

August 3, 1998  
Mr. Fu Sheng Jin <sup>Are.</sup>  
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

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Dear Dr. Elizabeth Yetley:

According to "Dietary Supplement Health and Education Act of 1994" Public Law 103-417, Now I write a petitioner about Evergreen Herbal drink (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 "Evergreen Herbal Drink" labeling again.

Evergreen Herbal Drink  
Manufactured by Xiamen Gulong Group, Ltd., Fujing, China  
Distributed by Chinese Herb Center, Inc.

I included following data for Evergreen Herbal Drink 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

*Fu Sheng Jin*

# A petitioner to FDA about Evergreen Herbal Drink

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

### 1. Name of Dietary supplement

- Chemical name: not available
- Common name: Evergreen Herbal Drink 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
- Taste: some sweet

### 4. Physical and Chemical properties:

- pH: ND
- Melting point: ND
- Water content: 1.0%
- Solubility: soluble in water.
- Specifications:

Evergreen Herbal Drink extract is manufactured by Xiamen Gulong Group.,LTD., Xiamen,China. They sent the samples of Evergreen Herbal Drink(batch N0.280501) for analysis, and they received the data from the Department of Chinese Herb, the Institute of Drug and Biochemistry of China, Beijing, China. The average data measured per drink tea are listed below.

#### (1) Content:

##### (a) Average amount of impurities, toxins and pesticides in the sample of the Evergreen Herbal Drink.

Heavy metal	Lead (Pb)	3.6ug/g
	Arsenic (As)	0.37ug/g
	Cadmium (Cd)	<0.1ug/g
	Mercury (Hg)	0.005ug/g
Others	Nitrite	ND
	Nitrate	ND

##### (b) Other toxins

Aflatoxin : not to be found in the samples of Evergreen Herbal Drink extract powder.

Mycotoxin: ND

##### (c) Contaminated pesticides such as 666 and DDT is not to be found in the sample of the Evergreen Herbal Drink extract powder.

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

**(2) Components:**

The Evergreen Herbal Drink extract powder contains Radix Astragali Seu Hedysari, Radix Ophiopogonis, **Radix Trichosanthis, Radix Angelicae Sinensis, Radix ginseng, Flos Carthami, Radix Paeoniae Alba.**

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

1. Heavy metals in Evergreen Herbal Drink extract powder (plant) are measured by following methods:  
Cadmium, Lead, and Mercury are measured by atomic absorption spectrophotometric method.
2. Arsenic is measured by Silver salt methods.
3. Aflatoxin is measured by thin layer chromatographic method.
4. 666 and DDT is measured by chromatographic method.

All data have been certified by the Department of the Chinese Herb, the Institute of Drug and Biochemistry of China, Beijing, China.

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 Evergreen Herbal Drink

### 1. Amount of Evergreen Herbal Drink proposed use in the United States

Projected marketing figures for Evergreen Herbal Drink have not been determined at this time.

### 2. Intended usage

Evergreen Herbal Drink is intended for use as a facial pigment dietary supplement.

### 3. Calculation of expected intake and daily consumption of Evergreen Herbal Drink :

From information given by Xiamen Golong Group., LTD, the capsule is to be taken three times a day, 1 bag each time. Each bag weights 900 mg, and this projects a daily consumption of 2700mg and yearly consumption of 986.0 g for an adult.

### 4. Labeling

#### Recommended use

Take 1 bag each time 3 times a day,  
after meal with water.

#### INGREDIENTS:

Each bag contains 900 mg extract  
powder.

- 1.Radix Astragli Seu Hedysari,
- 2.Radix Ophiopogonis,
- 3.Radix Trichosanthis,
- 4.Radix Angelicae Sinensis,
- 5.Radix ginseng,
- 6.Flos Carthami,
- 7.Radix Paeoniae Alba.

Store at a cool & dry location

Batch No:

MFG date:

100% Natural Herbs

## Evergreen Herbal Drink (Xiamen)

16 bags (900 mg each)

Manufactured by Xiamen Golong Group LTD, Fujian, China  
Distributed by Chinese Herb Products, Inc.  
1010 Vermont Ave, NW Suite 712, Washington, DC 20005

it has been used for thousand years, it is modified and refined by modern technology. It is a special dietary supplement which has an unique effect on microcirculation. Any questions about facial pigmented spots, mask of pregnancy, senile pigmentation etc, please call your doctor or TCM doctors or (202)393-1203.

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

### 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 Evergreen Herbal Drink such as Radix Astragli Seu Hedysari, Radix Ophiopogonis, **Radix Trichosanthis, Radix Angelicae Sinensis, Radix ginseng, Flos Carthami, Radix Paeoniae Alba** to treat a lot of symptoms in human. Now Each component herb has been kept till today and its efficacy is further improved by modern scientific studies. (See chart #1 and reference). Evergreen Herbal Drink 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 Xiamen Evergreen Herbal Drink every day. Also Evergreen Herbal Drink 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 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 medicinal herbs, include the components of Evergreen Herbal Drink. 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 medicinal herbs and formulas, the safe dosage was found to be relatively high: for a person weighting 50 kilograms, LD 50 was approximately 250

grams; when take in normal dosage, most medicinal herbs have almost no toxicity(see reference 1,2). Because seven component of Evergreen Herbal Drink consists of very common herbs, it is very safety.

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

<b>Heavy metal</b>	<b>Lead (Pb)</b>	<b>3.60ug/g</b>
	<b>Arsenic (As)</b>	<b>0.37 ug/g</b>
	<b>Cadmium (Cd)</b>	<b>&lt;0.1ug/g</b>
	<b>Mercury (Hg)</b>	<b>0.005ug/g</b>
	<b>Nitrite</b>	<b>ND</b>
	<b>Nitrate</b>	<b>ND</b>
<b>Other toxins</b>	<b>Aflatoxin</b>	<b>not to be found</b>
	<b>Mycotoxin</b>	<b>ND</b>

No contaminated pesticides such as 666 and DDT is not to be found in the sample Evergreen Herbal Drink extract powder.

**3. Microbiological examination of hawthorn extract powder: ND**

**Reference:**

1. Dr. William Chang: " Reference guide of commonly used herbal formilas". 1989.
2. Dr. Jin,Fu Sheng: " Guideline for New Drug Application in The United States of America in Chinese". 1997.

**F. Proposed tolerances**

No tolerances are required to insure the safety of Evergreen Herbal Drink, because of its non-toxic nature.

**G. Environmental Assessment**

1. **Date:** August 3, 1998
2. **Name of Petitioner:** Chinese herb Center, Inc.
3. **Address of Petitioner:**  
1010 Vermont Ave, NW Suite 712  
Washington DC 20005  
Tel: (202)393-1203

**4. Introduction of Evergreen Herbal Drink into Environment**

The Evergreen Herbal Drink powder extract 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 drink will cause any environmental pollution when discarded by consumer. The drink is packaged in paper and recycle plastic, and there are no direct or indirect additives or irradiated herbs used in Evergreen Herbal Drink extract powder. The amount of Evergreen Herbal Drink extract consumed or discarded in any one area will generate no toxicity and will have no impact on the local waste treatment system.

The Evergreen Herbal Drink 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, and product number for this product is to be granted by the Chinese government..