



DEC - 8 1997

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Mr. **Fu Sheng Jin**  
Manager  
Chinese Herb Center, Inc.  
2025 I Street N.W.  
Suite 507  
Washington, D.C. 20006

Dear Mr. Jin:

This is in response to your letters of November 28, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that the Chinese Herb Center, Inc. intends to make the following claims for the intended use of the products:

**San Jin** capsule and tablet

“**San Jin** extract capsule and tablet is intended for use as a dietary supplement which may reduce burning on urination, painful urination, urinary urgency and frequency, and **nocturia**”

**Shuang Huang Lian** capsule and tablet

“**Shuang Huang Lian** extract capsule and tablet is intended for use as a dietary supplement to help to release cold fever and may inhibit some bacteria and viral infection”

**Wu Jia Sheng** capsule and tablet

“ **Wu Jia Sheng** extract capsule and tablet is intended for use as a dietary supplement to help to release cold fever and may inhibit some bacteria and viral infection”

Section 403(r)(6) of the act 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, cure, mitigate, or prevent disease, namely urinary disorders, fevers associated with colds, and viral and bacterial infections. These claims do not meet the requirements of section 403(r)(6) of the act.

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These claims suggest that these products are intended for use as drugs within the meaning of section 201 Q)(I)(B) of the act, 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-3** 10,7520 Standish Place, **Rockville**, Maryland 20855.

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-MA200**

Nov 28,1997

Mr. **Fu Sheng Jin**

Chinese Herb Center, Inc.  
2025 I Street NW Suite 507  
Washington DC 20006  
Tel: (202)775-1 **108**

DEC - 3 1997

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 Wu Jia Seng capsule and **tablet(dietary supplement)** to notice of structure and **function** class for 30 days post-market. Although it has been delivered to the United State of America before October 15,1994, we need to revise the” Wu Jia Seng tablet “ labeling again. Therefore it is necessary to send Wu Jia Seng papers to FDA for petitioner.

Wu Jia Seng Capsule or tablet

Manufactured by **Harbin No.2 Chinese Medicine Factory, Harbin, China**

Distributed by Chinese Herb Center, Inc.

I included following data for Wu Jia Seng capsule and or Tablet 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

I am sorry to type "**Seng**" replace "**Sheng**" in the first certification letter.

Nov 28.1997  
Mr. Fu Sheng Jin  
Chinese Herb Center, Inc.  
2025 I Street NW Suite 507  
Washington DC 20006  
Tel: (202)775-1 108



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 **Shuang huang lian** capsule and **tablet**(dietary supplement) to notice of structure and **function** class for 30 days post-market. Although it has been delivered to the United State of America before October 15,1994, we need to revise the " **Shuang Huang Lian** capsule and tablet " labeling again. Therefore it is **necessary** to send **Shuang Huang Lian** papers to FDA for petitioner.

**Shuang Huang** Lian Capsule or tablet  
Manufactured by **Harbin** No.2 Chinese Medicine Factory, **Harbin**, China  
Distributed by Chinese Herb Center, Inc.

I included following data for **Shuang Huang** Lian capsule and or Tablet for you check it, If you have any questions, Please tell me or write a letter to above address.

Sincerely Yours  
*Fu Sheng Jin*  
Manager Mr. Fu Sheng Jin

# A petitioner to FDA about Shuang Huang Lian capsule and Tablet

## A. Identity; Composition; Physical, Chemical and Organoleptic Characteristics

### 1. Name of Dietary supplement

- Chemical name: not available
- Common name: **Shuang Huang Lian** extract powder
- CAS registry number: not available

### 2. Chemical identity:

- Structure formula: not available
- Molecular weight: not available
- Molecular formula: not available

### 3. Organoleptic properties:

- Appearance: powder
- Color: brown-yellow
- Taste: bitter

### 4. Physical and Chemical properties:

- pH: ND
- Melting point: ND
- Water content: ND
- Volubility: soluble in water.
- Specifications:

Shuang Huang Lian extract is manufactured by **Barbin** No.2 Chinese Medicine Factory. They sent 30 samples of Shuang Huang Lian extract powder (the batch number 970218-11) for analysis, and they received the certification from the Department of TCM Health, Research Institute of Drug and Biological Productive Health, Beijing, China. The average data measured per capsule are listed below.

#### 1) Content:

##### (a) Nutrition facts:

Serving size 8 tablets (contains 350mg); Server 8 tablets

Amount per serving

Calories ND

Calories from fat :ND

	ND	DRVs	% Daily value*
Total fat	ND	65g	ND
Cholesterol	ND		
Sodium	ND	2.4mg	ND
Total carbohydrate	ND	300g	ND
Protein	ND	50g	ND
Soft fiber	ND	25g	ND
Vitamin A		Vitamin C --	
Thiamin		Riboflavin --	
Niacin		Vitamin B6 --	
Vitamin E		Zinc	
Calcium		Iron	

\* Percent daily values are based on a 2,000 calorie

##### (b) Average amount of nutrition facts in one of 30 samples of the Shuang Huang Lian extract powder.

Reduce sugar	ND	Total sugar	ND	Carbohydrate	ND
Protein	ND	Fat	ND		
Fiber	ND	Cholesterol	ND	Others	ND

(c) Average metals contain in one of 30 sample of the Shuang Huang Lian extract powder

Sodium	ND	Calcium	ND	Iron	ND
Phosphorous	ND	Magnesium	ND	Zinc	ND
Copper	ND	Iodine	ND	Potassium	ND

(d) Average vitamin contain in one of 30 samples of the Shuang Huang Lian extract powder

Carotene	ND	Vitamin C	ND	Vitamin B1	ND
Niacin	ND	Vitamin A	ND	Vitamin D	ND
Vitamin E	ND				

(e) Average amount of impurities, toxins and pesticides in one of 30 sample of the Shuang Huang Lian extract powder

Heavy metal	Lead (Pb)	0.5ug/g
	Arsenic (As)	7.9ug/Kg
	Cadmium (Cd)	0.1ug/g
	Mercury (Hg)	0.86ug/g
Others	Nitrite	ND
	Nitrate	ND

(f) Other toxins

Aflatoxin B1: ND

Mycotoxin: ND

(g) No contaminated pesticides such as 666 and DDT in 30 sample of the hawthorn extract powder

“he amount of impurities and pesticides measured are lower than that specified in the FDA standard

2) Components:

The Shuang Huang Lian extract powder contains some Flos Ionicerae, Scutellaria root and Fructus forsythia extract.

**Method of measurement used in above tests:**

1. All productive metals in Shuang Huang Lian extract powder (plant) are measured by following methods:
2. Cadmium, Lead, and Mercury are measured by atomic absorption spectrophotometric method.
3. Arsenic is measured by Silver salt methods.
4. 666 and DDT are measured by gas chromatographic method.
5. Components are measured by high pressure liquid chromatographic method.

All nutritional indexes of method numbers have been referenced from” the methods of analysis for nutrition labeling,” 1993 by AOAC INTERNATIONAL.

**B. Intended use; projected average daily intake of Shuang Huang Lian extract powder; proposed labeling**

**1. Amount of Shuang Huang Lian extract proposed for use in the United States**

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

**2. Intended usage**

Shuang Huang Lian extract capsule and tablet is intended for use as a dietary supplement to help to release cold fever and may inhibit some bacteria and viral infection,

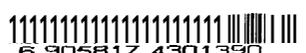
**3. Calculation of expected intake and daily consumption of Shuang Huang Lian extract powder:**

From information given by Harbin No.2 Chinese Medicine Factory, the capsule is to be taken three times a day, 4 capsules each time. Each capsule weights 700 mg, and this projects a daily consumption of 8.4g and yearly consumption of 3066 g for an adult. Each tablet weights 0.35g, three times a day, 8 tablets each time, and this projects a daily consumption of 8.4 g and yearly consumption of 3066 g for an adult.

**4.0. Capsule Labeling**

<b>Recommended use</b> Take 3 times a day, 4 capsules each time after meal. Each capsule contains 0.7g extract powder.	<b>100% Natural Chinese Herbs</b>
<b>INGREDIENTS:</b> Flos Lonicerae 33%; Scutellaria Root 33%; Fructus Forsythiae 33%; No artificial color, flavors or preservatives are added. No additives. Store at a cool & dry location Batch No: MFG date:	<b>Shuang Huang Lian Capsule</b>  100 Caps (700 mg each)  Manufactured by Harbin No.2 Chinese Medicine Factory, Harbin, China Distributed by Chinese Herb Products, Inc. 2025 Eye Street, NW Suite S07, Washington, DC 20006
 6 905817 4301390	

**4.1. Tablet Labeling**

<b>Recommended use</b> Take 3 times a day, 8 tablets each time after meal. Each tablet contains 350 mg extract powder.	<b>100% Natural Chinese Herbs</b>
<b>INGREDIENTS:</b> Flos Lonicerae 33%; Scutellaria Root 33%; Fructus Forsythiae 33%; No artificial color, flavors or preservatives are added. No additives. Store at a cool & dry location Batch No: MFG date:	<b>Shuang Huang Lian Tablet</b>  100 Tablets (350 mg each)  Manufactured by Harbin No.2 Chinese Medicine Factory, Harbin, China Distributed by Chinese Herb Products, Inc. 2025 Eye Street, NW Suite S07, Washington, DC 20006
 6 905817 4301390	

### C. The Method and result of intended Effect:

report from experiment data, Shuang Huang Lian extract inhibit RSV virus. (1); FLu virus(2);and inhibit pneumococci, Staphylococcus aureus, Streptococci A, S. typhoid, S. para-typhi A, E, Coli(3); and decrease fever(4),

Intended effect was established by above test results performed by many Chinese Medical University.

\*Above data has not been evaluated by the Food and Drug Administration now.

### D. Safety investigations (Toxicological studies)

#### 1. Overall toxicity:

As early as the 16th century, the most famous Chinese pharmacist, Shi Zhen Li, used Flos Lonicerae, Scutellaria root, and Fructus forsythia to treat "fever" patients from common cold. " and "to remove toxin" and treat diarrhea etc. This treatment has been kept till today and its efficacy is further improved by modern scientific studies. (See reference 5). Flos Lonicerae is a wild, flower growing in China. Its flower with a sweet taste is considered to be herb tea. Now Shuang Huang Lian extract is manufactured with a unique process that preserves and concentrates the richest component. Already there are over millions people in the world taking Harbin Shuang Huang Lian extract every day. Also Harbin's Shuang Huang Lian extract is delivered to many parts of the world, such as Asia, Europe, Africa, America, Canada and Australia, etc., and people's responses to this product have been extraordinary due to its effectiveness and safety. Also it 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 medical herbs, when the 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 is to be showed that the average LD50 was 225g/Kg, with the exception of raw Radix Aconniti Kusenezoffii and Semen Strychni. Thus, for most commonly used medical herbs and formulas, the safe dosage was found to be relatively high(5). They report that they can not get LD-50 dose of Shuang Huang Lian extract. For a person weighting 60 kilograms, The recommended usage for Shuang Huang Lian extract is 8.4g per day That is 8.4g per day/60 Kg=140g/KG. when take in normal dosage, most medical herbs have almost no toxicity(see reference 5). The recommended usage for Shuang Huang Lian extract is 8.4g per day; this dosage does not present safety concerns.

#### 2. Acute toxicity test for Shuang Huang Lian Extract Capsule

Animal species: Little white mice, Kun ming species of average weight 19-21g, is supplied by Department of animal He Long Jiang Provincial Institute of Oncology. ( Certification by Medical Animal Center, , China). The acute toxicity test has been done by Harbin No.2 Chinese Medicine Factory.

The acute toxicity experiment proved that one time ingestion of Shuang Huang Lian extract can not induce LD50 in mice. In the second part of experiment, 20 white mice are divided two groups: 10 male and 10 female. They made with 1/2 tablet(0.175g) Shuang Huang Lian extract solution three times a day(the maximum possible concentration). After observing for 7 days, every mice show normal quite life, can not present abnormal activity, and no mice is dead. After 7 days, the amount of ingestion is calculated 60 tablets/mice. For example, Mice body weight is 20g, each mice received Shuang Huang Lian's dose 60 tablets x 350m~21,000mg, that is equal to 1050g/Kg for mice. After observing 7 days, no toxicity reaction and deaths occurred at this maximum dosage level. You can not measure LD50 dose of Shuang Huang Lian extract. Above test shows that maximum daily dosage of ( 1050g/Kg/7 says= 150g/kg of body weight)May in mice can be sustained for an extended period. The dosages used in the toxicity studies are equivalent to (1050g/Kg/8.4g= 125 times )of clinic dosage (8.4g/day)in human(6).

#### 3. Long Term Toxicity Test for Shuang Huang Lian Extract

Animal species: big white mice (Wistar strain) used in the test are supplied by Institute of oncology. Animal are 7 weeks old, weight 90- 125g, half is male half is female. All mice are divided into three groups: negative, high dose, low dose, and males and females are distributed equally in each group. Administrating method, dosage, and volume ingested for 30 days are listed in following table.

Group	Number	Dose (g/Kg/D)	Volume (ML/100g/BW)	Equivalent clinic dose gram (in human)
1. Negative	n=20	0.00	2.0ml water	0.00
2. High Dosage	n=20	0.06	12.0% of 2.0ml	252
3. Low Dosage	n=20	0.03	6.0% of 2.0ml	126

We fed mice according to above table every afternoon for 30 days. There were no change in **weight**( $P>0.05$ ), appetite, hair, feces, There were no death, There were no toxic reactions and abnormality occurred in hematology (such as **RBC** count, reticular cells count, **WBC** count, **Hb**, platelet **count** and **blood clot time**,  $P>0.05$ ); **There** were no abnormal blood biochemical index (such as serum in **GOT**, **GPT**, **ALP**, **BUN**, **Ch**, **AL**, **Cr**, **Tp**, **T-bou**.  $p>0.05$  ); **and** there were no pathological damage occurred in the body organs by pathologist, including heart, liver, spleen, lung, adrenal gland, stomach, small intestine, large intestine, pancreas, **thymus** gland, **lymph node**, testis or **ovum** etc. The high dosage group (big white mice) taken Shuang Huang Lian powder is 30 times high than the clinic dosage. The results of **this** study combined with the result of acute toxicity study proved the short term and **long** term safety of Shuang Huang Lian extract. All experiments are performed by Harbin No.2 Chinese Medicine Factory.(7)(8)

4. **Impurities, byproducts(limits):**

<b>Heavy metal</b>	<b>Lead (Pb)</b>	<b>0.5ug/g</b>
	<b>Arsenic (As)</b>	<b>7.76ug/g</b>
	<b>Cadmium (Cd)</b>	<b>0.1ug/g</b>
	<b>Mercury (Hg)</b>	<b>0.86ug/g</b>
	<b>Nitrite</b>	<b>ND</b>
	<b>Nitrate</b>	<b>ND</b>
<b>Other toxins</b>	<b>Aflatoxin B1</b>	<b>ND</b>
	<b>Mycotoxin</b>	<b>ND</b>

**No contaminated pesticides** such as 666 and DDT in 30 sample of hawthorn extract powder

5. **Microbiological examination of Shuang Huang Lian extract powder: ND**

6. **Shuang Huang Lian Extract stables in colour, chemistry, physical change within 16 months.**(9)

**Reference:**

1. Effect of Shuang Huang Lian Extract on Respiratory Syncytial virus.
2. Effect of Shuang Huang Lian on Flu virus.
3. Effect of Shuang Huang Lian Extract on Bacteria.
4. Shuang Huang Lian Extract on decreasing fever.
5. Dr. William Chang: "reference guide of commonly used herbal formilas". 1989
6. Experiment data of Acute Toxicity Test for Shuang Huang Lian Extract.
7. Experiment data of Long term Toxicity for Shuang Huang Lian Extract.
8. Effect of Shuang Huang Lian Extract on Blood, Hematology and pathology.
9. Observing Shuang Huang Lian Extract of Colour, Chemistry, Physical Change Within 16 Months

## **E Proposed tolerances**

No tolerances are required to insure the safety of Shuang Huang Lian extract powder because of its non-toxic nature.

## **F. Environmental Assessment**

**1. Date: November 17, 1997**

**2. Name of Petitioner: Chinese herb Center, Inc.**

**3. Address of Petitioner:**

2025 Eye Street, NW Suite 507

Washington DC 20006

Tel: (202)775-1 108

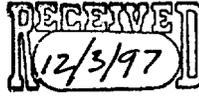
### **4. introduction of Shuang Hunag Lian extract into Environment**

The **Shuang Huang Lian** powder extract capsule and **tablet** is manufactured in **China** for importation into the United States. It is consumed in small quantities in households across the country, under no circumstances this capsule will cause any environmental pollution when discarded by consumer. The capsule is packaged in transparent gelatin capsule, and there are no direct or indirect additives or irradiated **herbs used** in **Shuang Hunag Lian extract** powder. The amount of **Shuang Huang Lian** extract consumed or discarded in any one area **will** generate no toxicity and will have no impact on the local waste treatment system.

The **Shuang Huang Lian extract** powder capsule and tablet is manufactured in China. The manufacture states that their manufacturing process does not result in the emission of any pollutants of concern, and the process does no harm to the environment. The manufacturing process is carried out in conformance with **all** Chinese laws covering environmentalaf safety.

The certification of **Shuang Huang Lian** on Non-Toxic Statement is followed below. “ This is **certify** that all (**Shuang Huang Lian**) **dietary** supplement in this shipment comply with **all** applicable rules or orders under TSCA ( Toxic Substance Control Act) and that I am not offering a **dietary** supplement for entry in violation of TSCA or any applicable rule or order under **TSCA**”. The certification is to be issued by China International Exchange Center of Traditional Chinese Medicine and KDT Co.

Nov 28.1997  
Mr. Fu Sheng Jin  
Chinese Herb Center, Inc.  
2025 I Street NW Suite 507  
Washington DC 20006  
Tel: (202) 775-1 108



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 San **Jin** capsule and **tablet**(dietary supplement) to notice of structure and function class for 30 days post-market. Although it has been delivered to the United State of America before October 15,1994, we need to revise the” San Jin capsule and tablet “ labeling again, It is necessary to send San Jin Capsule and Tablet papers to FDA for petitioner.

San Jin Capsule or Tablet  
Manufactured by Gui Lin San Jin Pharmaceutical Group Co, Gui Lin city, China  
Distributed by Chinese Herb Center, Inc.

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

Sincerely Yours

*Fu Sheng Jin*

Manager Mr. Fu Sheng Jin

## A petitioner to FDA about San Jin capsule and Tablet

### A. Identity; Composition; Physical, Chemical and Organoleptic Characteristics

1. **Name of Dietary supplement**
  - a. Chemical name: not available
  - b. Common name: San Jin extract powder
  - c. CAS registry number: not available
2. **Chemical identity:**
  - a. Structure formula: not available
  - b. Molecular weight: not available
  - c. Molecular formula: not available
3. **Organoleptic properties:**
  - a. Appearance: powder
  - b. Color: brown
  - c. Taste: bitter
4. **Physical and Chemical properties:**
  - a. pH: ND
  - b. Melting point: ND
  - c. Water content: ND
  - d. Solubility: soluble in water.
  - e. Specifications:

San Jin extract is manufactured by Gui Lin San Jin Pharmaceutical Group Co. They sent 30 samples of San Jin extract powder (the batch number 970608) for analysis, and they received the certification from the department of TCM Health, Research Institute of Drug and Biological Productive Health, Beijing, China. The average data measured per tablet are listed below.

1) Content:

(a) Nutrition facts:

Serving size 4 tablets (contains 175mg/tablet);,Server 4 tablets

Amount per serving

Calories ND                      Calories from fat :ND

	ND	DRVs	% Daily value*
Total fat	ND	65g	ND
Cholesterol	ND		
Sodium	ND	2.4mg	ND
Total carbohydrate	ND	300g	ND
Protein	ND	50g	ND
Soft fiber	ND	25g	ND
Vitamin A		Vitamin C	--
Thiamin		Riboflavin	--
Niacin		Vitamin B6	--
Vitamin E		Zinc	
Calcium		Iron	

\* Percent daily values are based on a 2,000 calorie

(b) Average amount of nutrition facts in one of 30 samples of the San Jin extract powder.

Reduce sugar	ND	Total sugar	ND	Carbohydrate	ND
Protein	ND	Fat	ND	Others	ND
Fiber	ND	Cholesterol	ND		

(c) Average metals contain in one of 30 sample of the San Jin extract powder

Sodium	ND	Calcium	ND	Iron	ND
Phosphorous	ND	Magnesium	ND	Zinc	ND
Copper	ND	Iodine	ND	Potassium	ND

(d) Average vitamin contain in one of 30 samples of the San Jin extract powder

Carotene	ND	Vitamin C	ND	Vitamin B1	ND
Niacin	ND	Vitamin A	ND	Vitamin D	ND
Vitamin E	ND				

(e) Average amount of impurities, toxins and pesticides in one of 30 sample of the San Jin extract powder

Heavy metal	Lead (Pb)	<1.0ug/g
	Arsenic (As)	1.0ug/Kg
	Cadmium (Cd)	0.3ug/g
	Mercury (Hg)	0.01ug/g
Others	Nitrite	ND
	Nitrate	ND

(f) Other toxins

Aflatoxin B1: ND

Mycotoxin: ND

(g) Contaminated pesticides such as 666 (0.006 ug/g) and DDT (0.01ug/g) in 30 sample of the San Jin extract powder.

The amount of impurities and pesticides measured are lower than that specified in the FDA standard

2) Components:

The San Jin extract powder per tablet contains 33% of Cherokee rose root extract and 33% of Bock's thorn, extract and 33% of Lygodium spore extract.

**Method of measurement used in above tests:**

1. All productive metals in extract powder (plant) are measured by following methods:
2. Cadmium, Lead, and Mercury are measured by atomic absorption spectrophotometric method.
3. Arsenic is measured by Silver salt methods.
4. 666 and DDT are measured by gas chromatographic method.
5. Components are measured by high pressure liquid chromatographic method.

All nutritional indexes of method numbers have been referenced from "the methods of analysis for nutrition labeling," 1993 by AOAC INTERNATIONAL.

## B. Intended use; projected average daily intake of San Jin extract powder; proposed labeling

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

Projected marketing figures for San Jin capsule and tablet have not been determined at this time.

### 2. Intended usage

San Jin extract capsule and tablet is intended for use as a dietary supplement which may reduce burning on urination, painful urination, urinary urgency and frequency, and nocturia. (I).

### 3. Calculation of expected intake and daily consumption of San Jin extract powder:

From information given by Gui Lin San Jin Pharmaceutical group Co, the capsule is to be taken three times a day, 2 capsules each time. Each capsule weights 350mg, and this projects a daily consumption of 2100mg and yearly consumption of 766.5 g for an adult. Each tablet weights 175mg, three times a day, 4 tablets each time, and this projects a daily consumption of 2100mg and yearly consumption of 766.5 g for an adult,

#### 4.0. Capsule Labeling

<b>Recommended use</b> <b>Take 3 times a day, 2 capsules each time after meal. Each capsule contains 350 mg extract powder.</b>	<b>100% Natural Chinese Herbs</b>
<b>INGREDIENTS:</b> Cherokee rose root 33%; Bock's thorn 33%; Lygodium spore 33%.	<b>San Jin Capsule</b>
No artificial color, flavors or preservatives are added. No additives. Store at a cool & dry location Batch No: MFG date:	100 Caps (350mg each)
 6 905517 4301390	Manufactured by <b>Gui Lin San Jin Pharmaceutical Group Co, Gui Lin, China</b> Distributed by <b>Chinese Herb Products, Inc.</b> 2025 Eye Street, NW Suite 507, Washington, DC 20006

#### 4.1. Tablet Labeling

<b>Recommended use</b> <b>Take 3 times a day, 4 tablets each time after meal. Each tablet contains 175 mg extract powder.</b>	<b>100% Natural Chinese Herbs</b>
<b>INGREDIENTS:</b> Cherokee rose root 33%; Bock's thorn 33%; Lygodium spore 33%.	<b>San Jin Tablet</b>
No artificial color, flavors or preservatives are added. No additives. Store at a cool & dry location Batch No: MFG date:	100 Tablets (175 mg each)
 6 905517 4301390	Manufactured by <b>Gui Lbs San Jin Pharmaceutical Group Co, Gui Lin, China</b> Distributed by <b>Chinese Herb Products, Inc.</b> 2025 Eye Street, NW Suite 507, Washington, DC 20006

### C. The Method and result of intended Effect:

**report** from experiment data, San Jin extract inhibit the E. Coli, S. typhoid, Staphylococcus aureus and Streptococci A B ,Pneumococci in the mice urination; may reduce burning on urination, painful urination, urinary urgency and frequency, and nocturia. (1).

Intended effect was established by above test results performed by many Chinese Medical University.

\*Above data has not been evaluated by the Food and Drug Administration (FDA)now.

### D. Safety investigations (Toxicological studies)

#### 1. Overall toxicity:

As early as the 16th century, the most famous Chinese pharmacist, Shi Zhen Li, used cherokww rose root, bock's thorn and lygodillm spore to treat patients with excessive internal heat and removing toxins and burning on urination as well as urinary urgency ( TCM term) This treatment has been kept till today and its efficacy is further improved by modern scientific studies. (1). Now San Jin extract is manufactured with an unique process that preserves and concentrates the richest component. Already there are over millions people in the world taking Gui Lin's San Jin extract every day. Also San Jin extract is delivered to many parts of the world, such as Asia, Europe, Africa, America, Canada and Australia, etc., and people's responses to this product have been extraordinary due to its effectiveness and safety. Also it 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 medical herbs, when the extracts were forced to male white mice using the Linchofield and Wilcoxon method, in order to determine the LD 50 of each herb. However, for most commonly used medical herbs and formulas, the safe dosage was found to be relatively high, with the exception of raw Radix Aconniti Kusenezoffii and Semen Strychni.(2). Three component of San Jin extract is one of most popular Chinese herb, They report that they can not get LD-50 dose of San Jin extract. For a person weighting 60 kilograms, The recommended usage for San Jin extract is2100mg per day. That is2 100mg per day/60 Kg=35mg/KG. when take in normal dosage, most medical herbs have almost no toxicity(1). The recommended usage for San Jin extract is2100mg per day; this dosage does not present safety concerns.

#### 2. Acute toxicity test for San Jin Extract Tablet

Animal species: Little white mice, Kun ming species of average weight 18-22g, half male and half female is supplied by Animal Room of Gui Lin No 2. Pharmaceutical Factory. ( Certification by Medical Animal Center, China). The acute toxicity test has been done by Department of Pharmacology, Gui Lin Medical University and Gui Lin San Jin Pharmaceutical Group, Co.(1)

The acute toxicity experiment proved that 20 white mice are divided two groups: IO male and 10 female. 1 time ingestion of San Jin extract ( the dose is O. 9ml raw herb /10g) for three times extract. After observing 7 days, no mice is dead, they can not measure LD50 dose of San Jin extract in mice. The maximum tolerant dose is 305g of raw herb/Kg/mice. The dosages used in the toxicity studies are equivalent to 480 times of clinic dosage (2. 1g/day)in human(2).

#### 3. Long Term Toxicity Test for San Jin Extract tablet

Animal species: big white mice (Wistar strain) used in the test are supplied by Animal Room Academy of Tadtional Medicine in Guang Xi Province.( Certification by Medical Animal Center of China). Animal are 7 weeks old, weight 90-120g, half is male half is female. All mice are randomly divided into four groups: negative, high dose, middle dose, low dose, and males and females are distributed equally in each group. Administrating method, dosage, and volume ingested for 12 weeks are listed in following table.

Group	Number	Dose (g/Kg/D)	Volume (ML/100g/BW)	Equivalent clinic dose gram (in human)
1. Negative	n=20	0.00	2.0ml water	0.00
2. High Dosage	n=20	67.2	3.86% of 2.0ml	80
3. Middle Dosage	n=20	33.6	1.93% of 2.0ml	40
4. Low dosage	n=20	16.8	0.97% of 2.0ml	20

We fed mice according to above table every afternoon for 84 days. There were no change in weight( $P>0.05$ ), appetite, hair, feces. There were no death. There were no toxic reactions and abnormality occurred in hematology (such as RBC count, reticular cells count, WBC count, Hb, platelet count and N/L ratio, ( $P>0.05$ ) in three group mice; There were no abnormal blood biochemical index (such as serum in AST, ALT, BUN, Cr., T-BIL, ALB, TOTAL PROTEIN, Cholesterol, GKU in three dose group ( $p>0.05$ ); and there were no pathological damage occurred in the body organs of three dose group by pathologist check, including heart, liver, spleen, lung, kidney, adrenal gland, stomach, small intestine, large intestine, pancreas, pituitary gland, thymus gland, lymph node, testis or ovum etc. ( $P>0.05$ ) The high dosage group (big white mice) taken San Jin powder is 80 times high than the clinic dosage. The results of this study combined with the result of acute toxicity study proved the short term and long term safety of San Jin extract. All experiments are performed by Department of Pharmacology, Gui Lin Medical University and Gui Lin San Jin Chinese Pharmaceutical Group, and pathological report is performed by Department of Pathology, Gui Lin Medical University. (1)

4. Impurities, byproducts(limits):

Heavy metal	Lead (Pb)	<1.0ug/g
	Arsenic (As)	1.0ug/g
	Cadmium (Cd)	0.3ug/g
	Mercury (Hg)	0.01ug/g
	Nitrite	ND
	Nitrate	ND
Other toxins	Aflatoxin B1	ND
	Mycotoxin	ND

Pesticides such as 666(0.006ug/g) and DDT(0.0 ug/g) in 30 sample of San Jin extract powder,

5. Microbiological examination of San Jin extract powder: ND

Reference:

- 1.Effect of San Jin Extract on pharmacology and Toxicology.
- 2.Dr. William Chang: "reference guide of commonly used herbal formulas". 1989

## **E Proposed tolerances**

No tolerances are required to insure the safety of San Jin extract powder because of its non-toxic nature,

## **F. Environmental Assessment**

1. **Date:** November 17, 1997

2. **Name of Petitioner:** Chinese herb Center, Inc.

3. **Address of Petitioned**

2025 Eye Street, NW Suite 507

Washington DC 20006

Tel: (202)775-1 108

4. **Introduction of San Jin extract into Environment**

The San Jin powder extract capsule and tablet is manufactured in China for importation into the United States. It is consumed in small quantities in households across the country, under no circumstances this capsule will cause any environmental pollution when discarded by consumer. The capsule is packaged in transparent gelatin capsule, and the tablet is coated sugar outside. There are no direct or indirect additives or irradiated herbs used in San Jin extract powder. The amount of San Jin extract consumed or discarded in any one area will generate no toxicity and will have no impact on the local waste treatment system.

The San Jin extract powder capsule and tablet is manufactured in China. The manufacture states that their manufacturing process does not result in the emission of any pollutants of concern, and the process does no harm to the environment. The manufacturing process is **carried** out in conformance with **all** Chinese laws covering environmental safety.

The **certification** of San Jin on Non-toxic statement is followed below. "this is to **certify** that **all** (San Jin) dietary supplement in this shipment comply with **all** applicable **rules** or orders under TSCA(Toxic Substance Control Act) and that **I** am not offering a dietary supplement for entry in violation of TSCA or any applicable rule or order under TSCA". The certification is issued by China International Exchange Center of **Traditional** Chinese Medicine and KST Co.

Nov 28, 1997  
Mr. Fu Sheng Jin  
Chinese Herb Center, Inc.  
2025 I Street NW Suite 507  
Washington DC 20006  
Tel: (202)775-1 108



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 Wu Jia Sheng capsule and tablet(dietary supplement) to notice of structure and **function** class for 30 days post-market. Although it has been delivered to the United State of America before October 15,1994, we need to revise the” Wu **Jia** Sheng tablet “ labeling again. Therefore it is **necessary** to send Wu **Jia** Sheng papers to FDA for petitioner.

Wu Jia Sheng Capsule or tablet  
Manufactured by **Harbin** No.2 Chinese Medicine Factory, **Harbin**, China  
Distributed by Chinese Herb Center, Inc.

I included following data for Wu Jia Sheng capsule and or Tablet for you check it, If you have any questions, Please tell me or write a letter to above address.

Sincerely Yours

*Fu Sheng Jin*  
Manager Mr. Fu Sheng Jin

## A petitioner to FDA about Wu Jia Sheng capsule and Tablet

### A. Identity; Composition; Physical, Chemical and Organoleptic Characteristics

1. Name of Dietary supplement
  - a. Chemical name: not available
  - b. Common name: Wu Jia Sheng extract powder
  - c. CAS registry number: not available
2. Chemical identity:
  - a. Structure formula: not available
  - b. Molecular weight: not available
  - c. Molecular formula: not available
3. Organoleptic properties:
  - a. Appearance: powder
  - b. Color: brown
  - c. Taste: bitter
4. Physical and Chemical properties:
  - a. pH: ND
  - b. Melting point: ND
  - c. Water content: ND
  - d. Volubility: soluble in water.
  - e. Specifications:

Wu Jia Sheng extract is manufactured by Barbin No.2 Chinese Medicine Factory. They sent 30 samples of Wu Jia Sheng extract powder (the batch number 970218-1 1) for analysis, and they received the certification from the Department of TCM Health, Research Institute of Drug and Biological Productive Health, Beijing, China. The average data measured per capsule are listed below

1) Content:

(a) Nutrition facts:

Serving size 4 tablets (contains 75mg); Server 4 tablets

Amount per serving

Calories ND                      Calories from fat :ND

	ND	DRVs		% Daily value*
Total fat	ND	65g		ND
Cholesterol	ND			
Sodium	ND	2.4mg		ND
Total carbohydrate	ND	300g		ND
Protein	ND	50g		ND
Soft fiber	ND	25g		ND
Vitamin A			Vitamin C	--
Thiamin			Riboflavin	--
Niacin			Vitamin B6	--
Vitamin E			Zinc	
Calcium			Iron	

\* Percent daily values are based on a 2,000 calorie

(b) Average amount of nutrition facts in one of 30 samples of the Shuang Huang Lian extract powder.

Reduce sugar	ND	Total sugar	ND	Carbohydrate	ND
Protein	ND	Fat	ND		
Fiber	ND	Cholesterol	ND	Others	ND

(c) Average metals contain in one of 30 sample of the Wu Jia Sheng extract powder

Sodium	ND	Calcium	ND	Iron	ND
Phosphorous	ND	Magnesium	ND	Zinc	ND
Copper	ND	Iodine	ND	Potassium	ND

(d) Average vitamin contain in one of 30 samples of the Wu Jia Sheng extract powder

Carotene	ND	Vitamin C	ND	Vitamin B1	ND
Niacin	ND	Vitamin A	ND	Vitamin D	ND
Vitamin E	ND				

(e) Average amount of impurities, toxins and pesticides in one of 30 sample of the Wu Jia Sheng extract powder

Heavy metal	Lead (Pb)	2.4ug/g
	Arsenic (As)	12.0ug/Kg
	Cadmium (Cd)	0.2ug/g
	Mercury (Hg)	0.009ug/g
Others	Nitrite	ND
	Nitrate	ND

(f) Other toxins

Aflatoxin B1: ND

Mycotoxin: ND

(g) No contaminated pesticides such as 666 and DDT in 30 sample of the hawthorn extract powder.

The amount of impurities and pesticides measured are lower than that specified in the FDA standard

2) Components:

The Wu Jia Sheng extract powder contains 50% of Acanthopanax root extract and Gin Sheng extract.

**Method of measurement used in above tests:**

1. All productive metals in Wu Jia Sheng extract powder (plant) are measured by following methods:
2. Cadmium, Lead, and Mercury are measured by atomic absorption spectrophotometric method.
3. Arsenic is measured by Silver salt methods.
4. 666 and DDT are measured by gas chromatographic method.
5. Components are measured by high pressure liquid chromatographic method.

All nutritional indexes of method numbers have been referenced from " the methods of analysis for nutrition labeling," 1993 by AOAC INTERNATIONAL.

## B. Intended use; projected average daily intake of Wu Jia Sheng extract powder; proposed labeling

### 1. Amount of Wu Jia Sheng extract proposed for use in the United States

Projected marketing figures for hawthorn have not been determined at this time,

### 2. Intended usage

Wu Jia Sheng extract capsule and tablet is intended for use as a dietary supplement to help to release cold fever and may inhibit some bacteria and viral infection.

### 3. Calculation of expected intake and daily consumption of Wu Jia Sheng extract powder:

From information given by Harbin No.2 Chinese Medicine Factory, the capsule is to be taken two times a day, 4 capsules each time. Each capsule weights 150 mg, and this projects a daily consumption of 600mg and yearly consumption of 219 g for an adult. Each tablet weights 75mg, two times a day, 4 tablets each time, and this projects a daily consumption of 600mg and yearly consumption of 219 g for an adult,

#### 4.0. Capsule Labeling

<b>Recommended use</b> Take 2 times a day, 2 capsules each time after meal. Each capsule contains 150 mg extract powder.	<b>100% Natural Chinese Herbs</b>
<b>INGREDIENTS:</b> Cortex Acanthopanax 50%; Ginseng 50%. No artificial color, flavors or preservatives are added. No additives. Store at a cool & dry location Batch No: MFG date:	<b>Wu. Jia Sheng Capsule</b>
 6 90581 7 4301390	100 Caps (150mg each) Manufactured by Harbin No.2 Chinese Medicine Factory, Harbin, China Distributed by Chinese Herb Products, Inc. 2025 Eye Street, NW Suite 507, Washington, DC ZOOM

#### 4.1. Tablet Labeling

<b>Recommended use</b> Take 2 times a day, 4 tablets each time after meal. Each tablet contains 75 mg extract powder.	<b>100% Natural Chinese Herbs</b>
<b>INGREDIENTS:</b> cortex Acanthopanax 50% ; Gin Shoenig 50%. No artificial color, flavors or preservatives as-e added. No additives. Store at a cool & dry location Batch No: MFG date:	<b>Wu Jia Sheng Tablet</b>
 6 90581 7 4301390	100 Tablets (75 mg each) Manufactured by Harbin No.2 Chinese Medicine Factory, Harbin, China Distributed by Chinese Herb Products, Inc. 2025 Eye Street, NW Suite 507, Washington, DC 20006

### C. The Method and result of intended Effect:

report from experiment data, Wu Jia Sheng extract increase more energy, present anti-fatigue, and treat insomnia and memory loss.(1).

Intended effect was established by above test results performed by many Chinese Medical University.

\*Above data has not been evaluated by the Food and Drug Administration now.

### D. Safety investigations (Toxicological studies)

#### 1. Overall toxicity:

As early as the 16th century, the most famous Chinese pharmacist, Shi Zhen Li, used Gin Sheng and Acanthopanax root to treat patients with insomnia, memory loss and fatigue and increase immunity etc. This treatment has been kept till today and its efficacy is further improved by modern scientific studies. (2). Gin Sheng and Acanthopanax root is a wild, plant growing in East-North part of China. Its root with a slight sweet tastes is considered to be herb tea. Now Wu Jia Sheng extract is manufactured with a unique process that preserves and concentrates the richest component. Already there are over millions people in the world taking Harbin's Wu Jia Sheng extract every day. Also Wu Jia Sheng extract is delivered to many parts of the world, such as Asia, Europe, Africa, America, Canada and Australia, etc., and people's responses to this product have been extraordinary due to its effectiveness and safety. Also it 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 medical herbs, when the 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 is to be showed that the average LD50 was 225g/Kg, with the exception of raw Radix Aconniti Kusenezoffii and Semen Strychni. Thus, for most commonly used medical herbs and formulas, the safe dosage was found to be relatively high(5). They report that they can not get LD-50 dose of Wu Jia Sheng extract. For a person weighting 60 kilograms, The recommended usage for Wu Jia Sheng extract is 600mg per day. That is 600mg per day/60 Kg=10mg/KG. when take in normal dosage, most medical herbs have almost no toxicity(see reference 5). The recommended usage for Wu Jia Sheng extract is 600mg per day; this dosage does not present safety concerns.

#### 2. Acute toxicity test for Wu Jia SHeng Extract Tablet

Animal species: Little white mice, Kun ming species of average weight 18-22g, is supplied by Department of animal He Long Jiang Provincial Institute of Oncology. ( Certification by Medical Animal Center, , China). The acute toxicity test has been done by Harbin No.2 Chinese Medicine Factory.

The acute toxicity experiment proved that one time ingestion of Wu Jia Sheng( the dose is 525g/Kg) for three days extract no mice is dead, they can not measure LD50 dose of Wu Jia Sheng extract in mice. In the second part of experiment, 20 white mice are divided two groups: 10 male and 10 female. They made with 350g/Kg of Wu Jia Sheng extract solution three times a day(the maximum possible concentration). After observing for 7 days, every mice survive. you can see more jumping after ingestion compare to normal mice, later fifteen, every mice keeps quite behavior in diet and activity. After 7 days, the maximum tolerant amount of ingestion is not lower than 60g/Kg of Wu Jia Sheng= 700g raw herb/mice. Every mice can be sustained for an extended period. The dosages used in the toxicity studies are equivalent to (60g/Kg/0.6g=500 times )of clinic dosage (0.6g/day)in human(2).

#### 3. Long Term Toxicity Test for Wu Jia Sheng Extract tablet

Animal species: big white mice (Wistar strain) used in the test are supplied by Institute of oncology. Animal are 7 weeks old, weight 80-100g, half is male half is female. All mice are randomly divided into three groups: negative, high dose, low dose, and males and females are distributed equally in each group. Administrating method, dosage, and volume ingested for 30 days are listed in following table.

Group	Number	Dose (g/Kg/D)	Volume (ML/100g/BW)	Equivalent clinic dose gram (in human)
1. Negative	n=20	0.00	2.0ml water	0.00
2. High Dosage	n=20	70	35.0% of 2.0ml	30
3. Low Dosage	n=20	35	17.5% of 2.0ml	15

We fed mice according to above table every afternoon for 0 days. There were no change in weight( $P>0.05$ ), appetite, hair, feces. There were no death. There were no toxic reactions and abnormality occurred in hematology (such as RBC count, reticular cells count, WBC count, Hb, platelet count and blood clot time,  $P>0.05$ ); There were no abnormal blood biochemical index (such as serum in GOT, GPT, ALP, BUN, UREA, AL, TOTAL PROTEIN, Cholesterol,  $p>0.05$ ); and there were no pathological damage occurred in the body organs by pathologist including heart, liver, spleen, lung, adrenal gland, stomach, small intestine, large intestine, pancreas, thymus gland, lymph node, testis or ovum etc. The high dosage group (big white mice) taken Wu Jia Sheng powder is 50 times high than the clinic dosage. The results of this study combined with the result of acute toxicity study proved the short term and long term safety of Wu Jia Sheng extract. All experiments are performed by Harbin No.2 Chinese Medicine Factory.(3), and pathological report is performed by Direct of Pathology of the Department of basic Experiment Center in He Long Jiang's Academy of Traditional Chinese Medicine.(4)

4. **Impurities, byproducts(limits):**

<b>Heavy metal</b>	<b>Lead (Pb)</b>	<b>2.4ug/g</b>
	<b>Arsenic (As)</b>	<b>12.0ug/g</b>
	<b>Cadmium (Cd)</b>	<b>0.2ug/g</b>
	<b>Mercury (Hg)</b>	<b>0.009ug/g</b>
	<b>Nitrite</b>	<b>ND</b>
	<b>Nitrate</b>	<b>ND</b>
<b>Other toxins</b>	<b>Aflatoxin B1</b>	<b>ND</b>
	<b>Mycotoxin</b>	<b>ND</b>

No contaminated pesticides such as 666 and DDT in 30 sample of hawthorn extract powder

5. Microbiological examination of **Shuang Huang Lian** extract powder: ND

6. **Shuang Huang Lian** Extract stables in colour, chemistry, physical change within 16 months.(4)

**Reference:**

- 1.Effect of Wu Jia Sheng Extract on pharmacology
2. Experiment data of Acute Toxicity Test for Shuang Huang Lian Extract.
3. Experiment data of Long term Toxicity for Shuang Huang Lian Extract.
4. Effect of Wu Jia Sheng Extract on mice pathological report.
- 5.Dr. William Chang: " reference guide of commonly used herbal formilas". 1989

## E Proposed tolerances

No tolerances are required to insure the safety of Wu Jia **Sheng** extract powder because of its non-toxic nature.

## F. Environmental Assessment

1. **Date:** November 17, 1997
2. **Name of Petitioner:** Chinese herb Center, Inc.
3. Address of Petitioner  
2025 Eye Street, NW Suite 507  
Washington DC 20006  
Tel: (202)775-1 108

### 4. Introduction of Wu Jia Sheng extract into Environment

The Wu Jia **Sheng** powder **extract** capsule and **tablet** is manufactured in China for importation into the United States. It is consumed in small quantities in households across the country, under no circumstances this capsule will **cause any** environmental pollution when discarded by consumer. The capsule is packaged in transparent gelatin capsule, and the tablet is coated sugar outside. There are no direct or indirect additives or irradiated herbs used in Wu Jia **Sheng** extract powder. The amount of Wu Jia **Sheng extract** consumed or discarded in any one area will generate no toxicity and **will** have no impact on the local waste treatment system.

The Wu Jia Sheng extract powder capsule and tablet is manufactured in China. The manufacture states that their manufacturing process does not result in the emission of any pollutants of concern, and the process does no harm to the environment. The manufacturing process is earned out in conformance with all Chinese laws covering environmental safety.

The **certification** of Wu Jia Sheng on Non-toxic statement is followed below. "this is to **certify** that all (Wu Jia **Sheng**) dietary supplement in this shipment comply with all applicable rules or orders under **TSCA**(Toxic Substance Control Act) and that I am not offering a dietary supplement for entry in violation of TSCA or any applicable ~~rule~~ or order under **TSCA**". The certification is issued by China International Exchange Center of Traditional Chinese Medicine and KST Co.

~~rule~~  
↓  
rule