



APR 20 1999

7 257 '99 MAY -7 P 2:09

Ms. Hetty Chen  
President  
Hetty Enterprise U.S.A. Inc.  
8250 E. Garvey Avenue  
Rosemead, California 91770

Dear Ms. Chen:

This is in response to your letter of April 8, 1999 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)).

Although you submitted your letter to FDA as the notification required by 21 U.S.C. 343(r)(6) and 21 CFR 101.93(a), it is not signed. Therefore, the notice does not meet the requirement in 21 CFR 101.93(a)(3) that it be signed by a responsible individual or the person who can certify the accuracy of the information presented and contained in the notice. Since your notice was not submitted in accordance with the requirements of 21 U.S.C. 343(r)(6) and 21 CFR 101.93(a), it does not meet the statutory requirements necessary for a dietary supplement to bear a claim under 21 U.S.C. 343(r)(6) on its label and labeling. Consequently, if you intend to make a claim for your product pursuant to 21 U.S.C. 343(r)(6), you must provide the notification required by that section in accordance with 21 CFR 101.93(a)(2).

Please contact us if we may be of further assistance.

Sincerely,

Robert J. Moore, Ph.D.  
Senior Regulatory Scientist  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals

975-0163

LET 269

Page 2 - Ms. Heddy Chen

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605 (Bowers)

GCF-1 (Dorsey)

HFV-228 (SBenz)

HFV-232 (ABrown)

f/t:HFS-456:rjm:4/19/99:docname:64734.adv:disc37

64734

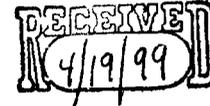
**HETTY ENTERPRISE U.S.A. INC.**

8250 E. Garvey Ave.  
Rosemead, CA 91770

Tel: (626) 571-6794

Fax: (626) 571-2033

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street SW  
Washington, DC 20204



April 8, 1999

**Notification Letter for Statement on Dietary Supplement**

Dear FDA officers:

I am the president of Hetty Enterprise U.S.A. Inc., who is, among other things, an manufacturer and distributor of dietary supplements, mostly herbal products in the United States. I am writing as per Code of Federal Regulations, Volume 21, Part 101.93, to notify you that we have included a statement on the label or 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:

Hetty Enterprise U.S.A. Inc.

8250 E. Garvey Ave.  
Rosemead, CA 91770  
Tel: (626) 571-6794  
Fax: (626) 571-2033

The above address is also used for consumer inquiries.  
Consumer Hot Line number is 800-979-2468

3. Product Identification:

The trade name of the product:

**HETTY HERBA DIET-β.**

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:

**Herbal Supplement for maintaining optimal blood sugar.**

**Hetty Herba Diet-β is a botanical blend of Chinese herbs formulated to maintain a healthy body, especially in support of normal metabolism to keep blood sugar at an optimal level.**

5. Ingredient Statement

This product is a proprietary blend of botanicals. The following is a complete list of dietary ingredients:

Common Name	Chinese Name	Latin Binomial	Part of Plant
American Ginseng	Xi Yang Shen	<i>Panax quinquefolium</i> L.	Root
Milk Vetch	Huang Qi	<i>Astragalus membranaceus</i> Fisch.	Root
Solomon's Seal	Huang Jin	<i>Polygonatum sibiricum</i> Red.	Root
Gynostenma	Qi Ye Dan	<i>Gynostenma pentaphyllum</i> Thunb.	Entire plant
Chinese Foxglove	Di Huang	<i>Rehmannia glutinosa</i> Libosch	Root
Snake Gourd	Tian Hua Feng	<i>Trichosanthes kirilowii</i> Maxim	Root

6. Intended Use:

This product is recommended to be used by adult over the age of 18. It can also be used, under the direction of a physician, by persons under the age and by pregnant and lactating women.

Dosage: 1 ~ 4 capsules (250 ~ 1,000 mg ) each time, three times a day, 15 minutes after meals.

Warning: This product is recommended to be used by adult over the age of 18. Consult your physician if you are under the age or you are a pregnant or lactating woman. Keep out of reach of children.

7. Statement of Affirmation:

We, as a 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 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:

**The 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  
1800 Century Park East, Suite 600  
Century City, CA 90067  
Tel: (310) 229-5748  
Fax: (310) 229-5749  
E-Mail: [crosslinks@aol.com](mailto:crosslinks@aol.com)

Sincerely,

Hetty Chen, N.C.C.A.O.M.  
President

Enclosure

**BRAND & LOGO**

**60 capsules  
(250 mg each)**

## **HETTY HERBA DIET-β**

**HERBAL SUPPLEMENT TO MAINTAIN OPTIMAL BLOOD SUGAR\***

*Hetty Herba Diet-β is a botanical blend of Chinese herbs formulated to maintain a healthy body, especially in support of body metabolism and to keep blood sugar at an optimal level.\**

**Directions:** To be used as an herbal supplement for adult. Take 1 ~ 4 capsules (250 ~ 1000 mg) each time, three times a day, 15 minutes after meals.

**WARNING:** This product is recommended to be used by adult over the age of 18. Consult your physician if you are under the age or you are a pregnant or lactating woman.  
Keep out of reach of children.

Manufactured by: Hetty Enterprise U.S.A. Inc., Rosemead, CA 91770

Consumer Inquiry: 800-979-2488

\* 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.

Product of U.S.A.

Exp.:

### **Supplement Facts**

Serving Size: 4 capsules (1000 mg)  
Servings per Bottle 15

Amount per serving: %Daily Value\*  
Calories 0

Proprietary blend 0.7g	†
American Ginseng (root)	†
Milk Vetch (root)	†
Solomon' s Seal (root)	†
Gynostenma (entire plant)	†
Chinese Foxglove (root)	†
Snake Gourd (root)	†

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

† Daily Value not established.

Attachment

Label of Hetty Herba Diet-β.