

Outsource Product Manufacture LLC

Intellectual Property - Product Development - Regulatory Compliance Concerns

新产品代理总公司

专利 - 商标 - 新产品 律师

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27 May 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

Re: Submission of 75-day Pre-market Notification for New
Dietary Ingredients: Radix ginseng, Cornu Cervi
Pantotrichum, Fructus Cnidii, Semen Cuscutae, Rhizoma
Kaempferiae as contained in the dietary supplement VI-28

Our Ref: Vigonic=1

Dear Madam:

Pursuant to 413 of the Federal Food, Drug and Cosmetic Act, and 21 C.F.R. section 190.6, please find attached submission of pre-market notifications for the Ingredients RADIX GINSENG, CORNU CERVI PANTOTRICHUM, FRUCTUS CNIDII, SEMEN CUSCUTAE, and RHIZOMA KAEMPFERIAE as contained in the dietary supplement VI-28, which Outsource Product Manufacture LLC is forwarding as counsel to the submitter, Vigonic (International) Ltd. of Hong Kong, SARHK.

Please note that this Notification is a submission in response to the letter received from the FDA dated March 19, 2004. With regard to the letter the FDA states that the previous Notification did not contain the Latin binomial and author for *Panax ginseng*, *Cnidium monnieri*, and *Kaempferia galanga*. The Latin binomials and authors have been included in this submission. The letter also states the previous Notification did not describe the chemical composition of the components, or the method of preparation of VI-28. Please note this information has been included in the letter. Lastly, the letter asserts there were discrepancies with the description of test articles used in

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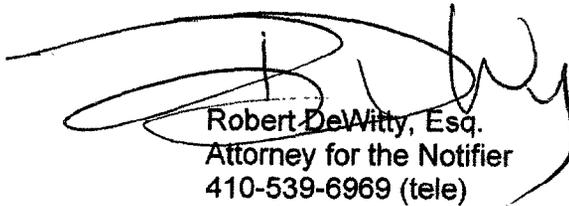
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studies cited in the original Notification. We have include a statement designed to clarify and clear any discrepancies.

If there are any further issues, feel free to contact me via fax, phone, or email.

Sincerely,

A handwritten signature in black ink, appearing to read 'Robert DeWitty', is written over a circular stamp or watermark.

Robert DeWitty, Esq.
Attorney for the Notifier
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410-510-1973 (fax)
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Enclosures.