



Memorandum

DEC - 3 2003

Date:
From: Division of Dietary Supplement Products, Office of Nutritional Products,
Labeling and Dietary Supplements, HFS-810
Subject: 75-Day Pre-market Notification of New Dietary Ingredients
To: Dockets Management Branch, HFA-305

Subject of the Notification: (Sanqi) *Panax notoginseng*
Firm: Cyber Store LLC

Date Received by FDA: February 26, 2003

90-Day Date: May 27, 2003

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day pre-market notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Attachments

95S-0316

RPT180



MAY 12 2003

Mr. Yao Huang, MBA
General Manager
Cyber Store LLC
77 Magnolia Ave. Apt 32
Jersey City, New Jersey 07306

Dear Mr. Huang:

This is to inform you that the notification, dated January 11, 2003, you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on February 26, 2003. Your notification identified the substance Panax notoginseng (sanqui) as the substance that you intend to market as a new dietary ingredient.

Federal regulations found at 21 CFR 190.6 specify the requirements for a pre-market notification on a new dietary ingredient. The notification you sent us concerning Panax notoginseng (sanqui) does not comply with the requirements of 21 CFR 190.6 and is incomplete. Your Notification failed to include English translations of submitted information, and provides no history of use or other evidence of safety which would provide a basis for reasonable assurance of safety. The notification states that there is a historical use of Panax notoginseng (sanqui) for hundreds of years in China but there was no supporting documentation. It is also unclear how the information submitted relates qualitatively and quantitatively to the proposed dietary supplement.

FDA is unable to determine whether the scientific studies you cite provide an adequate basis for a conclusion that the dietary supplement will reasonably be expected to be safe because the information you have provided is incomplete. If you market your product without submitting an amended notification that meets the requirements of 21 CFR 190.6, or market your product less than 75 days after submitting such a notification, your product is considered adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

You also indicate in your submission that your product is useful for a wide range of serious medical conditions. Under 21 U.S.C. 321(g)(1)(B), a drug is defined as an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. The information in your submission suggests that your product is intended to be used to treat medical conditions and is subject to regulation as a drug under

21 U.S.C. 321(g)(1)(B) and is not a dietary supplement. See 21 CFR 101.93(g). If you wish Panax to be evaluated for its use in the treatment of these medical conditions, you should contact FDA's Center for Drug Evaluation and Research (CDER).

Your notification will be kept confidential for 90 days after the filing date of February 26, 2003. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

Should you have any questions concerning this matter, please contact Victoria Lutwak at (301) 436-2375.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan J. Walker" with a stylized flourish at the end.

FOR
Susan J. Walker, M.D.
Acting Division Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

January 11, 2003
Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD, 20740-3835

Re: Marketing dietary ingredients under
Supplement Health and Education Act.

Cyberstore LLC is requesting marketing clearance for its Sanqi(a Chinese edible herb) Instant and Capsules. The pre-market notification information required by FDA's Office of Special Nutritional is as follows:

- a. Classification name: Notoginseng(Sanqi) Instant and Capsules
Latin binomial name: panax notoginseng(Burk) F.H.Chen
Common/Usual Name: Sanqi instant and Capsules
- b. Classification: Dietary supplements and their ingredients are governed and regulated under the Dietary Supplement Health and Education Act. Pursuant to Section 8 of the Act such dietary supplements must reasonably be expected to be safe. In consideration of the provisions of this new legislation, Cyberstore LLC. desires to import Notoginseng(sanqi) Instant and Capsules for use as a dietary ingredient in dietary supplements and as a standardized dietary supplement product. The product has passed the acute toxicity test in China and proved to be safe. The product also get the permission to be sold in Japan, Indonesia, Philippine. It all proved that it is reasonably be expected to be safe.
- c. Label/Lebeling/Advertisements: Draft copies of the package labeling and promotional material, acute toxicity test report for Notoginseng instant and Capsules are enclosed as Exihit 2.

We would appreciate your earliest attention to this submission. The Notoginseng(sanqi) Instant and Capsules will not be marketed in U.S market until we receive FDA clearance of our submission or upon the expiration of 75 days from this submission.

Sincerely yours,

Enclusures



Yao(Eric)Huang, MBA

General Manager

Cyberstore LLC

77 mangnolia Ave. apt 32 , Jersey City, NJ 07306, USA(201)656-0846

Exhibit 2

Sanqi (*panax notoginseng*) is the most precious natural herb in China. It has been used for hundreds of years to improve the overall health of human body by adjusting the internal balance.

Recent studies have shown that sanqi significantly provides its healing theorized as an adaptogenic process. Proximately, 30 ginsengosides have been identified as the active ingredient of sanqi. Ginsengosides act as cooling agents, which has tendency to lower the blood pressure, counteract inflammation, lower cholesterol and fat, activates blood circulation and restores energy levels. Continuous consumption will strengthen your immunity.

Notoginseng Instant and Capsules are made from the plant called Notoginseng also known as Sanqi, science formulas can keep its almost effective contents. The product made by Yunnan Xin Yun Sanqi Industrial Co.Ltd which is a new joint-venture invested by Hong Kong New World Group.

Cyberstore LLC is the only authorized supplier appointed by Xin Yun Sanqi Industrial Co.Ltd as its exclusive distributor and sole agent in U.S.A and Canada for the sale, distribution and marketing this product.

新云牌三七速溶粉产品说明书

本品是以三七、菊花和乳糖为主要原料制成的保健食品，经功能试验证明，具有耐缺氧和对化学性肝损伤有辅助保护作用的保健功能。

【主要原料】乳糖、三七、菊花。

【功效成份及含量】每 100g 含总皂甙（以三七皂甙 Re 计）0.74g。

【保健功能】耐缺氧，对化学性肝损伤有辅助保护作用。

【适宜人群】处于缺氧环境者，有化学性肝损伤危险者。

【不适宜人群】孕妇，婴幼儿，感冒发热者，乳糖不耐受者。

【食用方法及食用量】开水冲饮，每次一袋，每日三次。

【规格】5 克/袋。

【保质期】24 个月

【贮藏方法】密封，置阴凉干燥处保存。

【执行标准】Q/YXY02-2002.

【注意事项】本品不能代替药物，无补氧作用。

【生产商】云南新云三七产业有限公司

【地址】昆明市三市街 32 号 7 楼。邮编：650032

The product is made from sanqi (notoginseng)、chrysanthemum and lactose. By pharmacological experiments, show that it has great effects on be able to bare lacking oxygen, protecting liver harmed by chemical

Ingredients: lactose、Sanqi (notoginseng)、Chrysanthemum

Composition & content: Ginsengnoside(Re) 0.74g/100g

Health effects: Be able to bare lacking oxygen, help to protect liver harmed by chemical

People to be benefit: People in the condition of lacking oxygen. People whose liver harmed by chemical.

Abstain from: Pregnant, baby, people got cold and in fever.or allergy with lactose.

Usage: Dissolve in hot water, one bag each time, 3 times daily

Specification: 5g /bag

Quality guarantee period: 24 months.

Storage: sealed in dry and shadow place.

Executive standard: Q/YXY02-2002.

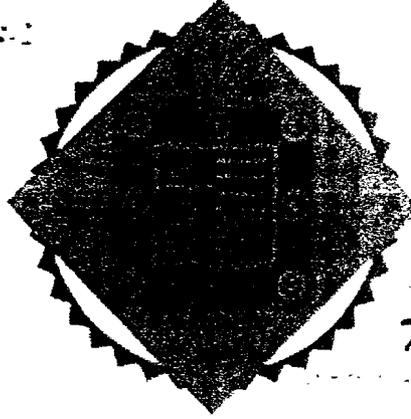
Note: Do not take it as medicine, not enrich the oxygen.

Producer: Yunnan Xin Yun Sanqi Industrial Co.,Ltd

Add: 32, sanshi street, Kunming, China.

THE UNIVERSITY OF CHICAGO
LIBRARY
1100 EAST 58TH STREET
CHICAGO, ILL. 60637
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检 验 报 告

(云动健)检字第 0006 号

(2000)量认(滇)字(Z0610)号

验报告书编号: 0006

样品名称: 新云三七速溶粉

样品编号: 健 2006

批号或生产日期: 2001/03/09

数量: 7.0 kg

样品性状: 袋装速溶粉

送检单位: 云南新云三七产业有限公司

送检日期: 2001.4.2.

生产单位: 云南新云三七产业有限公司

收样日期: 2001.4.2

送检人: 李彬

检验项目: 1 添加新云三七速溶粉大鼠、小鼠急性毒性试验

2 小鼠骨髓细胞微核试验和小鼠精子畸形试验

3 致畸试验

4 大鼠 30 天喂养试验

5 鼠伤寒沙门氏菌/哺乳动物微粒体酶试验

检验技术依据: 按中华人民共和国国家标准 GB 15193.3-94、4-94、5-94、7-94、14-94 和 13-94 进行

主要检验设备: 大型生物显微镜, 生化设备等

检验环境条件: 室温:16°C-20°C 相对湿度:25%-55%

结论: 1 云南新云三七产业有限公司送检的新云三七速溶粉, 经小鼠和大鼠灌胃, 剂量达到 15g/kg 体重, 未引起动物死亡。根据急性毒性试验毒性剂量分级标准为无毒级, 新云三七速溶粉安全无毒。2 新云三七速溶粉经小鼠骨髓微核试验和小鼠精子畸形试验, 试验组与对照组无明显差异, 新云三七速溶粉无潜在的致突变和精子致畸效应。3 新云三七速溶粉大鼠致畸试验, 溶剂对照组与各个试验组相比无显著性差异。胎鼠体重和身长各试验组与对照组相比亦无显著性差异, 骨骼透明标本和内脏标本观察, 对照组和试验组未见异常, 表明新云三七速溶粉不引起大鼠致畸胎作用。4 新云三七速溶粉加入饲料喂饲 Wistar 大白鼠 30 天, 对试验动物一般生理状态, 行为未发现异常现象, 亦未出现有中毒症状及死亡, 各项血液学指标正常, 各项生物化学指标正常, 肝脏及肾脏系数值正常。病理组织学观察亦未见对肝、肾、胃、十二指肠、结肠和直肠组织有明显损伤的变化。5 新云三七速溶粉在剂量为 156.25-10000 μ g/皿 之间, 无论加与不加 S₉, TA₉₇, TA₉₈, TA₁₀₀, TA₁₀₂ 各菌株的诱发回变菌落数未出现阳性结果, 新云三七速溶粉在本实验条件下无致突变作用。

校核及技术负责:

刘爱华

审核:

贺维顺

主检: 王蕊芳

参加人员:

刘爱华 贺维顺 王蕊芳 林世英 候意谛

报告日期: 2001 年 6 月 11 日

最终审校日期: 2001 年 6 月 18 日

The report of examination

The serial number of report:0006

Sample name: notoginseng herbal tea Serial number of sample: health 2006

Production date: 2001/3/9 Quantities: 7.0kg

The unit of sample issued: Yunnan Xin Yun Sanqi industrial Co, Ltd .

Manufacturer: Yunnan Xin Yun Sanqi industrial Co, Ltd .

Date of sample issued:2001/4/2

Delivered by: Libin

Date of accept sample:2001/4/2

Exam Items:

1. The acute toxicity test on rat and mouse by raising them "Xin Yun notoginseng instant "
2. The test of bone marrow cell micro-nuclear and sperm's deformity on mouse.
3. Lopsided-caused
4. Big mice fed with Xin Yun notoginseng instant
5. Mouse typhus Salmonella and mammal particle body enzyme test

Technological standard : GB 15193.3-94. 4-94. 5-94. 7-94. 14-94.13-94 from The people's Republic of China.

The main test equipment: large-scale biomicroscope, the biochemical equipment .etc

The environmental condition for the test. room temperature 16°C -- 20°C , relative umidity:25%--55%.

Conclusion:

1 It has not caused animal's death. by giving rat and mouse enema with the dosage up to 15g/kg of Xin Yun notoginseng instant issued by Yunnan Xin Yun Sanqi industrial Co.Ltd .So it has been testified that Xin Yun notoginseng is safe and nonpoisonous according to the standard of acute toxicity and toxicity dosage.

2 As a result of no obvious difference between "test group" and "contrasted group". after the test of bone marrow mirco-nuclear and mouse's sperm's deformity It indicates that Xin Yun notoginseng instant has no potential effect on causing sudden change and sperm lopsided.

3.From the test of causing lopsided by feeding mouse with Xin Yun notoginseng instant, no obvious difference have found between "solvent contrast group "and "the test group". The weight and height of Fetus are not unusual compared "test group" and "contrast group". And there are no remarkable disparity found from observing skeleton transparent and viscera sample.

4.We add Xin Yun notoginseng instant into fodder, feeding wistar mouse for 30 days. When the amount of instant powder reach up to 3 times, 50times, and 100times respectively as the intaked amount of human beings daily, the animal's general physiological state is normal ,and the behavior of animals has not found unusual. Neither poison nor death appear. Both blood index and biochemistry index is normal basically as well as the coefficient value of liver and kidney On the view of pathology

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histology, there are no obvious damaged-change in liver, kidney, stomach. twelve mean intestines, colon rectum organization. Taking the dosage of 156 25-10000 u g/ware of Xin Yun notoginseng instant, no positive displays on fungus No matter we add S9,TA97,TA98,TA100,TA102 or not. Under this experiment, Xin Yun notoginseng instant has no function to cause sudden change.

Checking and technology: Liuaihua Verify:Heweishun Mainly
examine.wangruifang

Date of report: June 11,2001. Final revise date: June 18,2001.

SANITARY SUPERVISOR OFFICIAL DISPATCH
OF THE PEOPLE'S REPUBLIC OF CHINA

D.W.S.J.Z.No. (2002) 024

Company Name: Yunnan Xin Yun Sanqi Industrial Co., Ltd

Company Category: Joint-venture.

Legal Representative: Ji Wenfeng

Address Registration: 32, Sanshi street, Kunming, China.

Tel: (0871) 3625337

Supervise opinions:

This is to certify that "Xin Yun Notginseng Instant" produced by Yunnan Xin Yun Sanqi Industrial Co., Ltd, Complies with the requirements of Chinese Good Manufacturing Practices for health food, after censor to the produce process, produce place and products formulates. Three batch of sample are inspected by the Yunnan Sanitary Inspection Centre, are accord with the demands of General standard for food.

Yunnan Provincial Bureau of Health
Branch of Sanitary Supervise



Two original: one for file of supervisor, one to supervisee

SANITARY SUPERVISE OFFICIAL DISPATCH
OF THE PEOPLE'S REPUBLIC OF CHINA

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证 明 书

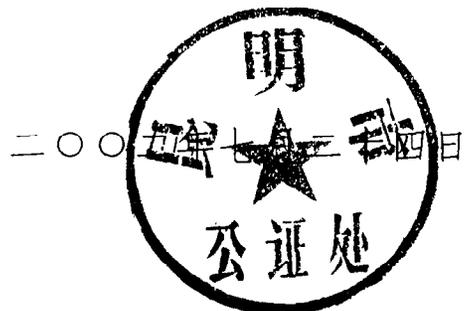
(2002)昆证外字第 7612 号

兹证明前面的复印件与云南省卫生厅卫生监督所于二〇〇二年七月十八日出具的 D.W.S.J.No.(2002)024 号英文本的《SANITARY SUPERVISE OFFICIAL DISPATCH OF THE PEOPLE'S REPUBLIC OF CHINA》的原件相符。原件上的“云南省卫生厅卫生监督所”的印鉴属实。

中华人民共和国云南省昆明市公证处

公证员

罗幼玲



XX04758565

CERTIFICATE
(TRANSLATION)

(2002) K. Z. W. Zi No 7612

This is to certify that the duplicated copy attached hereto is in conformity with the original *SANITARY SUPERVISE OFFICIAL DISPATCH OF THE PEOPLE'S REPUBLIC OF CHINA* in English, D. W. S. J. Z No. (2002) 024, issued on July 18, 2002 by Yunnan Provincial Bureau of Health Branch of Sanitary Supervise. The seal of "Yunnan Provincial Bureau of Health Branch of Sanitary Supervise" affixed on the original is authentic.

Notary: Luo Youling
Kunming Notary Public Office
Yunnan Province
The People's Republic of China
July 24, 2002

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