



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

AUG 17 1998

Mr. Fu Sheng Jin
Chinese Herb Center, Inc.
1010 Vermont Avenue, N.W.
Suite 712
Washington, D.C. 20005

1839 '98 AUG 21 P12:45

Dear Mr. Jin:

This is in response to your letter to the Food and Drug Administration (FDA) dated August 3, 1998, 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 the Chinese Herb Center, Inc. is making the following statements, among others, for the products:

Gulong Xiaochuansu capsule (Xiamen)

“It is a cough dietary supplement which is used for cough and sputum with the colds”
“Any questions about cough, sputum and breath hard caused by acute and chronic bronchitis or cough over one week...”

Heklin

“Any questions about headache,...”

Breslin

“Any questions about breast lumps,...”

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 statements that you are making for these products suggest that they are intended to treat, prevent, cure, or mitigate disease, namely colds, coughs, bronchitis, headaches, and breast cancer/tumors. The notifications also contain statements that Gulong Xiaochuansu capsule is intended for use as a “cough dietary supplement” and that Heklin and Breslin are intended for use as “breast lump” dietary supplements. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims and other information contained in your submissions suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are 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.

975-0163

LET 210

Page 2 - Mr. Fu Sheng Jin

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
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, Baltimore District Office, Compliance Branch, HFR-MA230

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file)

HFS-450 (r/f, file, OSN#60656)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

f/t:rjm:HFS-456:8/17/98:60656.adv:disc31

Rec'd 8/10/98

August 3, 1998
Mr. Fu Sheng Jin
Chinese Herb Center, Inc.
1010 Vermont NW Suite 712
Washington DC 20005
Tel: (202)393-1203

60654

Dr. Elizabeth Yetley
Office of Special Nutrition
HFS-450
200 C Street, S. W.
Washington, D. C. 20204

Dear Dr. Elizabeth Yetley:

According to " Dietary Supplement Health and Education Act of 1994" Public Law 103-417, Now I write a petitioner about Gulong Xiaochuansu capsule (dietary supplement) to notice of structure/function class for 30 days post-market. Also I want to get permission to import to the United States of America. Although it has been delivered to the United State of America before October 15, 1994, we need to revise the " Gulong Xiaochuansu capsules " labeling again.

Gulong Xiaochuansu Capsules
Manufactured by Xiamen Gulong Group.,Ltd., Fujing, China
Distributed by Chinese Herb Center, Inc.

I included following data for Gulong Xiaochuansu capsule for you check it, If you have any questions, Please tell me or write a letter to above address.

Sincerely Yours

Manager Mr. Fu Sheng Jin

B. Intended use; projected average daily intake of Gulong Xiaochuansu capsules

1. Amount of Gulong Xiaochuansu capsule proposed use in the United States

Projected marketing figures for Gulong Xiaochuansu capsule have not been determined at this time

2. Intended usage

Gulong Xiaochuansu capsule is intended for use as a cough dietary supplement.

3. Calculation of expected intake and daily consumption of Gulong Xiaochuansu extract powder:

From information given by Xiamen Gulong Group LTD, the capsule is to be taken three times a day, 3 capsules each time. Each capsule weights 300 mg, and this projects a daily consumption of 2700mg and yearly consumption of 986.0 g for an adult.

4. Labeling

Recommended use

Orally, take 3 capsules each time 3 times a day, after meal with water.

INGREDIENTS:

Each capsule contains 300 mg extract powder.

1. Cordyceps
2. Cinnamomi
3. Cecko
4. Rhizoma pinellae
5. Draconis
7. Paeoniae alba.
7. Coptidis
8. Glycyrrhizae.
9. Fritillariae ciirrhosae.

Keep out of children.

Store at a cool & dry location

Batch No:

MFG date:



6 905817 4301390

100% Natural Herbs

Gulong Xiaochuansu capsule

(Xiamen)

100 Caps (300 mg each)

Manufactured by Xiamen Gulong Group LTD, Fujian, China

Distributed by Chinese Herb Products, Inc.

1010 Vermont Ave, NW Suite 712, Washington, DC 20005

it has been formulated by ancient Chinese medicine, and modified and refined by modern technology. It is a cough dietary supplement which is used for cough and sputum with the colds. It is unique process and guaranteed potencies. Any questions about cough, sputum and breath hard caused by acute and chronic bronchitis or cough over one week, please call your doctors or TCM doctor or (202)393-1203.

August 3, 1998
Mr. Fu Sheng Jin
Chinese Herb Center, Inc.
1010 Vermont NW Suite 712
Washington DC 20005
Tel: (202)393-1203



Dr. Elizabeth Yetley
Office of Special Nutrition
HFS-450
200 C Street, S. W.
Washington, D. C. 20204

Dear Dr. Elizabeth Yetley:

According to " Dietary Supplement Health and Education Act of 1994" Public Law 103-417, Now I write a petitioner about Heklin dietary supplement to notice of structure/ function class for 30 days post-market. Also I want to get permission to import to the United States of America. Although it has been delivered to the United State of America before October 15, 1994, we need to revise the " Heklin " labeling again.

Heklin Tablet
Manufactured by Euro America Pharmaceutical Factory, Hong Kong China
Distributed by Chinese Herb Center, Inc.

I included following data for Heklin for you check it, If you have any questions, Please tell me or write a letter to above address.

Sincerely Yours

Manager Mr. Fu Sheng Jin

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B. Intended use; projected average daily intake of Heklin

1. Amount of Heklin proposed use in the United States

Projected marketing figures for Heklin tablet have not been determined at this time.

2. Intended usage

Heklin tablet is intended for use as a breast lump dietary supplement

3. Calculation of expected intake and daily consumption of Heklin :

From information given by Euro America Pharmaceutical Factory, the tablet is to be taken three times a day, 8 tablets a time, three times a day. Each Tablet weights 120 mg, and this projects a daily consumption of 2880mg and yearly consumption of 1050.0g for an adult.

4. Labeling

Recommended use

Orally, take 8 tablets each time, 3 times a day, after meal with water.

INGREDIENTS:

Each tablet contains 120 mg extract powder. *Cynanchum Pariculatum (bunge)* Kitag, White Chrysanthemum, Western Safflower, Kudzu Vine Root, Pollen Gastrodia, Ginseng, *Ligusticum Wallichii*, *Paconia Lactiflora*, Pearl.

Keep out of the children

Store at a cool & dry location

Batch No:

MFG date:

100% Natural Herbs

Heklin

80 tablets (120 mg each)

Manufactured by Euro America Pharmaceutical Factory,
Hong Kong, China

Distributed by Chinese Herb Products, Inc.
1010 Vermont Ave, NW Suite 712, Washington, DC 20005

it has been used formulated by Dr. Lam Kam Sang, it is modified and refined by modern technology. It is unique process and guaranteed. It is a special dietary supplement which has an effect on head circulation. Any questions about headache, please call your doctor or TCM doctors or (202)393-1203.

C. The Method and result of intended Effect: omit

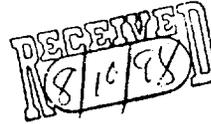
D. Safety investigations (toxicological studies)

1. Overall toxicity:

As early as the 16th century, the most famous Chinese pharmacist, Shi Zhen Li, used the components of the Heklin extract powder contains *Cynanchum Pariculatum (bunge)* Kitag, White Chrysanthemum, Western Safflower, Kudzu Vine Root, Pollen Gastrodia, Ginseng, *Ligusticum Wallichii*, *Paconia Lactiflora*, Pearl to treat a lot of symptoms in human for thousand years. Now Each components of the Heklin has been kept till today and its efficacy is further improved by modern scientific studies. (See reference 1,2). Heklin is manufactured with an unique process that preserves and concentrates the richest extract of fresh herb. Already there are over millions people in the world taking Heklin every day. Also Heklin is delivered to many parts of the world, such as Europe, Africa, America, Canada and Australia, etc., and people's responses to this product have been extraordinary due to its effectiveness and safety. Also each components of the Heklin has been delivered to the United States of America before October 15, 1994. Therefore it is considered as GRAS.

According to reports based on research experiments using 5% alcohol extracts derived from two hundred selected varieties of commonly used medicinal herbs, include the components of Heklin when said, extracts were forced to male white mice using the Linchofield and Wilcoxon method in order to determine the LD 50 of each herb, the conclusive results showed that the average LD50 was 2,000-5,000 milligrams, with the exception of raw *Radix Aconniti Kusenezoffii* and *Semen Strychni*. Thus, for most commonly used Chinese medicinal herbs and formulas, the safe dosage was found to be relatively high: for a person weighting 50 kilograms, LD 50 was approximately 250

August 3, 1998
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Dr. Elizabeth Yetley
Office of Special Nutrition
HFS-450
200 C Street, S. W.
Washington, D. C. 20204

Dear Dr. Elizabeth Yetley:

According to " Dietary Supplement Health and Education Act of 1994" Public Law 103-417, Now I write a petitioner about Breslin dietary supplement to notice of structure/ function class for 30 days post-market. Also I want to get permission to import to the United States of America. Although it has been delivered to the United State of America before October 15, 1994, we need to revise the " Breslin " labeling again.

Breslin Tablet
Manufactured by Euro America Pharmaceutical Factory, Hong Kong China
Distributed by Chinese Herb Center, Inc.

I included following data for Breslin for you check it, If you have any questions, Please tell me or write a letter to above address.

Sincerely Yours

Manager Mr. Fu Sheng Jin

60656

B. Intended use; projected average daily intake of Breslin

1. Amount of Breslin proposed use in the United States

Projected marketing figures for Breslin tablet have not been determined at this time.

2. Intended usage

Breslin tablet is intended for use as a breast lump dietary supplement.

3. Calculation of expected intake and daily consumption of Breslin :

From information given by Euro America Pharmaceutical Factory, the tablet is to be taken three times a day, six tablets a time, three times a day. Each Tablet weights 190 mg, and this projects a daily consumption of 3500mg and yearly consumption of 1278.0g for an adult.

4. Labeling

Recommended use

Orally, take 6 tablets each time, 3 times a day, after meal with water.

INGREDIENTS:

Each tablet contains 190 mg extract powder. Bulb of Fritillary, Plum Flower, Pearl, Chinese Angelica, Salvia Miltoiorrhia, Morinda Root, Notoginseng, Ginseng, Pollen, Green Tangerine Orange Peel, Scrophularia Root, Marine Alga, Frankincense.

Keep out of the children

Store at a cool & dry location

Batch No:

MFG date:

100% Natural Herbs

Breslin

180 tablets (190 mg each)

Manufactured by Euro America Pharmaceutical Factory,
Hong Kong, China

Distributed by Chinese Herb Products, Inc.

1010 Vermont Ave, NW Suite 712, Washington, DC 20005

it has been used formulated by Dr. Lam Kam Sang, it is modified and refined by modern technology. It is unique process and guaranteed. It is a special dietary supplement which has an effect on breast circulation. Any questions about breast lumps, please call your doctor or TCM doctors or (202)393-1203.

C. The Method and result of intended Effect: omit

D. Safety investigations (toxicological studies)

1. Overall toxicity:

As early as the 16th century, the most famous Chinese pharmacist, Shi Zhen Li, used the components of the The Breslin extract powder contains Bulb of Fritillary, Plum Flower, Pearl, Chinese Angelica, Salvia Miltoiorrhia, Morinda Root, Notoginseng, Ginseng, Pollen Green Tangerine Orange Peel, Scrophularia Root, Marine Alga, Frankincense, to treat a lot of symptoms in human for thousand years. Now Each components of the breslin has been kept till today and its efficacy is further improved by modern scientific studies. (See referencel.2). Breslin is manufactured with an unique process that preserves and concentrates the richest extract of fresh herb. Already there are over millions people in the world taking Breslin every day. Also Breslin is delivered to many parts of the world, such as Europe, Africa, America, Canada and Australia, etc., and people's responses to this product have been extraordinary due to its effectiveness and safety. Also each components of the Breslin has been delivered to the United States of America before October 15, 1994. Therefore it is considered as GRAS.

According to reports based on research experiments using 5% alcohol extracts derived from two hundred selected varieties of commonly used medicinal herbs, include the components of Breslin. when said, extracts were forced to male white mice using the Linchofield and Wilcoxon method in order to determine the LD 50 of each herb, the conclusive results showed that the average LD50 was 2,000-5,000 milligrams, with the exception of raw Radix Aconniti Kusenezoffii and Semen Strychni. Thus, for most commonly used Chinese medicinal herbs and formulas, the safe dosage was found to be relatively high: for a person weighting 50 kilograms, LD 50 was approximately 250