

Memorandum

Date: MAY 15 2006

From: Consumer Safety Officer, Division of Dietary Supplement Programs , Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: **“ACAPHA”**

Firm: Global Cancer Strategies

Date Received by FDA: February 3, 2006

90-Day Date: May 4, 2006

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

____Victoria Lutwak____

19955-0316

RPT337



Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

APR 17 2006

Dr. T. P. Chiang, C.E.O.
Global Cancer Strategies Ltd.
113-990 Beach Avenue
Vancouver, British Columbia V6Z 2N9
Canada

Dear Dr. Chiang

This is to inform you that the notification, dated January 31, 2006, that you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on February 3, 2006. Your notification concerned the substance that you identified as "ACAPHA" which you prepare from *Sophora tonkinensis* Gagnep., *Sonchus brachyotus* DC., *Prunella vulgaris* L., *Polygonum bistorta* L., *Dioscorea bulbifera* L. and *Dictamnus dasycarpus* Turcz. You intend to market "ACAPHA" as a new dietary ingredient in a dietary supplement product called "ProhibitRx".

According to your notification, "The recommended daily dose is 1.8g, 3 x 600 mg tablets/day.... The tablets should be consumed three times, one tablet at a time orally with water or liquid before meals." As to conditions of use, your notification states that "[t]he product is intended for use by healthy adult males and females who are seeking to supplement their diet with herbal supplement to support the health of their epithelial tissues such as the oro-pharyngeal and respiratory tissues, i.e., support normal respiratory function in a smoke-rich environment, support respiratory health for those exposed to second hand smoking, support body's ability to cope with a polluted environment, may help minimize the risks to long-term health posed by exposure to environmental toxins."

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing 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

considered 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.

This letter is to alert you within the 75-day notification period that FDA intends to complete its evaluation within a few weeks and send you a response to your notification. Please note that a lack of a response to a notification within the 75-day timeframe does not constitute a finding by the agency that the ingredient or a product that contains the ingredient is safe or is not adulterated under 21 U.S.C. 342. See 21 C.F.R. 190.6(f).

Your notification will be kept confidential for 90 days after the filing date of February 3, 2006. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter please contact Linda Pellicore, Ph.D. at (301) 436-2375.

Sincerely yours,

for 
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



Global Cancer Strategies Ltd. Preventive Health Division

Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD, 20740-3835
US

January 31st, 2006

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Dear Dr. Susan Walker:

Pursuant to Section 8 of the Dietary Supplement Health and Education Act of 1994, Global Cancer Strategies Ltd., Preventive Health Division, located at 113-990 Beach Avenue, Vancouver, BC, Canada V6Z 2N9, wishes to notify the Food and Drug Administration that it will market a new dietary supplement, ACAPHA, prepared from six commonly available botanicals: namely, Vietnamese Sophora (*Sophora tonkinensis* Gapnep), bistort (*Polygonum bistorta* L.), heal all (*Prunella vulgaris* L.), perennial sowthistle (*Sonchus brachyotus* DC), dense fruit dittany (*Dictamnus dasycarpus* Turcz), and air potato (*Dioscorea bulbifera* L.). Enclosed please find three (3) copies of this notification. Details of concentrations and content of the product, conditions of use stated in the labeling, and evidence of safety are documented in the enclosed attachment.

The dietary supplement will contain 600mg of ACAPHA in film coated tablet form with a suggested daily dose of 1.8g, (600mg/ tablet to be taken three (3) times per day).

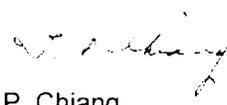
FDA traditionally considered dietary supplements to be composed only of essential nutrients. The Nutrition Labeling and Education Act of 1990 added "herbs, or similar nutritional substances", to the term "dietary supplement". ACAPHA contains six herbs that have been used as food or herbs for centuries in Asia and Europe. *Sophora tonkinensis*, *Polygonum bistorta*, *Prunella vulgaris*, *Dictamnus dasycarpus*, and *Dioscorea bulbifera* are listed in the Herb of Commerce book. Safety and toxicity studies of ACAPHA have been performed in rats, mice, dogs and healthy volunteers. They include mutagenicity, acute and sub-chronic toxicity tests in rodents and dogs, and tolerance of healthy human volunteers. The maximum tolerable daily dose is greater than 20g/kg in mice, 833 times the intended human dosage. Healthy volunteers taking 4.8g of ACAPHA daily, 2.7 times the proposed dosage for the new dietary supplement for as long as 4 weeks did not reveal any adverse reaction. Safety and toxicity studies showed that ACAPHA did not have accumulative toxicity in animals, nor was it mutagenic in bacteria and mice.

The proposed new dietary ingredient is to be labeled ProhibitRx to have the same ingredients as ACAPHA but at a lower dosage (ProhibitRx vs ACAPHA is at a ratio of 1.8g vs 4.8g). Attached please find the detailed information which establishes that this dietary supplement, when used under the conditions suggested in the label, is expected to be reasonably safe.

At a meeting in the summer of 2004 titled "Medicine in the 21st Century" held in Shanghai, China, we presented a paper related to ACAPHA and Dr. Alexander Sun also presented a herbal mixture called SV that is presently marketed in the US as a health product. He is presently conducting a phase III clinical trial on SV trying to obtain pharmaceutical status. The question was raised to the FDA representative whether ACAPHA can be marketed as a dietary supplement and was encouraged to go through the proper channel of application through your department.

Please direct all correspondence to me if you have any questions regarding this matter.

Very truly yours,


Dr. T. P. Chiang,
CEO

2006-812

Confidential

New Dietary Ingredient Notification

Product name: ACAPHA
Global Cancer Strategies Ltd.
Preventive Health Division
Vancouver, British Columbia, Canada

Date: Jan. 30, 2006

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