



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

JAN 12 2005

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

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, October 19, 2004, that you submitted on behalf of your client, Vigconic (International) Ltd., 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 November 3, 2004. Your notification concerns the substance called "VI-28" which consists of *Radix ginseng* (sic), antler from *Cervus elaphus* (L), *Fructus cnidii* (sic), *Semen cuscutae* (sic), and *rhizome Kaempferae* (sic) that you intend to market as a new dietary ingredient.

According to the notification, you intend to sell 300 mg capsules containing 75 mg of *Radix ginseng* (sic) [*Panax ginseng*], 75 mg antler from *Cervus elaphus* L, 60 mg *Fructus cnidii* (sic) [*Cnidium monnieri*], 60 mg *Semen cuscutae* (sic) [*Cuscuta chinensis*], and 30 mg of *rhizome Kaempferae* (sic) [*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 2 days for the second and third month, and twice a week, 2 capsules for the fourth month and as desired."

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.

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.

Please refer to the following regulations: 21 CFR 101.4 (h) & 190.6. The Latin binomial and author citation are required for any herb or other botanical as part of the name for the new dietary ingredient. Your notification did not properly identify the herbs *Cnidium monnieri* and *Rhizoma kaempferiae*. In addition, the regulations state that any reference to published information, submitted to establish history of use or safety, “shall be accompanied by reprints or photostatic copies of such references.” As part of the evidence of safety for “VI-28,” your notification included three abstracts which are insufficient for review.

Your notification fails to identify the new dietary ingredient that you call “VI-28.” Although a general manufacturing process is described, the notification fails to provide quantitative information about the composition of any of the numerous components said to be present in the raw materials. Information regarding the source and processing of the raw materials used to manufacture the dietary ingredients may have helped FDA. In addition, the “VI-28 Hong Kong” version tested in 12 individuals does not have the same composition as the “VI-28” product that is the subject of this notice. How the information from this study is relevant to evaluating the safe use of “VI-28” under the recommended conditions of use is not evident in the notice.

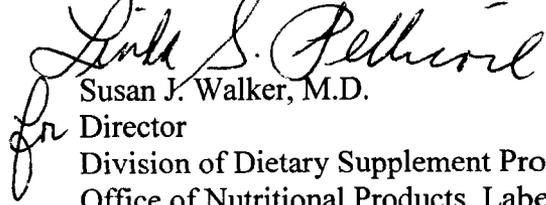
Therefore, FDA cannot make an assessment of safety for “VI-28” use as a dietary supplement because the identities of the dietary ingredients cited above are incomplete based on the information in the notification. Your notification did not demonstrate that each ingredient is qualitatively and quantitatively similar to substances that have a documented history of use and/or other information on which to base an assessment of the safety of 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 November 3, 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.

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

Sincerely yours,

A handwritten signature in black ink that reads "Linda S. Pellicore". The signature is written in a cursive style with a large, stylized initial "L".

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

R/D: HFS-810 v1 draft 12/09/04 & revisions 1/03/05; to Team Leader 1/4/05
Revisions/initials/mm/dd/yy
Final type/v1/01/10/05

Reviewed:

HFS-810/ Pellicore:

HFS-810/ Moore:

HFS-810/ Walker

Handwritten signature and date: "JR 01/10/05". The signature consists of the letters "JR" in a cursive style, followed by the date "01/10/05".

cc:

Dockets

GFC-1/OGC

HFA-224/ (yellow box copy)

HFS-605/ Field Programs

HFS-810/ Lutwak

NDI # 306

CTS Project #90051

DDSP 834

NDI 306 IAL 050114 (VI-28) (BOT)