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OCT 11 2006

Ms. Monica Wong
Regulatory Affairs Manager
PuraPharm International (H.K.) Ltd.
c/o Amerisearch, Inc.
1232 Q Street
Sacramento, California 95814

Dear Ms. Wong:

This is in response to your letters of September 16, 2006 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 PuraPharm International is making the following claims for the following products:

Nong's Wind-Cold Formula

"[S]oothe symptoms...including fever, white phlegm, nasal congestion, as well as running nose and muscle pain."

Nong's Wind-Heat Formula

"[S]oothe symptoms...headaches and fever...dry and sore throat, nasal congestion, running nose, turbid phlegm, thirst and muscle pain...."

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 these products suggest that they are intended to treat, prevent, or mitigate disease such as respiratory infections and related diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are 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 20852.

97S 0163 LET 906

Page 2 - Ms. Monica Wong

Please contact us if we may be of further assistance.

Sincerely yours,



Vasilios H. Frankos, Ph.D.
Acting 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, San Francisco District Office, Office of Compliance, HFR-PA140



PuraPharm 培力

PuraPharm International (H.K.) Ltd.
培力(香港)健康產品有限公司

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Nutritional Products, Labeling, and Dietary Supplements
5100 Paint Branch Parkway
College Park, Maryland 20740
FAX: 301-436-2639

SEP 21 2006

16 September 2006

Dear Sir / Madam,

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

On behalf of PuraPharm Corporation, with registered company address at AMERISEARCH, INC., 1232 Q Street, Sacramento, CA 95814, 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 **Nong's Wind-Cold Formula**. Accordingly, an original of this notification, the outer box layout is submitted for your reference.

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

Should you have further inquiries, please do not hesitate to contact the undersigned through phone at (852)2846 6245, fax at (852)2840 0778 or email at mwong@purapharm.com.

Regards,




Monica Wong
Regulatory Affairs Manager

Suites 4103-08, Jardine House, 1 Connaught Place, Central, Hong Kong.
G.P.O. Box 10122, Hong Kong
Telephone: (852) 2840-1840 • Facsimile: (852) 2840-0778
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電子郵件: info@purapharm.com
網址: www.purapharm.com

葛根湯
外感風寒沖劑
Wind-Cold Formula

此藥之功效
能治外感風寒
症之頭痛發熱
咳嗽痰多等症

安全有效，不用煎煮的即溶草本配方 • 6包 × 4克
SAFE & EFFECTIVE INSTANT HERBAL GRANULES • 6 sachets × 4g

外感風寒沖劑
Wind-Cold Formula



葛根湯
外感風寒沖劑
Wind-Cold Formula

批日期前每包：
Best Before:
生日期前每包：
Lot No:
4 895024 202297

農本方及 Nong's 為總代理(香港)健康產品有限公司之註冊商標。
Nong's and Nong's are registered trademarks of PuraPharm International (HK) Ltd.

NONG'S
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葛根湯 外感風寒沖劑
Wind-Cold Formula

功能 INDICATIONS :

農本方® 外感風寒沖劑能舒緩因外感風寒而引起之不適，如惡寒發熱、痰白、流清鼻涕、鼻塞及骨骼肌肉酸痛等徵狀，並能增強抵抗力以對抗病菌。
Nong's® Wind-Cold Formula can soothe symptoms caused by exterior wind-cold including aversion to cold, fever, white phlegm, nasal congestion, as well as running nose and muscle pain. It can also enhance the immune system.

用法・用量 DIRECTIONS & DOSAGE :

每日三次，每次一包，加熱水攪拌後即可服用。
Three times daily, one sachet each time. Stir granules in hot water to dissolve.
以上藥述未經食品及藥物管理局評估，本品並無用作診斷、醫治、治療或預防任何疾病之意。
These statements have not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

補充資料 Supplement Fact :

每包沖劑含 Each sachet contains	每日營養值 % daily value
葛根 Pueraria lobata (Willd.) Ohwi	727.2mg**
麻黃 Ephedra sinica Stapf	545.6mg**
生薑 Zingiber officinale Roscoe (fresh rhizome)	545.6mg**
桂枝 Cinnamomum cassia J. Presl (twig)	363.6mg**
炙甘草 Glycyrrhiza uralensis Fisch. ex DC. (prepared with honey)	363.6mg**
白芍 Paeonia lactiflora Pall. (root without bark)	363.6mg**
大棗 Ziziphus jujuba Mill	1090.8mg**

其他成分：糊粉、明膠 Other Ingredients: Dextrin, gelatin
**每日營養值未確定 Daily value not established

配方出典 SOURCE :

本方出典自漢代張仲景醫學名著《傷寒論》，張仲景創立了中國臨床醫學的辨症論治體系，一直影響中醫學的發展，被譽為漢代十大名醫之一。古往今來，本方均為歷代名醫所推崇，經臨床使用確認為有效之外感風寒處方。由於功效顯著，千多年來均受歷代名醫推崇備致，世代相傳，站用至今，為現代中醫師常用之外感風寒配方。
This formula is extracted from the *Discussion of Cold-induced Disorders*, a text written by Zhang Zhong Jing, one of the most renowned practitioners of the Han Dynasty. Zhang was revered as one of the "Ten Greatest Medical Practitioners of the Han Dynasty". This formula has been proven effective through numerous usages and venerated by later practitioners as the most effective wind-cold formula.

農本方® 即溶草本配方乃採用精選一級中草藥，以最先進的提取濃縮技術製造而成，所有製造過程符合國際GMP製造標準，並獲發安全測試合格證書，為安全有效、不用煎煮的即溶藥粒。
Nong's® Instant Chinese Herbal Granules incorporates only the finest herbs and is produced using cutting edge extraction technology. All the production processes conform to GMP (Good Manufacturing Practice) standards. Nong's® has gone through rigorous safety and quality tests and is certified safe and effective.

總代理(香港)健康產品有限公司產品
A Product of PuraPharm International (H.K.) Ltd
Imported by: PuraPharm Corporation
Address: AMERISEARCH INC 1232 Q Street
Sacramento CA 95814



PuraPharm 培力

PuraPharm International (H.K.) Ltd.
培力(香港)健康產品有限公司

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

Should you have further inquiries, please do not hesitate to contact the undersigned through phone at (852)2846 6245, fax at (852)2840 0778 or email at mwong@purapharm.com.

Regards,

Monica Wong
Regulatory Affairs Manager

#1789

06-7368

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香港郵政總局信箱10122
電話: (852) 2840-1840 • 傳真: (852) 2840-0778

Address: AMERISEARCH INC 1232 O Street
 Sacramento CA 95814
 A Product of PuraPharm International (H.K.) Ltd.
 Prepared by PuraPharm Corporation
 總代理：香港豐本方有限公司

本方®即草本配方乃採用精選一般中草藥，以最先
 進的提煉過程技術製造而成，所有製造過程符合國際
 GMP認證標準，並獲發安全證書合格證書，為安全有
 效、不用煎煮的即溶草藥。
 Nong's® Instant Chinese Herbal Granules incorporates only the
 finest herbs and is produced using cutting edge extraction
 technology. All the production processes conform to GMP (Good
 Manufacturing Practice) standards. Nong's® has gone through
 rigorous safety and quality tests and is certified safe and effective.

配方出處 SOURCE:
 本方出典自清代醫學家吳鞠通所著《溫病條辨》，吳鞠通
 為溫病學派的主要代表人物之一，研製了許多新方，從而
 成為一代名醫。廣為後世傳頌。古往今來，本方受歷代
 名醫推崇，用於風熱外感，效果顯著，又經傳承使用確證
 為有效之外感配方。
 This formula is extracted from the Systematic Differentiation of Warm
 Diseases, a text written by Wu Ju Tong, one of the most renowned
 practitioners of the Qing Dynasty. He invented many formulas, which
 have been passed on from generations to generations to this day.
 The Wind-Heat formula has been proven effective through
 numerous clinical usages and recreated by later practitioners as
 the most effective wind-heat formula.

補充資料 Supplement Fact:
 (每份重 3 包 Serving Size: 3 sachets)
 每日服用量 % daily value
 每包沖劑量

金銀花	Lonicera japonica Herb.	605.1mg
薄荷	Mentha haplocalyx	363.8mg
綠茶	Platyodon grandiflorum (Tea), A. DC	363.8mg
牛蒡子	Arctium lappa L.	363.8mg
桑葉	Lophatherum gracile	242.4mg
夏枯草	Gynura urens Fieb. ex DC	303.0mg
黃芩	Scutellaria baicalensis	303.0mg

其他成分：糖精、防腐劑、Dextrose, Erythritol, Stevia
 每份重量以毫克計。Daily value not established.

功能 INDICATIONS:
 本方®外感風熱沖劑能舒緩因外感風熱而引起之不適，如頭
 痛發熱、咳嗽、喉嚨腫痛、鼻塞、流涕、喉痛、痰黃、口渴及
 骨節肌肉痠痛等徵狀，並能增強抵抗力。
 Nong's® Wind Heat Formula can soothe symptoms caused by exterior
 Wind-Heat including headaches and fever, coughing, dry and sore throat,
 nasal congestion, running nose, stuffy phlegm, thirst and muscle pain.
 It can also enhance the immune system.
用法。用量 DIRECTIONS & DOSAGE:
 每日三次，每次一包，加熱水攪拌後即可服用。
 Three times daily, one sachet each time. Stir granules in hot water to dissolve.
 以上藥味未經食品及藥物管理局評估。本品並無用作診斷、醫治、治療
 或預防任何疾病之意。
 These statements have not been evaluated by the Food & Drug Administration.
 This product is not intended to diagnose, treat, cure or prevent any disease.

NONG'S 豐本方
 銀翹散
 外感風熱沖劑
 Wind-Heat Formula

NONG'S 豐本方
 銀翹散
 PuraPharm



外感風熱沖劑
 Wind-Heat Formula

散
 外感風熱沖劑
 Wind-Heat Formula

安全有效，不用煎煮的即溶草本配方 • 6包 x 4克
 SAFE & EFFECTIVE INSTANT HERBAL GRANULES • 6 sachets x 4g



此日期前最佳：
 Best Before
 生產編號：
 Lot No.

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NONG'S 豐本方
 散
 外感風熱沖劑
 Wind-Heat Formula