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OCT 28 2004

Mr. Donald Chu
President & CEO
Tronex Company
One Tronex Centre
3 Lugar Road
Denville, New Jersey 07834

Dear Mr. Chu:

This is in response to your letter of September 21, 2004 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 Tronex Company is making the following claims, among others, for the product ONCOZAC:

"[F]or those combating serious illnesses."

"[I]mprove the immune function of people suffering from serious illnesses, alleviate the side effects caused by invasive treatments and assist convalescence."

"[A]djunct health supplement complementary to conventional invasive treatments which usually cause many side effects including decline of immune function, reduction of red and white blood cell counts, oral ulcer, nausea, vomiting and anorexia."

"[E]nhance the host resistance to bacterial and fungal infections and abnormal cell growth."

"[C]omplement the treatment effect of conventional invasive treatments."

"[I]mprove the health status and overall quality of life of people suffering from serious illnesses."

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, including the recommendations for uses before, during and after invasive treatments or surgery and curing convalescence after cancer treatment, suggest that it is

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intended to treat, prevent, or mitigate disease. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this products 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

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

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

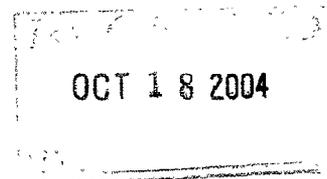
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, New Jersey, Office of Compliance, HFR-CE340



Date : 21st September, 2004.

Dr. Robert Moore, Branch Chief,
Compliance and Enforcement Branch
Division of Dietary Supplement Program/ONPLDS
Center for Food Safety and Applied Nutrition
Food and Drug Administration
HFS-810
200 C Street, SW
Washington, DC 20204



Subject: 30-Days Notification Letter of Dietary Supplement's Statement

Dear Dr. Moore,

As the authorized U.S. Agent and distributor for Principle, Purapharm International (H.K.) Limited, with registered Company address at One Tronex Centre, 3 Luger Road, Denville, NJ 07834, notice is hereby given pursuant to the requirements of Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 343(r)(6)) of the intent of us to market in the U.S. a dietary supplement, brand-named as ONCOZAC, which contains 340mg grams of Standardized Yunzhi (Coriolus Versicolor) Extract, equivalent to 3.4 grams of dried natural and wild Yunzhi (Coriolus Versicolor). Accordingly, an original and two copies of this notification, the text of Bottle Label and the Packing Insert are submitted for your reference.

I hereby also certify that, to the best of my knowledge, all the information submitted here is true and accurate.

Please direct all correspondence to me and feel free to call me at (973)-627-3800 if you have any question regarding this matter.

Sincerely yours,

Donald Chu
President & CEO

Cc: PuraPharm International (HK) Ltd.

Tronex Company

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information@tronexcompany.com www.tronexcompany.com

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Oncozac 300's label (English)

Oncozac™ is a new generation Yunzhi(Coriolus Versicolor)-derived adjunct remedy with enhanced efficacy and consistency developed for those combating serious illnesses. Made from 100% wild Yunzhi, Oncozac™ is produced with sophisticated and proprietary production processes under strict GMP standards. It contains pure Yunzhi extract, which consists of highly concentrated absorbable peptidoglucon (APG) that can effectively improve/enhance bodily immune function. Every batch of Oncozac™ is tested with established hygienic, chemical and immunological assays to warrant its safety, consistency and efficacy.

Ingredients: 100% Yunzhi extract (containing absorbable peptidoglucon).

Dosge: 5 capsules, two times daily or as directed by physician.

Packing: 300 capsules / bottle, net weight 102g.

Storage: Keep in a cool dry place. Avoid direct sunlight.

Supplement Fact

Serving size: 10 capsules

<u>Each Capsule Contains</u>	<u>% Daily Value</u>
<u>Yunzhi (Coriolus Versicolor) extract</u>	<u>340mg**</u>

** Daily value not established

Other ingredients: Gelatin

* These statements have not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Oncozac insert (English)

Description:

Each capsule contains 340mg absorbable peptidoglucon (APG) – containing Yunzhi (Coriolus Versicolor) extract, which is equivalent to 3.4g natural and wild Yunzhi. Oncozac™ is produced under proprietary production processes derived from extensive scientific researches. The efficacy, quality and consistency of Oncozac™ are proven by established immunological, hygienic and chemical tests. Evidences indicate that Oncozac™ can effectively improve the immune function of people suffering from serious illnesses, alleviate the side effects caused by invasive treatments and assist convalescence.

Action:

Oncozac™ is a new generation Yunzhi extract which displays the following actions:

- Invigorate the major immune cells such as T-lymphocytes, B-lymphocytes, monocytes/macrophages, bone marrow cells and natural killer cells etc.,
- Promote the production of antibodies, complements and various cytokines such as interleukin (IL)-2, IL-6 and interferons, etc.,
- Enhance the cytotoxic activity of lymphocytes,
- Restore the compromised immune status caused by invasive treatments.

Indication and Usage:

Oncozac™ is an adjunct health supplement complementary to conventional invasive treatments which usually cause many side effects including decline of immune function, reduction of red and white blood cell counts, oral ulcer, nausea, vomiting and anorexia. Oncozac™ can reinforce the immune defense so as to enhance the host resistance to bacterial and fungal infections and abnormal cell growth. It can also complement the treatment effect of conventional invasive treatments. Continuous administration of Oncozac™ could improve the health status and overall quality of life of people suffering from serious illnesses.

Dosage and Administration:

Take the capsules with plenty of water preferably before meals. For best effects, Oncozac™ should be taken regularly in accordance with the following recommendations:

- 1) Before invasive treatments or surgery:
Take 5 capsules each time, 2 times daily starting from 7 days before those treatments or surgery, or under appropriate medical advice.
- 2) During and after invasive treatments or surgery:
Take 5 capsules each times, 2 times daily continuously for 6 months or under appropriate medical advice.
- 3) Unable to undergo invasive treatments or operation:
Take 8 capsules each time, 2 times daily continuously for 6 months. Dosage could be adjusted according to the health conditions or appropriate medical advice.
- 4) Convalesce after cancer treatment:
Take 2-3 capsules each time, 2 times daily continuously during the convalescent period.

Adverse Reactions:

Adverse reactions to Yunzhi extract were rarely found. Gastrointestinal discomfort

usually subsides after several administrations of Oncozac™ or when it is taken after meals.

Drug Interactions:

Adverse drug interaction between Yunzhi extract and other drugs has not been reported. However, co-administration of immunosuppressants and Oncozac™ is not recommended.

Contraindications:

For those patients with a history of hypersensitivity to Yunzhi and other edible mushrooms, please seek medical advice before usage.

Ingredient:

100% Yunzhi extract (containing absorbable peptidoglucon APG)

Packaging:

Each capsule contains 340mg highly concentrated Yunzhi extract supplied in either 100's blister pack (10 capsules/blister) or 300's bulk pack.

Storage:

Store in cool, dry place. Avoid direct sunlight.

A product of PuraPharm International (H.K.) Ltd.

Distributed by: Tronex Pharmaceutical Industries Denville NJ 07834 USA