



AUG 18 1998

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

1842 '98 AUG 21 P12:45

Dear Mr. Jin:

This is in response to your letter of July 31, 1998 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 the Chinese Herb Center, Inc. is making the following statement, among others, for the product "Fu Kang tablets:"

"...to stable body and mind from excessive abuse substance. Any substance addiction and dependence question, Please call your doctor or TCM doctors or herbalist..."

In addition to the above label statement, your submission contains information that states that the intended use of the product is to "remove narcotic intoxication to relieve the pain and to strengthen the body and to tranquilize the mind and release abstinent symptoms by addicts with dependence of opium - several kind of drugs including morphine, heroin and dolantin, cocaine, hemp and ice drug and thus withdrawing drug dependence."

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 this product suggests that it is intended to treat, prevent, or mitigate disease, in that it is intended to treat, prevent, cure, or mitigate diseases of addiction. These claim do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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.

978-0163

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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, r/f)  
HFS-450 (r/f, file, OSN#60550)  
HFD-310 (BWilliams)  
HFD-314 (Aronson)  
HFS-600 (Reynolds)  
HFS-605 (Bowers)  
GCF-1 (Nickerson, Dorsey)  
r/d:HFS-456:Moore:8/10/98  
Init:GCF-1:DDorsey:8/14/98  
f/t:rjm:HFS-456:8/17/98:60550.adv:disc31

July 31, 1998  
Mr. Fu Sheng Jin  
Chinese Herb Center, Inc.  
1010 Vermont Ave. NW Suite 712  
Washington DC 20005  
Tel: (202)393-1203

60550

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 Fu Kang tablet (dietary supplement) to notice of structure/ function class for 30 days post-market. Also I want to import to the United States of America .Although Fu Kang tablet contain many single herb which has been delivered to the United State of America before October 15,1994, now I send the" Fu Kang tablet " labeling again.

Fu Kang tablet Manufactured by Lan Zhou Wei Xin Pharmaceutical Factory, Lan Zhou,hina.  
Distributed by Chinese Herb Center, Inc.

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

I have another big question, I know this is a good nature herb for drug addict use, I don't know which hospital or medical researcher do research drug addict ? For FDA, what is normal procedure can I write down the medical claim for special herb in the labeling? How do I fill out application , and then I can make medical claim in the labeling?

Sincerely Yours

Manager Mr. Fu Sheng Jin

*Fu Sheng Jin*



## B. Intended use; projected average daily intake of Fu Kang; proposed labeling

### 1. Amount of hawthorn extract proposed for use in the United States

Projected marketing figures for Fu Kang have not been determined at this time.

### 2. Intended usage

Fu Kang extract tablet is intended for use as a dietary supplement to release of addicts for improving or enhancing their immunological function.

### 3. Calculation of expected intake and daily consumption of Fu Kang extract powder:

From information given by Lan Zhou Wei Xin Pharmaceutical factory, the tablet is to be taken three times a day, four tablets each time for 6 days. Each tablet weights 120 mg, and this projects a daily consumption of 1440mg and six day consumption of 8.64g. But after one takes 72 tablets of Fu Kang, one will consult doctors and herbalist and acupuncturist. now we can not determine how many dose of Fu Kang yearly consumption for an adult.

### 4. Labeling

## Fu Kang tablets

#### Recommended Usage

Take 4 tablets a time three a day after meals with water.

#### INGREDIENTS:

Each tablet contains 120 mg pure herb extract.

- |                       |                         |
|-----------------------|-------------------------|
| 1. Dioscorea batata   | 2. Rehmannia glutinosa  |
| 3. Cornus officinalis | 4. Paeonia suffruticosa |
| 5. Poria cocos        | 6. Ophiopogon           |

Attention: Contraindicated to those with failure of the liver and kidney and pregnant women.

Manufactured by Gansu Academy of National Science and Technology & Lan Zhou Wei Xin Pharmaceutical Factory, Lan Zhou, China.  
Distributed by Chinese Herb Center, Inc. Washington, DC 20005

## Fu Kang tablets

#### Indication:

It has been formulated by ancient Chinese medicine, and modified by modern doctor. It is a special herbal dietary supplement to stable body and mind from excessive abuse substance. Any substance addiction and dependence question, Please call your doctor or TCM doctors or herbalist or (202)393-1203.

Keep out of children.

Store at a cool & dry location.

Batch No.:

Expire Date: