

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: CaTh-F1

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*\_\_\_\_\_

*1995S-0316*

*RPT317*



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

FEB - 6 2006

Dear Dr. Wang:

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. Your notification concerns the substance called "*Ganoderma lucidium* (Fr.) Karst" or "Lingzhi Polysaccharides" that you intend to market as a new dietary ingredient in a dietary supplement product which you call "CaTh-F1."

According to your notification, "CaTh-F1" will be in a tablet containing 100 or 120mgs of Lingzhi Polysaccharides per capsule. The conditions of use that will be suggested or recommended on the label state: "...[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.

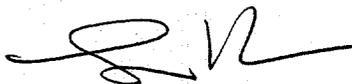
Your notification concerning "CaTh-F1" does not comply with the requirements of 21 CFR 190.6 and is incomplete. For example, it is unclear to us from the information in your notice the exact amount of "Lingzhi Polysaccharide" in each capsule. In addition, your notification does not contain history of 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, MD.  
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

*LAB 2/3/05  
POA*

Dear Dr. Pellicore,

Based on your guidance (please see following attachment), I prepared the premarket notification documents for Zephantech's dietary supplements, separately. The notification documents are prepared for products: CaTh-F1, CaPv-F2, CaCh-F3, and Trimthinon. Also, one document for a product called "Lubao" has been prepared for premarket notification in the package.

Please direct all correspondence to me and feel free to contact me by email at [zp16988@yahoo.com](mailto:zp16988@yahoo.com) if you have any question regarding the notifications.

Many thanks!

Sincerely yours,



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

11-18-2005

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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

23  
AB/FDA

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

Re: Premarket Notification for Dietary Supplements

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<br>--- <i>Panax ginseng</i> C. A. Meyer | 2.7% Ginsenosides             |

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

CaTh-F1:                   200 mg of Lingzhi Polysaccharides per capsule  
                                  60 capsules per bottle  
                                  2 capsules a day with meals  
                                  Immune Support

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.

2005-7970  
AIMS

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  
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Please direct all correspondence to me and feel free to contact me by email at [zp16988@yahoo.com](mailto:zp16988@yahoo.com) if you have any question regarding the notifications.

Many thanks!

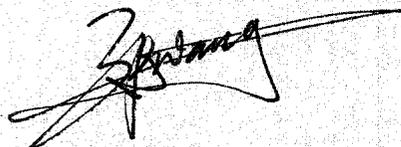
Sincerely yours,



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

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](mailto: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 flourish 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](mailto:zp16988@yahoo.com)

# Premarket Notification for Dietary Supplement

## CaTh-F1

**Notification Date:**

10-25-2005

**Distributor:**

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

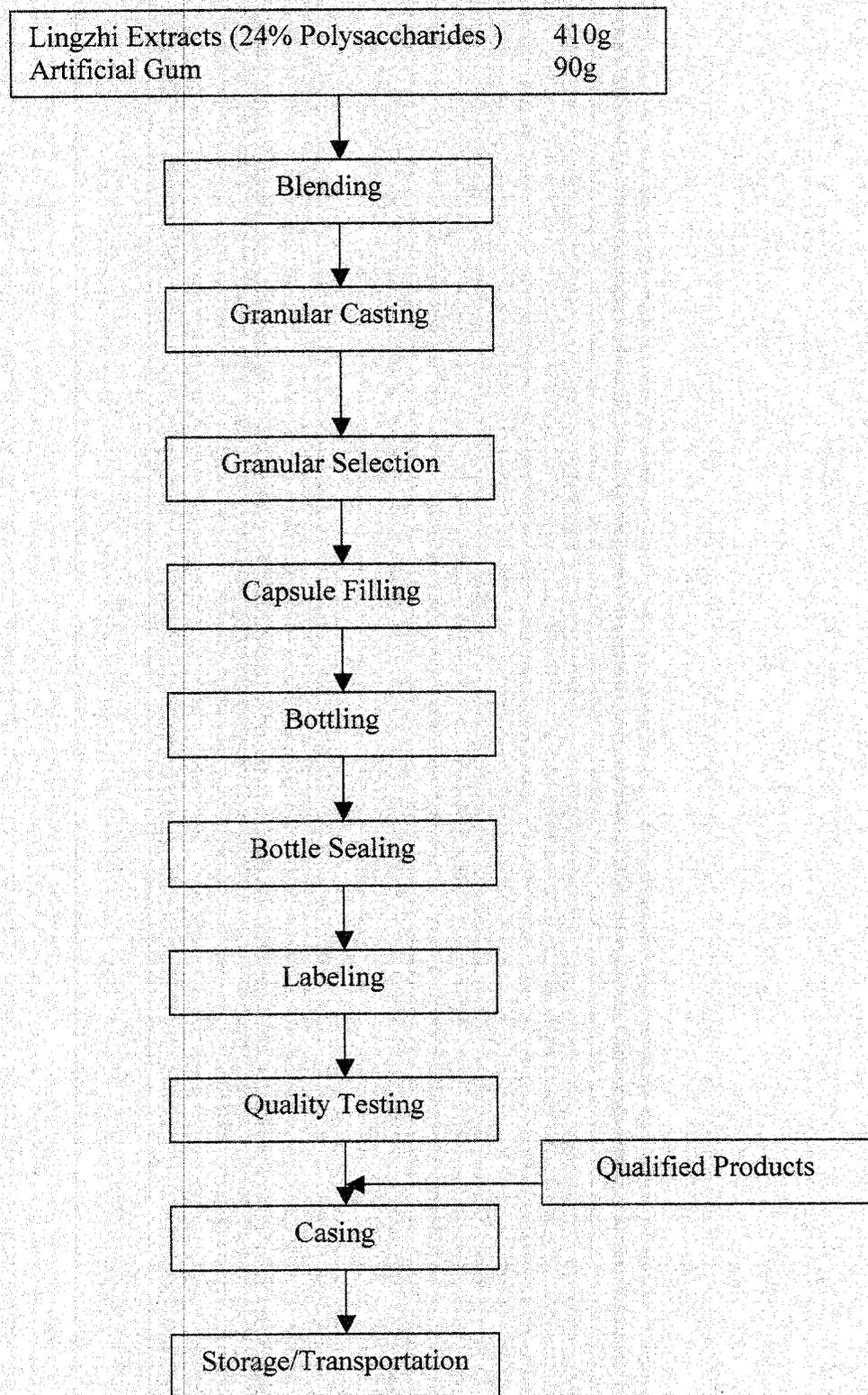
**Manufacture: (Registered Facility No In US-FDA: 19113312268)**

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

**Products:**

Product name:	<b>CaTh-F1</b>
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:	Servicing Size: 1 capsule Servicing per container: 60 Amount per serving: %DV Lingzhi Polysaccharides 120mg (*Daily value not established). Other Ingredients: Multiple Amino Acids. No Artificial Color. No Artificial Flavors. No Preservatives. No Chemical Solvents, Yeast or Gluten.
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: CaTH-F1  
Content: 100 mg polysaccharides 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)
<i>E. coli</i>	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