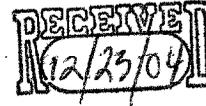




Date: 16th December, 2004.



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) 586-1278 if you have any question regarding this matter.

Sincerely yours,

Donald Chu
President & CEO

cc: PuraPharm International (H.K.) Ltd.

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Tronex Company

One Tronex Centre 3 Luger Road Denville, NJ 07834 U.S.A. Tel: 973 627 3800 Fax: 973 625 7630
info@tronexpharmaceuticals.com www.tronexcompany.com

A product of Parapharm International (K.) Limited
 韋力(香港)健康產品有限公司總經
 Distributed by: Trione Pharmaceuticals
 One Thine Center, 3 Lager Road, Danville, NJ 07834, U.S.A.

Oncozac™ is a licensed product of Parapharm International (K.) Ltd.
 安固生™是韋力(香港)健康產品有限公司總經。

電話號碼 011107
 傳真號碼 011011107

安固生™雲芝膠囊是一種針對免疫功能受損人士而設計之新一代輔助保健產品。採用100%純天然雲芝菌，經現代科技提煉，並透過專有的生產程序及GMP認證過程精煉而成。無論在服用及質量皆於國際最高標準。安固生™雲芝膠囊純潔無毒，為全球最潔淨可靠之保健產品。經嚴密反覆地進行身體之免疫功能。每批產品皆經過安全、化學及免疫學測試，確保質量及效用均安全可靠。

成份：100% 純天然雲芝菌 (雲芝菌經可回收製成膠囊)

服法：每日兩次，每次5粒。或遵照醫生指示服用

包裝：每盒100粒膠囊，淨重34克

儲存：置於陰涼乾燥處，避免陽光直接照射

規格資料	
每盒粒數：	100粒
每粒淨重：	340mg*
每盒淨重：	
每片裝藥膠囊淨重：	

其他說明：明察
 *以上數據並非產品保證書之保證，亦並非政府註冊之數據，香港
 政府註冊之產品有售。

Oncozac
 安固生

Oncozac

安固生
 雲芝膠囊



Oncozac™ is a new generation Yunzhi (Cordyceps sinensis) extract adjusted formula with enhanced efficacy and consistency developed for those facing serious immune challenges. Made from 100% wild Yunzhi, Oncozac™ is produced with sophisticated and proprietary extraction processes under strict GMP standards. It contains pure Yunzhi extract, which consists of highly concentrated polysaccharide peptidolipid (PAP) that can effectively improve body 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 assimilable leptodoglican)

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

Packing: 100 capsules/bottle, net weight 34g

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

Supplement Facts

Serving size: 5 capsules

Each Serving Contains:

Yunzhi (Cordyceps sinensis) extract 340mg*

** Daily value not established

Other Ingredients: Glycerin

* 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™ is a new generation Yunzhi (*Coriolus Versicolor*) - derived adjunct remedy with enhanced efficacy and consistency developed for those facing serious immune challenges. 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 peptidoglucan (APG) that can effectively improve 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 peptidoglucan)

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

Packing : 100 capsules/bottle, net weight 34g

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

Supplement Facts

Serving size: 10 capsules

Each Capsule Contains

Yunzhi (<i>Coriolus Versicolor</i>) extract	340mg**
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** 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.

HC187415A

A product of PurafPharm International (H.K.) Limited
培力(香港)健康產品有限公司產品
Distributed by: Tronex Pharmaceutical
One Tronex Center, 3 Luger Road, Donville, NJ 07834, U.S.A.

安固生™ 雲芝膠囊是一種針對免疫功能受損人士而製的新
一代輔助保健食品。採用100%純天然野生雲芝，運用代
科技研發，並透過專有的生產程序及按GMP製藥標準精製
而成，無論在效用及質量皆被證實達至最高標準。安固生™
雲芝膠囊純度極高，內含高濃度可吸收β-葡聚糖，能直接
顯著地改善身體之免疫功能。每粒膠囊皆經過衛生、化學
及免疫功能測試，確保質量及效用均安全可靠。

成份：100% 純天然野生雲芝 (含高濃度可吸收β-葡聚糖)

劑量：每日兩次，每次5粒，可參閱醫生指示服用

(如有需要請參閱說明書內說明)

包裝：每盒300粒膠囊，淨重102克

儲存：置於陰涼乾燥處，避免陽光直接照射

補充資料

每份份量：10粒

每瓶膠囊含

雲芝膠囊

346mg

* 每日需要備用膠囊

其他成分：明膠

以上傳統未經改良的藥物管理員評核，產品並非用特效藥、藥油、滋養或傳統
任何藥物之類

Oncozac

安固生
雲芝膠囊

Oncozac™ is a new generation Yunzhi (Cordyceps Versicolor) -
Bovheni spored remedy with enhanced efficacy and consistency
developed for those facing serious immune challenges. 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 peptidoglycan (APG) that can effectively improve 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 peptidoglycan)

Dosage: 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 Facts

Serving size: 10 capsules

Each Capsule Contains

Yunzhi (Cordyceps Versicolor) extract

346mg

* 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™ is a new generation Yunzhi (*Coriolus Versicolor*) - derived adjunct remedy with enhanced efficacy and consistency developed for those facing serious immune challenges. 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 peptidoglucan (APG) that can effectively improve 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 peptidoglucan)

Dosage: 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 Facts

Serving size: 10 capsules

Each Capsule Contains

Yunzhi (<i>Coriolus Versicolor</i>) extract	340mg**
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** 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

安固生
雲芝膠囊

安固生[™]雲芝膠囊是一種針對免疫功能受損人士而設的新一代輔助保健食品；採用100%純天然野生雲芝，經現代科技研發，並透過專有的生產程序及按GMP國際標準精製而成，無論在效用及質量皆被證實達至最高標準。安固生[™]雲芝膠囊純度極高，內含高濃度可吸收的聚糖，服後能顯著地改善身體之免疫功能。每批產品皆經過衛生、化學及免疫功能測試，確保質量及效用均安全可靠。

成份：100%純天然野生雲芝（含有濃縮可吸收的聚糖）

服法：每日兩次，每次5粒，或遵照醫生指示服用

（用法及服量詳情請參閱盒內說明）

包裝：每盒300粒膠囊，淨重102克

儲存：置於陰涼乾燥處，避免陽光直接照射

補充資料

每盒份量 10粒

每顆膠囊含

雲芝精提

340mg**

**每日總量尚未確定

其他成份：明膠

*以上資料均與食品標籤的營養成分不同，不具任何營養、醫療、治療或預防任何疾病之效。

Oncozac

安固生

Oncozac

安固生
雲芝膠囊

Oncozac[™] is a new generation Yunzhi (Coriolus Versicolor)-derived adjunct remedy with enhanced efficacy and consistency developed for those facing serious immune challenges. 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 peptidoglycan (APG) that can effectively improve bodily immune function. Every batch of Oncozac[™] is tested with established hygiene, chemical and immunological assays to warrant its safety, consistency and efficacy.

Ingredients: 100% Yunzhi extract (containing absorbable peptidoglycan)

Dosage: 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 Facts

Serving Size: 10 capsules

Each Capsule Contains

Yunzhi (Coriolus Versicolor) extract 340mg**

** 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.



Expiry Date 有效日期
Lot No 生產編號

A product of ParaPharm (International) P.L.K. Limited
奇力 (香港) 藥業產品有限公司出品
Distributed by: Hui Hai Pharmacy Group
One Tinoco Centre, 2 Tinoco Road, Don Mills, NJ 07834, U.S.A.
Oncozac[™] is a trademark of the company: Hui Hai Pharmacy (H.H.P.) Ltd.
安固生[™] 為奇力 (香港) 藥業產品有限公司之商標

Oncozac™ is a new generation Yunzhi (Coriolus Versicolor) - derived adjunct remedy with enhanced efficacy and consistency developed for those facing serious immune challenges. 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 peptidoglucan (APG) that can effectively improve 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 peptidoglucan)
- Dosage** : 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 Facts

Serving size: 10 capsules

Each Capsule Contains

Yunzhi (Coriolus Versicolor) extract	340mg**
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Other ingredients: Gelatin

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