

# Outsource Product Manufacture LC

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



**FAXED**

21 Jan 2004

**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.

# STUDY OF VI-28<sup>1</sup>

## SUMMARY

Evidence of the safety of VI-28 is shown in the study focused on the administration of the supplement to human subjects.

12 human subjects were administered the supplement for a period of 13 months. The supplement was administered in accordance with the instructions of the manufacturer (Vigconic (International) Ltd.). The subjects were given a health evaluation and bodily fluids were analyzed between the dates 4 August 2003 to 18 August 2003. Information about the subjects is provided in the letter from Dr. Laurence S.L. Shek<sup>2</sup>. The subjects were male, between the ages of 50 and 64. They exhibited a variety of lifestyles, such as smokers and non-smokers, social drinkers and daily drinkers. The subjects also possessed a variety of health conditions.

Biochemical analysis and urinalysis of the bodily fluids of the subjects was performed. The results of the urinalysis show normal conditions from the subjects following administration of VI-28 including absence of blood, bilirubin, protein (except A112), nitrites, ketones, and glucose. The results of the biochemical study compare the existing condition of the patients before administration of VI-28 and their condition following administration. According to Dr. Shek, these results are favorable.

Detailed discussion was made by Dr. Shek of subject A138, specifically the positive effect the supplement had on his chronic hepatitis. In summary, Dr. Shek concludes that based on the test results, the supplement does not have an adverse effect on the liver and/or kidney functions of VI-28 supplement users.

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<sup>1</sup> VI-28 is a dietary supplement that contains the ingredients: RADIX GINSENG, CORNU CERVI PANTOTRICHUM, SEMEN CUSCUTAE, FRUCTUS CNIDII, KAEMPFERIAE RHIZOMA. The dietary supplement is recommended to 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 each time for the fourth and future months.

<sup>2</sup> Letter dated 29 August 2003. Dr. Shek is a specialist in Internal Medicine in Hong Kong SAR.