

COLIN WORLDWIDE CORPORATION

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MAY 23 2002

May 20, 2002

Mr. Foret
Director Division of Compliance and Enforcement
FDA Office of Nutritional Products
Labeling & Dietary Supplements
Division of Standards & Labeling Regulation
HFS-820 5100 Paint Branch Parkway
College Park, MD 20740

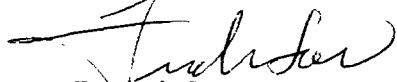
Dear Mr. Foret,

Thank you very much for replying to our letter (copy included) regarding our importation and distribution of the nutritional supplement **Paecilomyces hepiali chen & Ganoderma**. You indicated two claims that did not properly conform to proper labeling.

I have enclosed a revised letter **deleting** the non-conforming claims "**enhances recovery of sickness**" and "**assists in strengthening body after radiotherapy and chemotherapy**". I intend to use the wording as per this revised letter and would appreciate your comments and approval to our revised phrasing. I want to ensure that all the labeling claims on our nutritional supplement conforms to properly accepted labeling requirements.

I thank you in advance for your timely effort regarding this matter.

Sincerely,



Frederic Lou
Vice President
Colin Worldwide Corporation

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May 20, 2002

FDA Office of Nutritional Products
Labeling & Dietary Supplements
Division of Standards & Labeling Regulation
HFS-820 5100 Paint Branch Parkway
College Park, MD 20740

Dear Sir Madam,

I will be importing and distributing within the US the following nutritional supplement. The ingredients and its uses will be as follows:

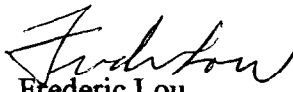
- 1) Paecilomyces hepiali chen & Ganoderma: 4gm granule packets, adenosine \geq .05%,
-Paecilomyces hepiali chen, Ganoderma, Fructus Lycii, Lactose, Steviosin, Dextrin
- 2) Paecilomyces hepiali chen & Ganoderma: 0.5gm capsule, adenosine \geq .20%
-Paecilomyces hepiali chen, Ganoderma, Fructus Lycii

Uses for this nutritional supplement:

- Promotes vitality and stamina
- Increases energy level
- Nourishes and enriches blood circulation as well as strengthening the body
- Nourishes the kidney and liver
- Enhances sexual function
- Helps in relaxation of body
- Enhances anti-oxidants system in the body
- Assists in memory stimulation
- Enhances immune system

I know that the FDA does not approve dietary supplements however I have listed ingredients as well as uses for this dietary supplement and I would appreciate your opinion regarding the aforementioned supplement. I thank you in advance for your time and effort regarding this matter.

Sincerely,



Frederic Lou
Vice President
Colin Worldwide Corporation



Copy

MAY 16 2002

Mr. Frederic Lou
Vice President
Colin Worldwide Corporation
P.O. Box 96
Tenafly, New Jersey 07670

Dear Dr. Lou:

This is in response to your letter of April 28, 2002 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 Colin Worldwide Corporation is making the following claims, among others, for the product **Paecilomyces hepiali chen & Ganoderma**:

“Enhances recovery of sickness;”

“Assists in strengthening body after radiotherapy and chemotherapy.”

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 suggest that it is intended to prevent diseases. 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.

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Please contact us if you require 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, New Jersey District Compliance, HFR-MA340