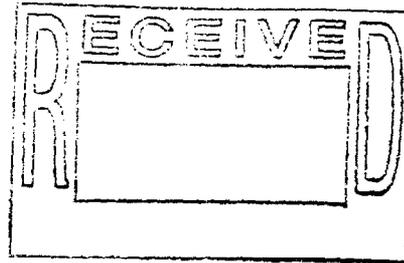


October 16, 2000
Mr. Fu Sheng Jin
Chinese Herb Center, Inc.
1010 Vermont NW Suite 712
Washington DC 20005
Tel: (202)393-1203
Fax: (301)838-0524.

2638 '00

NOV 16 9 22 37 AM '00



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 Nasalin capsule and Ovarin (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 "Nasalin capsules" and "Ovarin capsules" labeling again.

Nasalin Capsules
Ovarin Capsules
Manufactured by Euro American Pharmaceutical Factory, Ltd., Hong Kong, China
Unit 1716, 17/F., Miramar Tower, 1 Kimberley Road,
Tsim Sha Tsui, Kowloon, Hong Kong.

Distributed by Chinese Herb Center, Inc.

I included following data for Nasalin capsule and Ovarin capsule 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

975-0162

Get 6117

A petitioner to FDA about Ovarin capsule

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

1. Name of Dietary supplement
 - a. Chemical name: not available
 - b. Common name: Ovarin 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: not sour
4. Physical and Chemical properties:
 - a. pH: ND
 - b. Melting point: ND
 - c. Water content: 1.3%
 - d. Solubility: soluble in water.
 - e. Specifications:

Ovarin extract is manufactured by Euro America Factory, LTD. They sent the samples of Ovarin extract powder (the batch number 980908,) for analysis, and they received the data from the Strasburger & siegel, Inc., Analytical and Consulting Services 7249 National Drive Hanover, Maryland 21076. The following data measured per capsule are listed below.

(1) Content:

(a) Average amount of impurities, toxins and pesticides in one of capsule of the Ovarin extract powder

Heavy metal	Lead (Pb)	3.82ppm
	Arsenic (As)	ND
	Cadmium (Cd)	ND
	Mercury (Hg)	<12ppb
Others	Nitrite	ND
	Nitrate	ND

(b) Other toxins

Aflatoxin: contains less than 30 ppb in samples of Ovarin extract powder.

Mycotoxin: ND

(c) Contaminated pesticides: ND

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

(2) Components:

The Ovarin extract powder contains Radix Polyponi Multiflor 700mg, Bulbus Fritillariae 700mg, Flos Rosae Chinensis 600mg, Myrrha 400mg, Resina Olibani 400mg, Concha Margarifera Usta 200mg.

Method of measurement used in above tests:

1. Official Methods of Analysis (1995), 16th ED., AOAC International, Gaithersburg, MD
2. Laboratory Information Bulletin No. 3640 (toxin Elements), Determination of the low levels of lead in foods by Graphite Furnace Atomic Absorption, U.S. Food and Drug Administration, Washington, DC
3. Bacteriological Analytical Manual (1995), 8th ED., U.S. Food and Drug Administration, Washington, DC
4. Compendium of methods for the Microbiological Examination of Foods (1992), 3ed., APHA, Washington, DC

All data have been certified by the STRASBURGER & SIEGEL, INC. Job NO 811-13-198-06/08.
All nutritional indexes of method numbers have been referenced from "the methods of analysis for nutrition labeling," 1995 by AOAC INTERNATIONAL.

B. Intended use; projected average daily intake of Ovarin capsules:

1. Amount of Ovarin capsule proposed use in the United States
Projected marketing figures for Ovarin capsules have not been determined at this time.
2. Intended usage
Ovarin capsule is intended for use as a dietary supplement for ovaries circulation.
3. Calculation of expected intake and daily consumption of Ovarin extract powder:
From information given by Euro American Pharmaceutical Factory, the capsule is to be taken two times a day, 6 capsules each time. Each capsule weights 500 mg, and this projects a daily consumption of 3000mg and yearly consumption of 1080.0 g for an adult.
4. Labeling

Supplement Facts

Serving Size: 6 capsules

INGREDIENTS:

Each capsule contains 500 mg extract powder.

1. Radix Polygoni Multiflor 700mg
2. Bulbus Fritillariae 700mg
3. Flos Rosae Chinensis 600mg
4. Myrrha 400mg
5. Resina Olibani 400mg
6. Concha Margaritifera 200mg

Daily values not established

Other ingredients:

Rice powder, gelatin capsule

Keep out the children

Store at a cool & dry location

Batch No:

LAM KAM SANG
100% Natural Herbs
Dietary

Ovarin

180 Caps (500 mg each)

The statement has not been approved by the Food & Drug Administration. This product is not intended to diagnosis, treat, cure, or prevent any disease.

Manufactured by Euro America Pharmaceutical Factory LTD, Hong Kong, China

Introduction

it has been formulated by Dr. Lam Kam Sang, president of the Lam Kam Sang Medical Institute. It is a special dietary supplement circulation. It is modified and refined by modern technology. It is an unique process and guaranteed potencies. Any questions about dosage and questions, please consult your physician or TCM doctor or call 202-393-1203.

Recommended use:

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

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

Lot:

Expire date:

C. 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 Ovarin extract powder such as Radix Polyponi Multiflor, Bulbus Fritillariae, Flos Rosae Chinensis, Myrrha, Resina Olibani, Concha Margarifera Usta to treat a lot of symptoms in human. Now this treatment has been kept till today and its efficacy is further improved by modern scientific studies. (See chart #1 and reference). Ovarin extract is manufactured with a unique process that preserves and concentrates the richest extract of fresh herb. Already there are over millions people in the world taking Ovarin extract every day. Also Ovarin extract 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, 1991. 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 Ovarin capsule. 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 Aconiti 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). The recommended usage for Ovarin extract is 9 g per day; this dosage does not present any safety concerns. According to acute toxic test and long term test, they can not determine LD50 dosage in mice and Wistar big mice.

2. Acute toxicity test for Ovarin Extract Capsule

Animal species: Little white mice, Kun ming species of average weight 30g, is supplied by Department of animal, the institute of drug Research of Military Medical Academy, Beijing. The acute toxicity test has been done by the same unit.

(a) The acute toxicity experiment proved that one time ingestion of 33% of 3ml in Ovarin extract for 10 mice. Each mice received dosage 10g/Kg, after observe one week, they don't find any mice death, therefore they can not induce LD50 in mice. In the second part of experiment in Wister big mice, Wister species of average weight 190+/-10 g, half male, half female, total 20 wister big mice. one time ingestion of 10g/Kg of Ovarin extract They made with 33% Ovarin extract solution (the maximum possible concentration. The amount of ingestion is calculated from 33% of 10g/Kg body weight one times. For example, Wistar body weight is 190g, each Wistar mice received 1.9g Ovarin extract. After observing for 7 days, no toxicity reaction and deaths occurred at this maximum dosage level. Above test shows that maximum daily dosage of 10g/kg of body weight/day in mice can be sustained for an extended period. The dosages used in the toxicity studies are equivalent to 556 times of clinic dosage (0.36g/day) in human. Therefore they can not get LD50 in Wistar mice.

(b) in the second part of experiment in Wister big mice, Wister species of average weight 190+/- 10 g, half male, hafe female, total 20 Wister big mice. One time ingestion of 180g/Kg of the Ovarin extract, the made with 33% Ovarin in maximum possible concentration. The amount of ingestion is calculated from 33% of 540 g/Kg body weight three time a day. For example, Wister big mice body weight is 199 g, each mice received 34.2 g Ovarin extract. After observing for 24 hours, there are no toxicity reaction and deaths at this maximum dosage level. Above test shows that maximum daily dosage of 540g/Kg of the body weight/day in mice can be sustained for an extended period. The dosages used in the toxicity studies are equivalent to 2400 times of clinic dosage in human. Therefore they can not get the data of LD 50 in Wister mice.

3. Long term toxicity test for Ovarin extract capsule:

The third part of the experiment in Wister big mice, Wister species of average weight 190+/- 10g, half male and half female, total 20 Wister big mice. Each Wister big mice received 5.7 g

Ovarin extract (equal to 30g/Kg body weight). The amount of the Ovarin used in the toxicity studies are equivalent to 400 times of clinic dosage in human. After ingestion for four month, there are normal response in each mice growth, blood and index of the biochemistry; also there are no unusual change in the organ in the pathology.

4. Impurities, byproducts(limits):

Heavy metal	Lead (Pb)	3.82ppm
	Arsenic (As)	ND
	Cadmium (Cd)	ND
	Mercury (Hg)	<12ppb
	Nitrite	ND
	Nitrate	ND
Other toxins	Aflatoxin B1	<30ppb
	Mycotoxin	not to be found

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

5. Microbiological examination of Ovarin extract powder: <3 MPN E.Coli/g

Reference:

1. Dr. William Chang: " Reference guide of commonly used herbal formilas".1989.
2. Official Methods of Analysis(1995),16th Ed., AOAC International, Gaithersburg, MD
3. Bacteriological Analytical Manual (1995), 8th Ed., U.S. Food and Drug Administration, Washington,DC
4. Compendium of method for the Microbiological Examination of Foods (1992), 3rd Ed., APHA, Washington,DC
5. Laboratory Information Bulletin No. 3640 (toxic Elements), Determination of low levels of lead in foods by Graphite Furnace Atomic Absorption, U.S.Food and Drug Administration, Washington,DC