



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

MAR 19 2004

Mr. Robert DeWitty, Esq.
Outsource Product Manufacture LLC
111 S. Calvert Street, Suite 2700
Baltimore, Maryland 21202

Dear Mr. DeWitty:

This is to inform you that the notification dated, December 15, 2003, 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 January 7, 2004. Your notification concerns the substance called "VI-28" which consists of *Panax ginseng*, *Cornu cervi pantotrichum*, *Cuscuta chinensis*, *Cnidium monnieri*, and *Kaempferia galanga* that you intend to market as a new dietary ingredient.

According to the notification, you intend to sell 300 milligram (mg) capsules containing 75 mg of *Panax ginseng*, 75 mg *Cornu cervi pantotrichum*, 60 mg *Cnidium monnieri*, 60 mg *Cuscuta chinensis*, and 30 mg of *Kaempferia galanga*. Under the conditions of use stated in the labeling of your product, the manufacturer recommends that the dietary supplement "VI-28" be used in the following manner: 2 capsules daily for the first month, 2 capsules every two days for the second and third months, and 2 capsules twice a week for the fourth and following months.

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.

955-0316

RPT 227

FDA has carefully considered the information in your submission, and the agency has concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing “VI-28” will reasonably be expected to be safe.

Your notification fails to identify the Latin binomial including the author of the new dietary ingredients in “VI-28” as required for any herb or other botanical by Federal regulations found in 21 CFR 190.6(b)(2). Since the notification did not include the Latin binomial and author for *Panax ginseng*, *Cnidium monnieri*, and *Kaempferia galanga*, it is impossible for FDA to identify which varieties of botanicals were used in the “VI-28” capsules which you intend to market.

Your notification does not fully describe the chemical composition of the components in “VI-28”, including a description of the method of preparation. A description of the method of manufacturing may have helped FDA identify your product. There were also discrepancies with the description of the test articles used in studies cited in your notification. For example, one study reported that it was conducted with “VI-28”. Other studies cited were conducted with test substances that may be similar to “VI-28”, however, the relationship of these test materials to the botanical preparations that are the subject of the notification was not stated. Therefore, it is unclear how the information submitted relates qualitatively and quantitatively to the proposed new dietary ingredient called “VI-28”.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that your product containing “VI-28,” when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of January 7, 2004. 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 Victoria Lutwak at (301) 436-2375.

Sincerely yours,

Linda S. Pellicore 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

Outsource Product Manufacture LLC

Intellectual Property- Product Development - Regulatory Compliance Concerns

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21 January 2004

Susan Walker, M.D.
Division Director
Division of Dietary Supplement
Office of Nutritional Products, Labeling, and Dietary Supplements
Center for Food Safety and Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740-3835

VIA FACSIMILE
Courtesy Copy to Follow

Re: New Dietary Supplement VI-28 Pre-market Notification
Our Ref: Vigconic=1

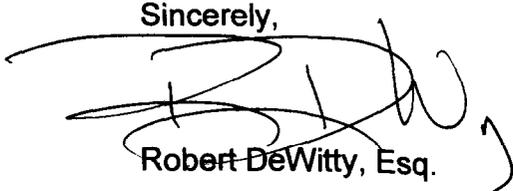
ATTN Dr. Walker:

This letter is written to clarify the intentions of the Pre-market Notification dated 15 December 2003 (filing date 7 January 2004).

Our intention of the Pre-market Notification was to obtain approval to market one (1) dietary ingredient called VI-28 which consists of RADIX GINSENG, CORNU CERVI PANTOTRICHUM, FRUCTUS CNIDII, SEMEN CUSCUTAE, and RHIZOMA KAEMPFERIAE.

If you have any questions or concerns, feel free to contact our offices via fax or phone.

Sincerely,


Robert DeWitty, Esq.

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Outsource Product Manufacture LLC

Intellectual Property- Product Development - Regulatory Compliance Concerns

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15 December 2003

DB/FDA

Division of Standards and Labeling Requirements
Office of Nutritional Products, Labeling, and Dietary Supplements
Center for Food Safety and Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740-3835

Re: 75-day Pre-market Notification for New Dietary Ingredients:
Radix ginseng, Cornu Cervi Pantotrichum, Fructus Cnidii,
Semen Cuscutae, Rhizoma Kaempferiae

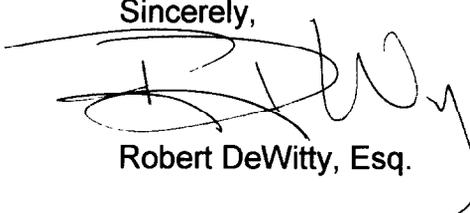
Dear Sir or Madam:

Pursuant to 413 of the Federal Food, Drug and Cosmetic Act, and 21 C.F.R. section 190.6, please find attached pre-market notifications for the Ingredients Radix ginseng, Cornu Cervi Pantotrichum, Fructus Cnidii, Semen Cuscutae, and Rhizoma Kaempferiae to be used in the dietary supplement VI-28, which Outsource Product Manufacture LLC is forwarding as counsel to the submitter, Vigconic (International) Ltd. of Hong Kong, SARHK.

We have enclosed discussions of the scientific data and literature showing the Ingredients, when used under the conditions suggested in the labeling of VI-28, will reasonably be expected to be safe.

An original and two copies of the pre-market notifications have been enclosed. If you have any questions or concerns, feel free to contact our offices via fax, phone, or email.

Sincerely,


Robert DeWitty, Esq.

Enclosures.

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