DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Public Health Service

# Memorandum

Date NOV 23 1998

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From Senior Regulatory Scientist, Regulatory Branch, Division of Programs & Enforcement Policy (DPEP), Office of Special Nutritionals, HFS-456

Subject 75-day Premarket Notification for New Dietary Ingredient

To Dockets Management Branch, HFA-305

| | |
|---|---|
| New Dietary Ingredients: | LingDanWang<br>*(Imperata cylindrica)*<br>*(Isodon glaucocalyx)*<br>*(Ganoderma lucidum)* |
| Firm: | P&Y American Dietary Supplements, Inc. |
| Date Received by FDA: | September 22, 1998 |
| 90-day Date: | December 20, 1998 |

In accordance with the requirements of section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification for the aforementioned new dietary ingredient should be placed on public display in docket number 95S-0316 after December 20, 1998.

Robert J. Moore

Robert J. Moore, Ph.D.

95S-0316

RPT 33

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

NOV 23 1998

Mr. Simon Ko
President & CEO
P & Y American Dietary Supplements, Inc.
288 N. Ridge Road
P.O. Box 327
Marathon, Wisconsin 54448

Dear Mr. Ko:

This is in response to your letter to the Food and Drug Administration (FDA) dated September 10, 1998, making a submission for a new dietary ingredient pursuant to 21 U.S.C. 350b(a)(2) (section 413 of the Federal Food, Drug, and Cosmetic Act (the Act)) and 21 CFR 190.6. Your letter notified FDA of your intent to market a product (named LingDanWang) containing the ingredients Royal Bee Jelly, root of *Imperata cylindrica*, whole plant of *Isodon glaucocalyx*, and *Ganoderma lucidum*.

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement that contains 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 section 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 deemed 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 submission contained information that you believe establishes that the new dietary ingredients root of *Imperata cylindrica*, whole plant of *Isodon glaucocalyx*, and *Ganoderma lucidum*, when used under the conditions recommended or suggested in the labeling of the dietary supplements, will reasonably be expected to be safe. The information in your submission does not meet the requirements of 21 CFR 190.6 (copy enclosed) because it does not include reprints or photostatic copies of references to published information offered in support of the notification

(see 21 CFR 190.6(b)(4)). Moreover, 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 summaries you have provided are incomplete and do not include adequate information about the methods used or the actual results of the studies. You may submit an amended notification that cures the defects described above. If you market your product without submitting an amended notification that meets the requirements of 21 CFR 190.6, or 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).

Please contact us if you have any questions concerning this matter.

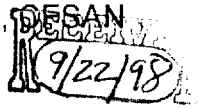
Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

# P&Y American Dietary Supplements, Inc.

288 N. Ridge Rd, P.O. Box 327
Marathon, WI 54448
Tel: 715-443-3338 Fax: 715-443-2818

Robert J. Moore, Ph.D.
Director, Division of Programs and Enforcement Policy
Office of Special Nutritionals (HFS-455), CFSAN
U.S. Food and Drug Administration
200 "C" Street, S.W.
Washington, D.C. 20204




September 10, 1998

Dear Dr. Moore,

Pursuant to the requirement of section 413(a)(2) of the Federal Food, Drug and Cosmetic Act for Dietary Supplement, P&Y Dietary Supplements Inc., on its own behalf and on behalf of Ling Dan Wang Health Foods, 28 Tianzhu Road, Lingyin, HangZhou, China, wish to notify the Food and Drug Administration that it will market a new dietary product, LingDanWang capsule on the U.S. Market 75 days after this notice.

The LingDanWang capsule contains Royal Bee Jelly and 3 new herbal ingredients, root of Imperata cylindrica, whole plant of Isodon Glaucocalyx and Ganoderma lucidum at 25% each. Base on the information available, we recommend a maximum daily intake of 6 capsules each time, 2-3 times a day in the direction for use. The total daily intake is less than 15% of the established safe dose of all 3 dietary ingredients recommended by the Pharmacopoeia of the People's Republic of China and other documents.

All those 3 herbal ingredients have long history of use in the Chinese medicine dated back to 16th Century. They were recorded in Ben Cao Gang Mu (or The Great Herbal) written by Li Shi Zhen, one of the great Chinese medical doctors 400 years earlier. They have been used for various symptoms even today. The pharmacological effectiveness and the lack of toxicity were recorded in many Chinese medical books such as Grand Dictionary of Traditional Chinese Medicine, Zhejiang Medicinal Plant Record, and the Pharmacopoeia of the People's Republic of China.

Attached please find the English translation of the summary of toxicological test of LingDanWang capsule in mice and rats. The studies were carried out at the Zhejiang Medical University Medicine Research and Testing Center in 1995. This Center is one of the most well known and reputable testing centers in China. They concluded that the product is so safe that the LD50 could not be established in mice. The tolerance in mice is greater than 53.67 g/Kg. That is about 300 times of the suggested human dose. This product was also tested in rats at about 400 times human dose, once daily for 13 weeks and no pathological and histological toxicities were found in animal organs.



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**P&Y American Dietary Supplements, Inc.**

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A copy of English translation of the summary of the pharmacology and toxicology of LingDanWang capsule is also attached for your reference. This study was carried out in 1993 at the same above mentioned Center. The study concluded that this product has shown some protective effect on liver and enhanced its immunity system.

Based on the above mentioned historical records, animal toxicological studies and the safe human use record from marketing in China for last 3 years, we concluded that when used under the conditions suggested in the label, this dietary supplement is reasonably expected to be very safe.

Enriched with natural vitamin B complex, folic acid and omega-hydroxy-decenoic acid from royal bee jelly, and minerals from the herbal ingredients, LingDanWang capsule is an ideal dietary supplement for physical and mental fatigue. The herbal ingredients also known to increase the hepatic immune function according to traditional Chinese medicine. The statement of nutritional support reads as follows:

" Ideal supplement for physical and mental fatigue, and for improvement of hepatic immune function."

This statement will be accompanied by the required disclaimer: " This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

We appreciate your timely response to acknowledge the receipt of this notice. Please also provide us a written confirmation that the above stated claims and labeling is in compliance with the Dietary Supplement Health and Education Act of 1994. Thank you very much for your cooperation.

Sincerely yours,

Simon Ko
President & CEO
P&Y American Dietary Supplements, Inc.
288 N. Ridge Rd, P.O. Box 327
Marathon, WI 54448