

Mr. Fu Sheng Jin
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1010 Vermont NW Suite 712
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7694 '00 DEC -1 17:19



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 Yin Xin Brand Ginkgo Biloba capsule and oral-liquid(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" Ginkgo Biloba capsules " labeling again.

Ginkgo Biloba Capsules
Ginkgo Biloba oral-liquid
Manufactured by Wuhan Juli Biology Engineering Co., Ltd, Wuhan, China
221 Zhongshan Ave,
Hankou, Wuhan, China

Distributed by Chinese Herb Center, Inc.

I included following data for Ginkgo Biloba capsule and oral-liquid 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

Received
10/25/00
12:02 P

975-0162

LET 6170

A petitioner to FDA about Yin Xin brand Ginkgo Biloba capsule

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

1. Name of Dietary supplement
 - a. Chemical name: not available
 - b. Common name: Ginkgo Biloba leaf 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: light brown yellow powder
 - c. Taste: not sour
4. Physical and Chemical properties:
 - a. pH: 3.5-5.5
 - b. Melting point: ND
 - c. Water content: <2.0 %
 - d. Solubility: soluble in water.
 - e. Specifications:

Ginkgo Biloba extract is manufactured by Wuhan Juli Biology Engineering Co., LTD. They sent the samples of Ginkgo Biloba extract powder (the batch number Neozge-24-423,) 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 Ginkgo biloba leaf extract powder

Heavy metal	Lead (Pb)	66.7 ppb
	Arsenic (As)	ND
	Cadmium (Cd)	ND
	Mercury (Hg)	<20 ppb
Others	Nitrite	ND
	Nitrate	ND

(b) Other toxins

Aflatoxins (B1, B2, G1, G2): contains less than 12 ppb in samples of Ginkgo Biloba leaf 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 Ginkgo Biloba leaf extract powder contains 24.3% ginkoheterosides, 6.1% terpene lactones (ginkgolide A,B,C, and bilobalides).

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 004-20-262-01/02
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 Ginkgo Biloba capsules:

1. Amount of Ginkgo Biloba capsule proposed use in the United States

Projected marketing figures for Ginkgo Biloba capsules have not been determined at this time.

2. Intended usage

Ginkgo Biloba capsule is intended for use as a dietary supplement for ovaries circulation.

3. Calculation of expected intake and daily consumption of Ginkgo Biloba extract powder:

From information given by Wuhan Juli Biology Engineering Co., Ltd, the capsule is to be taken two times a day, one capsules each time. Each capsule weights 120mg of extract Ginkgo Biloba leaf powder, and this projects a daily consumption of 240mg and yearly consumption of 87.6 g for an adult.

4. Labeling

Supplement Facts		Introduction
Serving Size: 1 capsules	Yin Xin 100% Natural Herbs Dietary	it has been formulated by Wuhan Juli BiologyEngineering Co., Ltd, China. It is a special dietary supplement for Brain 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.
INGREDIENTS:	Ginkgo Biloba	
Each capsule contains 120 mg Ginkgo Biloba extract powder .	100 Caps (120 mg each)	
Daily values not established		Recommended use:
Other ingredients:		Orally, take 1 capsules each time 2 times a day, after meal with water.
Rice powder, gelatin capsule		
Keep out the children	The statement has not been approved by the Food & Drug Administration.	Distributed by Chinese Herb Products, Inc. 1010 Vermont Ave, NW Suite 712. Washington, DC 20005
Store at a cool & dry location	This product is not intended to diagnosis, treat, cure, or prevent any disease.	Lot:
Batch No:		Expire date:
	Manufactured by Wuhan Juli Biology Engineering Co., Ltd. China	

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 Ginkgo Biloba leaf extract powder 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). Ginkgo Biloba 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 Ginkgo Biloba extract every day. Also Ginkgo Biloba 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, 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 Ginkgo Biloba 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 Ginkgo Biloba extract is 240mg 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 Ginkgo Biloba Extract Capsule

Animal species: Little white mice, Kun ming species of average weight 30g, is supplied by Department of animal, the institute of Quarantine station in Hu Bei Province. The acute toxicity test has been done by the same unit.

(a) The acute toxicity experiment proved that one time ingestion of 40ml/KG.BW(equal to 200g)/kg Body Weight in Ginkgo Biloba leaf extract for 10 mice. Each mice received dosage 200g/Kg, after observe one week, they don't find any mice death, therefore they can not measure LD50 in mice. Three kind of test are negative in the Ames test, mouse sperm deformity test, RBC micro-nuclear in mice bone marrow test.

(b) In the second part of experiment in Wistar big mice, Wistar species of average weight 70+/-10 g, half male, half female, total 80 wistar big mice. They continue to feed each mice for 30 days, 80 Wistar big mice are divided into three group and another control group each group contains 20 mice, each mice received 50% of 6.6 ml, 16.5ml, 33ml Ginkgo Biloba. After observing for 30 days, There are no death, hair growth and behavior change in the three groups; there is no significant difference comparison by control group ($p > 0.05$), also they do the blood test including Hb, RBC, WBC count+DC platelet, reticular cell, all the blood test are in the normal range, There is no significant difference comparison by control group mice ($P > 0.05$). They also do the blood index test, including ALT, AST, BUN, total cholesterol, Cre, Glucose, Albumin/globulin ratio, all test results are in the normal range, there is no significant difference comparison to control group mice ($P > 0.05$). There are no pathological change in the heart, liver lung spleen, kidney, brain. all organ weight are in the normal range, there is no significant difference comparison to control group mice ($P > 0.05$)

The dosages in the three group used in the toxicity studies are equivalent to 50, 125, 250 times of clinic dosage (240mg/day) in human. Therefore they can not get LD50 in Wistar mice.

3. Impurities, byproducts(limits):

Heavy metal	Lead (Pb)	66.7 ppb
	Arsenic (As)	ND
	Cadmium (Cd)	ND
	Mercury (Hg)	<20 ppb
	Nitrite	ND
	Nitrate	ND
Other toxins	Aflatoxin B1,B2,G1,G2	<12 ppb
	Mycotoxin	not to be found

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

4. Microbiological examination of Ginkgo Boloba 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
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E. Proposed tolerances

No tolerances are required to insure the safety of Ginkgo Biloba capsule, because of its non-toxic nature.

F. Environmental Assessment

1. Date: October 20, 2000

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 Ginkgo Biloba extract into Environment

The Ginkgo Biloba powder extract capsule 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 Ginkgo Biloba extract powder. The amount of Ginkgo Biloba extract consumed or discarded in any one area will generate no toxicity and will have no impact on the local waste treatment system.

The Ginkgo Biloba extract powder capsule is manufactured in China. The manufacturer 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..

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Each capsule contains 120 mg Ginkgo Biloba extract powder .	100 Caps (120 mg each)	
Daily values not established Other ingredients: Rice powder, gelatin capsule		Recommended use: Orally, take 1 capsules each time 2 times a day, after meal with water.
Keep out the children Store at a cool & dry location Batch No:	The statement has not been approved by the Food & Drug Administration. This product is not intended to diagnosis, treat, cure, or prevent any disease.	Distributed by Chinese Herb Products, Inc. 1010 Vermont Ave, NW Suite 712, Washington, DC 20005
	Manufactured by Wuhan Juli Biology Engineering Co., Ltd. China	Lot: Expire date: