

Memorandum

*Rec'd 3/10/06
JB*

Date: FEB 16 2006

From: Consumer Safety Officer, Division of Dietary Supplement Programs, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: CaPv-F2

Firm: Zephantech, LLC

Date Received by FDA: November 23, 2006

90-Day Date: February 21, 2006

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket 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.

Victoria Lutwak

19955-0316

RPT318



5100 Paint Branch Parkway
Food and Drug Administration
College Park, Maryland 20740

Paul ZP. Wang, M.D., Ph.D.
Senior Scientist
Zephantech, LLC.
3610 St. Johns Lane
Ellicott City, Maryland 21042
Dear Dr. Wang:

FEB - 6 2006

This is to inform you that the notification, dated November 18, 2005, 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 November 23, 2005. The notification concerns the substance called "CaPv-F2" which you assert is a new dietary ingredient.

According to your notification, "CaPv-F2" will be in a tablet containing 50 mg of Lingzhi Polysaccharides, *Ganoderma lucidum* (Fr.) Karst," 100 mg Yunzhi Polylysaccharides, *Coriolus versicolor*, and 100 mg selenium per capsule. The conditions of use that will be suggested or recommended on the label state are the following: "...[F]or adults, [t]ake one capsule with breakfast meal and one capsule with dinner meal... Store, out of reach of children...."

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21 U.S.C. 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

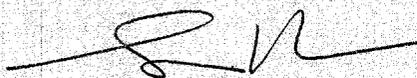
Your notification concerning "CaPv-F2" does not comply with the requirements of 21 CFR 190.6 and is incomplete. For example, your notification does not contain history of use or other evidence of

safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe, including any citation to published articles or other evidence that is the basis on which you have concluded that the new dietary supplement will reasonably be expected to be safe. If you market your product without submitting a notification that meets the requirements of 21 CFR 190.6 (<http://www.cfsan.fda.gov/~lrd/cfr190-6.html>), 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).

Your notification will be kept confidential for 90 days after the filing date of November 23, 2005. 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.

If you have any questions concerning this matter please contact Linda Pellicore, Ph.D., at (301) 436-2375.

Sincerely yours,



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

11-18-2005

Linda S. Pellicore, Ph.D.
Senior Supervisory Toxicologist
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway, HFS-810
College Park, Maryland 20740

301-436-1448 (office)
301-436-2636 (fax)

Re: Premarket Notification for Dietary Supplements

DB/FDA

Dear Dr. Pellicore,

Based on FDA regulation of premarket notification of dietary supplements which contains new ingredients and on behalf of Zephantech, LLC. ("Zephantech") marketing of dietary supplements, notice is hereby given pursuant to the requirements of Section 413 (a)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 350B) of the intent of Zephantech to market **new dietary ingredients**. They are:

- | | |
|--|-------------------------------|
| 1. <i>Ganoderma lucidum</i> (Fr.) Karst | 24.2% Lingzhi Polysaccharides |
| 2. <i>Coriolus versicolor</i> | 40.0% Yunzhi Polysaccharides |
| 3. Green Tea ---- <i>Camellia sinensis</i> (L.) Kuntze | 40.0% EGCg |
| 4. Velvet Antler Powder ---- <i>Cervus elaphus</i> L. | 64.1% protein; 1.3% Fat |
| 5. Chinese Red Ginseng Powder
---- <i>Panax ginseng</i> C. A. Meyer | 2.7% Ginsenosides |

The dietary product (Supplement) formed using the ingredients above-mentioned is:

CaPv-F2:	Servicing Size:	1 capsule
	Servicing per container:	60
	Amount per serving:	%DV
	Lingzhi Polysaccharides	50mg
	Yunzhi Polysaccharides	100mg
	Selenium	100mcg

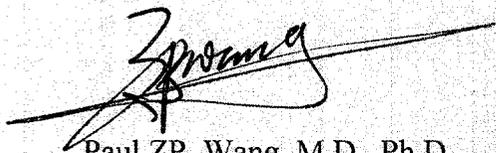
Microorganisms and pesticide were not detected in all products or individual ingredient. Contents of heavy metals in the products are under the safe ranges required by FDA and pharmaceutical manufacture standards.

The possible benefits of all above dietary supplements to humans are based on the prior research and applications in animals and humans. The related literature references have been prepared in this package for you to review.

2005-7974
AIMS

According to a long history of extensively applications of all ingredients in our product in humans, we have concluded that our dietary product will reasonably be expected to be safe under the recommended Directions For Use. Please direct all correspondence to me and fell free to contact me by email at zp16988@yahoo.com if you have any question regarding this notification.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'ZP Wang', with a long horizontal line extending to the right.

Paul ZP. Wang, M.D., Ph.D.
Senior Scientist
Zephantech, LLC.
3610 St. Johns Lane
Ellicott city, Maryland 21042
Email: zp16988@yahoo.com

Premarket Notification for Dietary Supplement

CaPv-F2

Notification Date:

10-25-2005

Distributor:

Zephantech, LLC.
3610 St. Johns Lane
Ellicott City, MD 21202, USA.

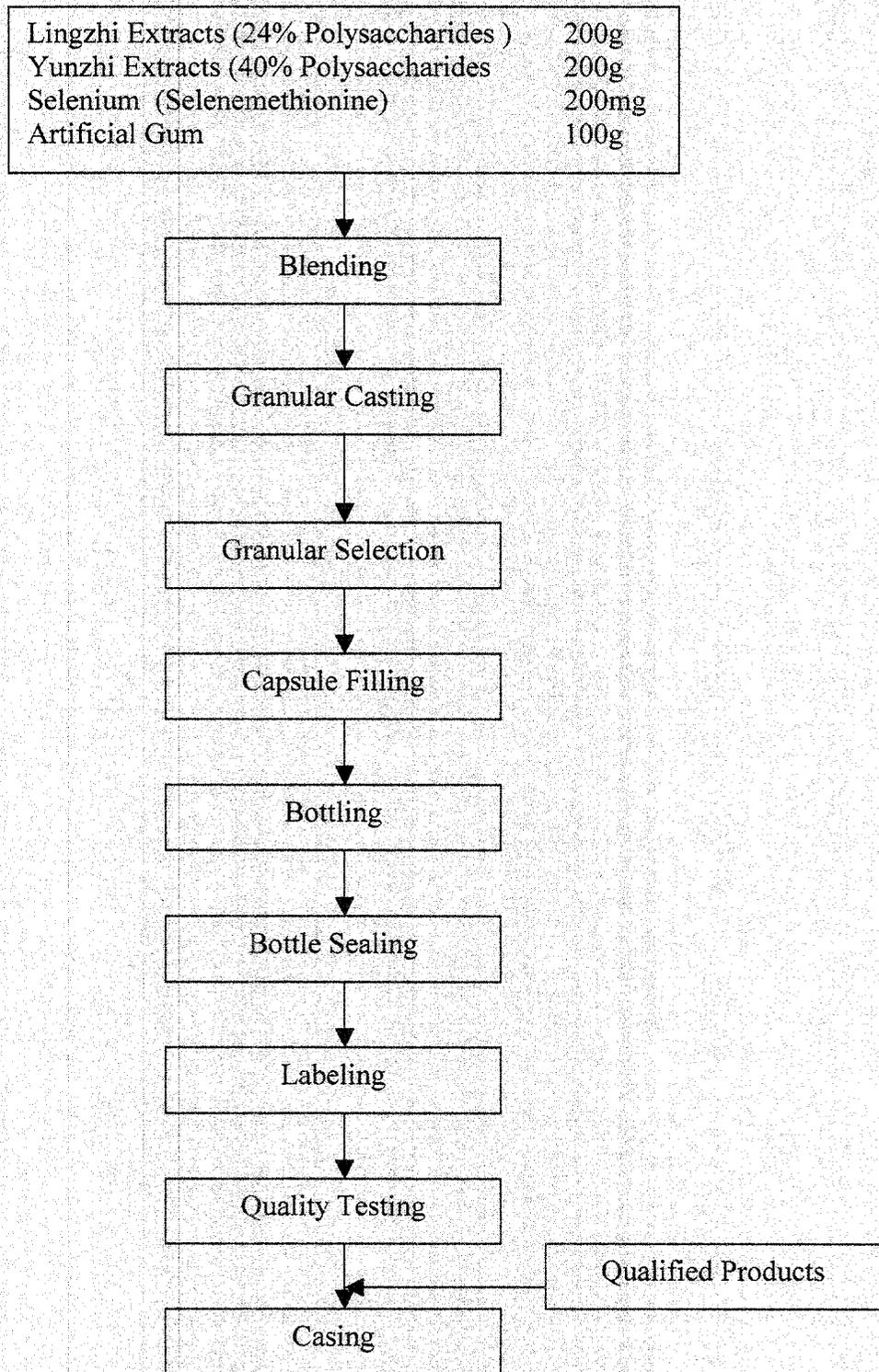
Manufacture: (Registered Facility No In US-FDA: 19113312268)

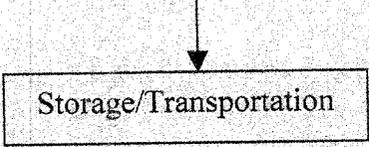
North China Pharmaceutical Corporation (NCPC)
#380 Heping Rd., Shijiazhuang
Hebei province, P.R. China. PC 050015

Products:

Product name:	CaPv-F2												
Package:	60 capsules per bottle												
Suggested use:	As a nature dietary supplement for adults, Take one capsule with breakfast meal and one capsule with dinner meal. Keep bottle tightly closed. Store in a cool, dry place, out of reach of children. Do not use if imprinted seal under cap is broken or missed.												
Supplement Facts:	<table><tr><td>Servicing Size:</td><td>1 capsule</td></tr><tr><td>Servicing per container:</td><td>60</td></tr><tr><td>Amount per serving:</td><td>%DV</td></tr><tr><td>Lingzhi Polysaccharides</td><td>50mg</td></tr><tr><td>Yunzhi Polysaccharides</td><td>100mg</td></tr><tr><td>Selenium</td><td>100mcg</td></tr></table> (*Daily value not established). Other Ingredients: Multiple Amino Acids. No Artificial Color. No Artificial Flavors. No Preservatives. No Chemical Solvents, Yeast or Gluten.	Servicing Size:	1 capsule	Servicing per container:	60	Amount per serving:	%DV	Lingzhi Polysaccharides	50mg	Yunzhi Polysaccharides	100mg	Selenium	100mcg
Servicing Size:	1 capsule												
Servicing per container:	60												
Amount per serving:	%DV												
Lingzhi Polysaccharides	50mg												
Yunzhi Polysaccharides	100mg												
Selenium	100mcg												
Functional Claim:	Immune Support												

Process of capsule preparation (1,000 capsules):





Product Specifications (translated version from Chinese version by NCPC manufacture attached below)

Product Name: CaPv-F2
Content: 150 mg polysaccharides and 200 mcg Selenium per capsule
Manufacture Level: GMPs
Manufacturer: North China Pharmaceutical Corporation (NCPC)
380# East Heping Rd., Shijiazhuang, Hebei Province, China.
PC050015

Microorganisms:
Total plate count 0/g (Less than 10 CPU/g)
E. coli 0/100g (Less than 30 CFU/100g)
Yeast Not detected
Pathogenic bacteria Not detected

Heavy Metals:
Arsenic < 1.0 ppm
Cadmium < 1.0 ppm
Mercury < 0.5 ppm
Lead < 1.0 ppm
Copper < 20 ppm

Pesticide Contamination:

Hexachlorobenzene	Not Detected
Quintozene	
Pentachloronitrobenzene (PCNB)	Not Detected
Pentachloroaniline	Not Detected
Pentachlorothioanisol	Not Detected
Lindane	Not Detected