



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

*Rec'd
11/6/2000*

Mr. Fu Sheng Jin
Manager
Chinese Herb Center, Inc.
1010 Vermont Avenue, N.W.
Suite 712
Washington, DC 20005

NOV 8 2000

Dear Mr. Jin:

This is in response to your letter of October 16, 2000 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 claims, among others, for the product **Nasalin**:

- “Natural Support For nose Helper”
- “...improve nose condition”
- “Any questions about chronic allergic rhinitis, please call your doctors or TCM”

Your notification also states that the intended use of the product is “for use as a chronic allergic rhinitis dietary supplement.”

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, cure or mitigate diseases, namely allergic rhinitis. These claims 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.

975-0163

LET 420

Page 2 - Mr. Fu Sheng Jin

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
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, Office of Compliance, HFR-MA240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810

HFS-811 (file)

HFD-310

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Nickerson)

f/t:HFS-811:rjm:10/390/00:docname:73065.adv:disc52

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.

73065



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

A petitioner to FDA about Nasalin

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

1. Name of Dietary supplement

- Chemical name: not available
- Common name: Nasalin 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: not sour

4. Physical and Chemical properties:

- pH: ND
- Melting point: ND
- Water content: 1.3%
- Solubility: soluble in water.
- Specifications:

Nasalin extract is manufactured by Euro America Factory, LTD. They sent the samples of Nasalin extract tablet (the batch number 981002,) 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 sample of the Nasalin extract powder

Heavy metal	Lead (Pb)	3.01 ppm
	Arsenic (As)	ND
	Cadmium (Cd)	ND
	Mercury (Hg)	<12 ppb
Others	Nitrite	ND
	Nitrate	ND

(b) Other toxins

Aflatoxin contains less than 30 ppb in the samples of Nasin powder.

Mycotoxin: ND

(c) Contaminated pesticides: ND

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

(2) Components:

The Nasalin extract powder contains Radix Astragali Seu Hedysari, Flos Chryanthemi Indici, Flos Magnoliae Flos campsis, Herb patriniae.

Method of measurement used in above tests:

1. Official Methods of Analysis(1995), 16th Ed., AOAC International, Gaithersburg, MD
2. Bacteriological Analytical Manual (1995), 8th Ed., U.S. Food and Drug Administration, Washington, DC
3. Compendium of Methods for the Microbiological Examination of Foods(1992), 3ed., APHA, Washington, DC

All data have been certified by Strasburg & Siegel, Inc; Job NO.:811-13-198-08/08

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 Nasalin capsules

1. Amount of Nasalin capsules proposed use in the United States

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

2. Intended usage

Nasalin capsule is intended for use as a chronic allergic rhinitis dietary supplement.

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

From information given by Euro America Pharmaceutical Factory., LTD, 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 6.0g and yearly consumption of 2190.0 g for an adult.

4. Labeling

Supplement Facts

Serving Size: 6 capsules

- 1. Radix Astragali Seu Hedysari,
- 2. Flos Chryanthemi Indici,
- 3. Flos Magnoliae
- 4. Flos campsis,
- 5. Herb patriniae.

Above herb daily values not established

OTHER INGREDIENTS: rice powder.

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

**Nasalin
(LAM KAM SANG)**

Hong Kong

100 Caps (500 mg each)

Natural Support For nose Helper*

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnosis, treat, cure, or prevent any disease.

Manufactured by Euro America
Pharmaceutical Factory, Ltd.

Recommended use:

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

Keep out of children.

Store at a cool & dry location

Do not use If seal is broken.

Batch No:

It has been formulated by ancient Chinese medicine, and modified and refined by modern technology. It is to be used for chronic nose problem of dietary supplement which is used for improve nose condition. I unique process and guaranteed potencies. Any questions about chronic allergic rhinit please call your doctors or TCM doctor or 202-393-1203

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

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 Nasalin extract powder such as Radix Astragali Seu Hedysari, Flos Chryanthemi Indici, Flos Magnoliae Flos campsis, Herb patriniae to treat a lot of symptoms in human disorder. Now this treatment has been kept till today and its efficacy is further improved by modern scientific studies. (See chart #1 and reference). Nasalin extract 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 components of the Nasalin extract every day. Also Nasalin 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. Each components of the Nasalin 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 Nasalin 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 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). Because 5 components of Nasalin is the mixture of the very common herb. It is very safety. Based on the following acute toxic and long term test database. According to acute toxic test, they can not determine LD50 dosage in mice and Wistar big mice.

2. Acute toxicity test for Nasalin Extract Capsule

(a) The acute toxicity experiment prove that one time ingestion of 33% of the Nasalin extract for 10 mice. each mice received dosage 60g/Kg/a day for 7 days. After 7 days, they don't find any mice death and any an unusual changes in the urine, body weight, blood, liver and kidney function. Therefore they can not induce LD50 in mice. The dosages used in the toxicity studies are equivalent to 650 times of clinic dosage in human. Therefore they can not get LD50 in mice.

(b) 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 180g/Kg of Nasalin extract They made with 33% Nasalin (the maximum possible concentration. The amount of ingestion is calculated from 33% of 540g/Kg body weight three times a day. For example, Wistar body weight is 190g, each Wistar mice received 34.2g Nasalin extract. After observing for 24 hours, there are no toxicity reaction and deaths occurred at this maximum dosage level. Above test shows that maximum daily dosage of 540g/kg of body weight/day in mice can be sustained for an extended period. The dosages used in the toxicity studies are equivalent to 1950 times of clinic dosage in human. Therefore they can not get LD50 in Wistar mice.

3. Long term toxicity test for Nasalin Extract Capsule:

The third part of experiment in Wister big mice, Wister species of average weight 190+/- g, half male and half female, total 20 Wister big mice. Each Wister big mice received 5.7 g Nasalin extract(equal to 30g/Kg body weight). The amount of the Nasalin used in the toxicity studies are equivalent to 325 times of clinic dosage in human. After ingestion for four months There are normal response in animal 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)	3.01 ppm
	Arsenic (As)	ND
	Cadmium (Cd)	ND
	Mercury (Hg)	<12 ppb
	Nitrite	ND
	Nitrate	ND
Other toxius	Aflatoxin B1	<30 ppb
	Mycotoxin	ND

No contaminated pesticides: ND.

5. Microbiological examination of Nasalin powder: Ecoli < 3

Reference:

1. Dr. William Chang: " Reference guide of commonly used herbal formilas".1989.

F. Proposed tolerances

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

G. Environmental Assessment

1. **Date:** October 04, 1999
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 Nsalin extract into Environment

The Nasalin powder extract capsule is manufactured in Hong Kong to import 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 Nasalin extract powder. The amount of Nasalin extract consumed or discarded in any one area will generate no toxicity and will have no impact on the local waste treatment system.

The Nasalin extract powder capsule is manufactured in Hong Kong. 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 Hong Kong's laws covering environmental safety, and product number for this product is to be granted by the Hong Kong government..