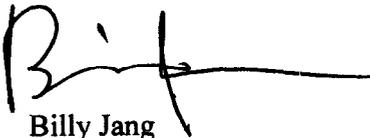
**These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**

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](mailto:crosslinks2000@aol.com)

Sincerely,

A handwritten signature in black ink, appearing to read 'Billy Jang', with a long horizontal line extending to the right.

Billy Jang  
President

Enclosures

## Supplement Facts

Serving Size 6 capsules (about 2900 mg)

(Based on a daily consumption)

Servings per container 30

Amount per Serving

**Total Calorie** 5                      Fat Cal. 0

% Daily Value\*

**Total Fat** 0 g                              **0%**

**Sodium** 40 mg                              **2%**

**Total Carbohydrate** 1g                      **0%**

**Protein** 0 g

Proprietary blend (2.5g)

Benificial Bacteria Mix —

*Bifidobacterium longum*

*Bifidobacterium bifidum*

*Lacto-bacillus acidophilus*

Fermented Soybean Powdeer 78% —

Turmeric (*Curcuma longa*) root 3% —

Magnesium Stearate 2% —

Green Tea —

Wamwood (*Artemisis cappilaries*

thunberg) entire plant extract \_

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

† Daily Value not established.

**Label:**

GREENCHUNGKOOK  
Dietary Supplement

[www.greenchungusa.com](http://www.greenchungusa.com)

480 mg x 180 capsules

**Dietary Supplement for the overall health of men and women \***

- 1. Assist the promotion of better digestion \***
- 2. Support the boosting of immune function \***
- 3. Help to increase the resistance to infection \***

Suggested Use: For adults above the age of 16.  
Two capsules (about 1000 mg) each time, three times daily.

**Caution:**

1. Avoid direct light
2. Keep at cool and dry place
3. Keep out of the reach of children.

**Distributed by:**

Greenchung (USA), Inc.  
Los Angeles, CA 90036

Ingredients obtained from Korea  
Product of USA

Customer Service: 866-371-0330

\* 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.