



OCT 13 2005

Robert M. DeWitty, Esq.  
111 S. Calvert Street Ste 27  
Baltimore, Maryland 21202

Dear Mr. DeWitty:

This is to inform you that the notification, dated August 11, 2005, 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 August 18, 2005. Additional information dated August 29, 2005 was received September 9, 2005. Your notification concerns the substances called *Kaempferia galanga* L, *Cuscuta chinensis* Lam., *Panax ginseng* C.A. Mey., and *Cnidium monnieri* (L.) Cusson ex. Juss. as well as the substance that you call "Cornu Cervi Pantotrichum". You identify these five substances as new dietary ingredients that you intend to market in a dietary supplement product that you call "VI-28".

According to your notification, "VI-28" will be marketed in capsule form. The conditions of use suggested on the label will be "1 time daily, 2 capsules each time" for the first month of use, "1 time every 2 days, 2 capsules each time" for the second and third month, and "2 times every week, 2 capsules each time" for the "[f]ourth [m]onth 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 21 U.S.C. 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) (section 402(f)(1)(B) of the Act) 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 "VI-28 will reasonably be expected to be safe.

FDA was unable to identify any of the new dietary ingredients that will be used to make "VI-28". For example, you identify "Cornu Cervi Pantotrichum" variously as "pilose antler" "deer antler" and "deer velvet". Your notification did not specify which species within the genus *Cervus* will be the source of this ingredient. Material in your notification refers variously to spotted deer, red deer, North American elk and *Cervus elaphus nelsoni* but it is unclear if any, all or none of these species will be the source of the "Cornu Cervi Pantotrichum" used in your product. Moreover, your notice does not clearly state which part of the animal will be used to make "Cornu Cervi Pantotrichum" or how the starting material will be processed or manufactured. Similarly, your notification does not state the part of the plant or how the raw plant material will be processed for any of the four botanical ingredients of VI-28.

Because FDA was unable to identify the dietary ingredients in "VI-28", it is unclear how these ingredients are qualitatively or quantitatively similar to the substances described in the information that you present as evidence of safety for your dietary supplement product, or how that information is relevant to evaluating the safe use of your dietary supplement product under the recommended conditions of use.

Furthermore, your notification contains no description of the manufacturing process used to combine the five new dietary ingredients or any information about the safety of the five combined ingredients or of your dietary supplement product, "VI-28".

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that "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 August 18, 2005. 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.

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If you have any questions concerning this matter please contact Dr. Linda Pellicore 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