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MAR 12 2003

Dongning Wen
President
Knature Corporation
10655 NE 4th Street, #400
Bellevue, Washington 98004

Dear Mr. Wen:

This is in response to your letter of January 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 Knature Corporation is making the following claim, among others, for the product **Fu Ning Kang** :

“Relief for Menopause Symptoms such as...Insomnia, Depression....”

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 prevent diseases (i.e., it is promoted treat or mitigate conditions associated with menopause that are diseases such as depression and insomnia). 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, 7520 Standish Place, Rockville, Maryland 20855.

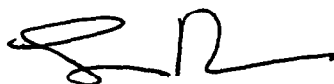
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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Walker', with a long horizontal stroke extending to the right.

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, Seattle Office, Office of Compliance, HFR-PA340

KNATURE CORPORATION

10655 NE 4th Street, #400
Bellevue, WA 98004

Tel: (425) 649-2075 Fax: (425) 649-1784

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

FFB 21 2003

Jan. 15th, 2003

Notification letter for Statement on Dietary Supplement

Dear FDA officers:

I am the president of Knature Corporation, who is, among other things, a 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 distributor for mailing and other communication purposes, are as follows:

Knature Corporation

10655 NE 4th Street, #400
Bellevue, WA 98004

Tel: (425)649-2075, Fax: (425)649-1784

The above address is also used for consumer inquiries.

3. Product Identification:

The trade name of the product:

Fu Ning Kang

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:

**Menopause Support for women
Dietary Supplement**

**Relief for Menopause Symptoms such as:
Hot Flashes, Vaginal Dryness, Insomnia, Depression & Irritability, Night Sweats.**

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
Ginseng	Ren Sheng	<i>Panax ginseng</i>	Root
Rehmannia, prepared	Shu Di Huang	<i>Rehmannia glutinosa</i> Libosch	Root
Cornus Fruit	Shan Zhu Yu	<i>Cornus officinalis</i> Sieb.et Zucc.	Fruit
Morinda Root	Ba Ji Tian	<i>Morinda officinalis</i> How	Root
Epimedium	Yin Yand Huo	<i>Epimedium macranthum</i> Morr. et Decne.	Stem
Cibot Rhizome	Gou Ji	<i>Cibotium barometz</i> J. Sm.	Rhizome
Dodder Seed	Tu Si Zi	<i>Cuscuta chinensis</i> Lam.	Seed
Wolfberry Fruit	Gou Qi Zi	<i>Lycium chinense</i> Mill.	Seed
Phellodendron Bark	Huang Bai	<i>Phellodendron amurense</i> Rupr.	Bark
Chinese Angelica	Dong Quai	<i>Angelica sinensis</i> (Olive) Diels	Root

6. Intended Use:

This product is intended to be used by adult female over the age of 16.

Dosage: Take 3-4 tablets, 2-3 times a day.

Warning: Not recommended for use by pregnant or nursing woman. Should you have any questions regarding the use of this product, please consult your doctor or call the product hot line in U.S. at 1888-810-4368. Keep out of reach of children. To be kept in a dry and cool place.

7. Statement of Affirmation:

We, as a 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.

Should there be any question or comment, please contact the Vendor through the information in No. 2 above.

Sincerely,



Dongning Wen
President

Enclosure

KNATURE

Fu Ning Kang

**Menopause Support for women
Dietary Supplement**

Relief for Menopause Symptoms such as:
Hot Flashes, Vaginal Dryness, Insomnia,
Depression & Irritability, Night Sweats*

**120 Tablets
(750 mg each)**

Supplement	Facts
Serving Size: 10 tablets (7500 mg) Servings per bottle 12	
Amount per Serving	% Daily Value
Calories	
Total Carbohydrates	
Proprietary blend	
Not a significant source of other nutrients. * Percent Daily Values are based on a 2,000 calorie diet. + Daily Value not established.	

Ingredients: Ginseng (Ren Sheng) , Prepared Rehmannia Root (Shu Di Huang) , Cornus Fruit (Shan Zhu Yu) , Morinda Root (Ba Ji Tian) , Epimedium (Yin Yang Huo) , Cibot Rhizome (Gou Ji) , Dodder Seed (Tu Si Zi) , Wolfberry Fruit (Gou Qi Zi) , Phellodendron Bark (Huang Bai) , Radix Angelicae Sinensis (Dang Gui) .

Directions:
Take 3-4 tablets, 2-3 times a day.

This herbal supplement may relieve all the discomfort experienced by some women during menopause and also may help irregular and painful period and reduce dry skin and age spot . *

Warning: Not recommended for use by pregnant or nursing woman. Should you have any questions regarding the use of this product, please consult your doctor or call the product hot line in U.S. at 1888-810-4368. Keep out of reach of children. To be kept it in a dry and cool place.

* 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.

Distributor:
Knature Corporation
10655 4th St. #400,
Bellevue, WA 98004
Tel:(425)649-2075 Fax: (425)649-1784

Product of China