

Nov 19, 2004  
A.B./FDA

19 October 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

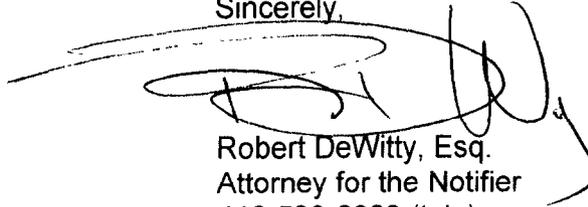
Our Ref: Vigconic=1

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, and supporting documents, which Outsource Product Manufacture LLC is forwarding as counsel to the submitter, Vigconic (International) Ltd. of Hong Kong, SARHK.

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', with a long horizontal flourish extending to the left.

Robert DeWitty, Esq.  
Attorney for the Notifier  
410-539-6969 (tele)  
410-510-1973 (fax)  
bobdewitty@chemical-prototype.net

Enclosures.

## TABLE OF CONTENTS

Contents:	Page:
<b>I. Part I: Information about VI-28 (dietary supplement)</b>	
i. Notifier Information	1
ii. Notice of Intention	1
iii. Study of VI-28 (see footnote	2
iv. Method of Manufacture of VI-28	3
v. Microbes and Pesticide Control	3
vi. Chemical composition of Ingredients of VI-28	3
<b>II. Part II: Dietary Ingredients in VI-28</b>	
i. Radix Ginseng	6
ii. Antler of Cervus elaphus (Lin.)	8
iii. Semen cuscutae	11
iv. Fructus cnidii	12
v. Kaempferiae rhizome	13
<b>III. Part III: Supporting Studies and Articles</b>	

## **PART I: Information about VI-28 (dietary supplement)**

### **NOTIFIER INFORMATION**

This Notification is filed on behalf of

Vigconic (International) Ltd.  
5B, Cheong Wah Factory Building  
39-41 Sheung Heung Road, Tokwawan  
Kowloon, HONG KONG

### **NOTICE OF INTENTION**

It is the intention of this Pre-market Notification to obtain approval to market one (1) dietary supplement known as VI-28. VI-28 consists of the dietary ingredients Radix ginseng, Antler from Cervus elaphus (linnaeus) (aka Cornu Cervi Pantotrichum), Fructus cnidii, Semen cuscutae, and Rhizoma kaempferiae. Detailed information on the safety of each ingredient is provided in subsequent sections of this Notification. VI-28 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 for the fourth month and as desired.

## STUDY OF DIETARY SUPPLEMENT VI-28

### SUMMARY

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

**Please note the supplement used in this study contains ingredients different from the supplement that is the subject of this Notification.** The ingredient list is below:

#### Research Study VI-28 vs. Pre-market Notification VI-28<sup>1</sup>

<b>Ingredients of supplement used in study (VI-28 Hong Kong version)</b>	<b>Ingredients of supplement that is the subject of this Notification (VI-28 US version)</b>
<i>Radix Ginseng</i>	<i>Radix Ginseng</i>
<i>Cornu Cervi Pantotrichum</i>	<i>Cornu Cervi Pantotrichum</i>
<i>Cordyceps</i>	X
<i>Radix Salviae Miltiorrhizae</i>	X
<i>Tuber Onion Seed</i>	X
<i>Fructus Cnidii</i>	<i>Fructus Cnidii</i>
<i>Fructus Evodiae</i>	X
<i>Rhizoma Kaempferiae</i>	<i>Rhizoma Kaempferiae</i>
X	<i>Semen Cuscutae</i>

12 human subjects were administered the supplement for a period of 13 months from July 2002 to August 2003. 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 \_\_\_\_\_<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

<sup>1</sup> The Pre-market Notification VI-28 version is the version that will be marketed in the United States

<sup>2</sup> Letter dated 29 August 2003

administration of VI-28 and their condition following administration. According to \_\_\_\_\_ these results are favorable.

Detailed discussion was made by \_\_\_\_\_ of subject A138, specifically the positive effect the supplement had on his chronic hepatitis. In summary, \_\_\_\_\_ 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.

#### METHOD OF MANUFACTURE OF VI-28

##### Phase A

Radix ginseng, Antler from Cervus elaphus (linnaeus) (aka Cornu Cervi Pantotrichum), and Rhizome kaempferiae are ground to a fine powder under low temperature.

##### Phase B

Fructus cnidii and Semen cuscutae are water decocted, filtered, the solution is oven dried, and reduced to a fine powder via grinding process.

Phase A and B are mixed in proper proportion to form the final mix. The final mix is heat treated at 80°C for 24 hours, and then filled into gelatin capsules.

#### MICROBES AND PESTICIDE CONTROL

In the control of microbes, it is believed the method of manufacture, namely the use of heat treatment 80°C for 24 hours, is sufficient to address any microbes that may be present.

Regarding pesticide monitoring, the final mix is subject to pesticide monitoring in accordance with the Hong Kong Standards and Testing Centre (report of 2003-02-14 enclosed herewith).

## CHEMICAL COMPOSITION OF INGREDIENTS OF VI-28

### Radix ginseng

- 2-3% Ginsenosides (triterpene saponins)
- 0.05% essential oil (limonene, terpineol, citrol, polyacetylenes)
- sugar
- starch

### Antler of Cervus elaphus (Linnaeus) (Cornu Cervi Pantotrichum)

- 34% Ash
- 12% moisture
- nitrogen
- fats
- collagen
- glycosaminoglycans (chondroitin sulfate, keratin sulfate, hyaluronic acid, dermatan sulfate, chondroitin sulfate proteoglycan, decorin)
- lipids (polysaccharides)
- growth hormone and prostaglandins (IGF-1, IGF-2)

### Semen cuscutae

- quercetin 3-O-beta-D-galactoside-7-O-beta-D-glucoside (I)
- quercetin 3-O-beta-D-apiofuranosyl-(1-->2)-beta-D-galactoside (II)
- hyperoside (III)
- isorhamnetin (IV)
- kaempferol (V)
- quercetin (VI)
- d-sesamin (VII)
- 9(R)-hydroxy-d-sesamin (VIII)
- Vitamin A

### Fructus cnidii

- osthol
- imperatorin
- xanthotoxin
- isopimpinellin
- bergapten

## Kaempferiae rhizoma

- cineol
- borneol
- 3-carene
- camphene
- kaempferal
- kaempferide
- cinnamaldehyde
- p*-methoxycinnamic acid
- ethyl cinnamate
- ethyl *p*-methoxycinnamate

## Inactive Component

- rice powder

## Capsule

- Gelatin Capsule

## **PART II: Dietary Ingredients in VI-28**

Ingredient: Radix Ginseng

I. INGREDIENT NAME: RADIX GINSENG (Ginseng)

II. INTENDED USE AND IDENTIFICATION: Radix Ginseng is intended for use as an ingredient in the dietary supplement VI-28. The dietary supplement will contain 75 mg of Radix Ginseng per capsule, for a dietary intake of up to maximum 150 mg per day.

Radix ginseng can be identified as an herb in accordance with 21 U.S.C. 321(ff).

III. HISTORY OF USE/SAFETY EVIDENCE FOR COMPONENT:

The history of use of Radix Ginseng can be established with a brief review of products currently offered in the United States that contain this component. Examples of such products include FeminiCare™ dietary supplement, Viatexx™ dietary supplement, and Betterman™ dietary supplement. With regard to Betterman™ dietary supplement, attention would like to be directed to the short term study of American men administered the dietary supplement. It was determined that there were no side effects or adverse reactions following administration of the supplement<sup>3</sup>.

Radix Ginseng is the dried root of Panax Ginseng (***Panax Ginseng C.A. Meyer, Araliaceae***). Pharmacologically, Radix Ginseng has an "adaptogenic" effect, which produces an increase in the body's defenses against outside stress factors and chemicals. According to Herbal Drugs and Phytopharmaceuticals, Radix Ginseng is not a therapeutic agent, but rather an agent which regulates the resistance of the organism to various outside influences<sup>4</sup>. Further, Herbal Drugs, states that side effects are "...relatively rare and only with high doses and/or use over very long periods of time"<sup>5</sup>. Side effects include sleepnesses, nervousness, diarrhea, menopausal bleeding, and hypertony. The daily dosage as indicated by the literature is 1-2 grams<sup>6</sup>.

---

<sup>3</sup> See page 3, "Research Studies on the scientific proof that BetterMAN improves erections and prostate...III Short-term Study with American Men...".

<sup>4</sup> Wichtl, M. "Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice...", pp. 236-238

<sup>5</sup> Id at pp. 237.

<sup>6</sup> Id at pp 237, bottom, last column (boxed).

#### IV. CONCLUSION

The ingredient as used throughout the cited studies (Ginseng Radix, Radix Ginseng) is the same as the new ingredient stated herein. As the cited studies utilize the ingredient in doses significantly higher than the proposed use in VI-28 (1-2 grams daily vs. maximum 150 mg daily), it is believed the proposed ingredient and its use in VI-28 can reasonably be expected to be safe.

Ingredient: Antler of Cervus elaphus (Linnaeus)

I. INGREDIENT NAME: Antler of Cervus elaphus (Linnaeus)  
(Cornu Cervi Pantotrichum) (Pilose Antler<sup>7</sup>)

II. INTENDED USE AND IDENTIFICATION: Antler of Cervus elaphus (Linnaeus)<sup>8</sup> (Cornu Cervi Pantotrichum) is intended for use as a component in the dietary ingredient VI-28. The dietary ingredient will contain 75 mg of Cornu Cervi Pantotrichum per capsule, for a dietary intake of up to maximum 150 mg per day.

Antler of Cervus elaphus can be identified as a dietary ingredient for use by man to supplement the diet by increasing total dietary intake in accordance with 21 U.S.C. 32 (ff), namely by increasing amounts of fats, collagen, growth hormone, and prostaglandins.

III. HISTORY OF USE/SAFETY EVIDENCE FOR INGREDIENT:

The history of use of Cornu Cervi Pantotrichum can be established via a review of literature. In China, the red deer species is raised for their young pilose antlers<sup>9</sup>. According to the literature, red deer, a member of the Cervus species, has been farmed to produce velvet antler teas, extracts, capsules and tablets for health related products<sup>10</sup>. Currently, many countries produce velvet antler including New Zealand (450 tons/year), China (400 tons/year), Russia (80 tons/year), United States (20 tons/year), and Canada (20 tons/year)<sup>11</sup>. Velvet antler supplements have been the subject of numerous studies<sup>12</sup>.

In one study, Senescence-Accelerated Mice were administered subchronic oral doses of hot-water extract of pilose antler (Rokujo)<sup>13</sup>. Doses were given orally for 8 successive days in amounts of 0, 100, or 200 mg/kg/d<sup>14</sup>. In a scientific review, researchers studied acute and sub-chronic toxicity of powdered deer velvet at dose levels of 2000 mg/kg for single oral treatment, and

---

<sup>7</sup> Monograph, "Cornu Cervi Pantotrichum", [www.healthlink.com.au/ant\\_lib/htm-data/htm-herb/bhp927.htm](http://www.healthlink.com.au/ant_lib/htm-data/htm-herb/bhp927.htm).

<sup>8</sup> Senseman, R. (on-line), Animal Diversity Web. Accessed September 7, 2004 at [http://animaldiversity.ummz.umich.edu/site/accounts/information.cervus\\_elaphus.html](http://animaldiversity.ummz.umich.edu/site/accounts/information.cervus_elaphus.html).

<sup>9</sup> "Young Pilose Antler- A Precious Crude Drug", pp. 43-45.

<sup>10</sup> Batchelder, H. "Velvet Antler: A Literature Review", [www.natraflex.com/studies/VA2.htm](http://www.natraflex.com/studies/VA2.htm)

<sup>11</sup> Id. at pp. 1.

<sup>12</sup> Id., Antler extract was orally administered to rat and dog to determine plasma level of chondroitin sulfate (pp. 8-9), Antler extract was administered to rats to study level of monocytes (pp. 11), antler was administered to male athletes to determine effect (pp. 14).

<sup>13</sup> Wang et al. "Effects of Repeated Administration of Deer Antler Extract on Biochemical Changes Related to Aging in Senescence-Accelerated Mice", Chem Pharm. Bull. 36, pp. 2587-2592.

<sup>14</sup> Id. at pp. 2589

500 mg/day orally for 90 days in rats<sup>15</sup>. It was reported that there were no pathological findings. Further, deer velvet powder was tested on reproduction and developmental toxicity, which was shown to have no effect on conception rates<sup>16</sup>.

#### Bovine Spongiform Encephalopathy (BSE) and Antler of Cervus elaphus (Linnaeus) (Cornu Cervi Pantotrichum)

CWD is known to be an infectious agent present in free-ranging deer and elk in Wyoming and Colorado. As for transmission to humans, current epidemiologic and laboratory investigations have concluded there is no strong evidence for a causal link between CWD and Creutzfeldt-Jakob disease (CJD-the form of TSE in humans)<sup>17</sup>. In developing such conclusion, the researchers reviewed several cases of humans who died of apparently rare neurological disorders. The patients did not appear to possess a common history with regards to exposure to deer or elk. Some patients apparently consumed venison, however it was not clear that the meat was infected with CWD. In some cases, the meat was from areas not known to be infected with CWD (Michigan)<sup>18</sup>. In addition, the report concluded that because there has not been an increase in the cases of CJD in Colorado and Wyoming (areas known to be infected with CWD), the risk of transmission to humans is low.

Further research has shown that a barrier at the molecular level likely limits the susceptibility of non-cervid species to CWD<sup>19</sup>.

#### Method of Preparing Antler of Cervus elaphus (Linnaeus) (Cornu Cervi Pantotrichum)

Antler of Cervus elaphus (Linnaeus) (Cornu Cervi Pantotrichum) as used in VI-28 is obtained from the People's Republic of China, an area not known to contain instances of CWD-infected deer. It is also believed the method of preparation of Cornu Cervi Pantotrichum likely addresses potential prion proteins. Cornu Cervi Pantotrichum is boiled and dried, then ground into a powder and incorporated into VI-28.

#### IV. CONCLUSION

The ingredient as used throughout the cited studies (Antler of Cervus elaphus (Linnaeus) (Cornu Cervi Pantotrichum)) is the same as the ingredient

---

<sup>15</sup> Suttie, J. and Harris, S. "Clinical Properties of Deer Velvet", [www.positivehealth.com/permit/Articles/Nutrition/sut54.htm](http://www.positivehealth.com/permit/Articles/Nutrition/sut54.htm).

<sup>16</sup> Id

<sup>17</sup> Belay et al. "Chronic Wasting Disease and Potential Transmission to Humans", Emerging Infectious Diseases, Center for Disease Control and Prevention, Vol. 10, No. 6 (2004).

<sup>18</sup> Id. at pages 4-5

<sup>19</sup> Raymond et al., "Evidence of a molecular barrier limiting susceptibility at humans, cattle, and sheep to chronic wasting disease", The EMBO Journal, Vol. 19, No. 17 (2000)

stated herein. The literature shows the ingredient administered at doses (2000mg/kg and 500 mg/day for 90 days) that are significantly higher than that of VI-28 (maximum 150 mg daily), with no ill effects. Further, because of the method of preparing the Antler, it is believed that prion proteins are likely eliminated. Therefore, it is believed the ingredient as used in VI-28 can reasonably be expected to be safe.

## Ingredient: Semen Cuscutae

I. INGREDIENT NAME: SEMEN CUSCUTAE (Cuscuta Chinensis Lam.; Cuscuta japonica Choisy)

II. INTENDED USE AND IDENTIFICATION: Semen Cuscutae is intended for use as an ingredient in the dietary supplement, VI-28. The dietary supplement will contain 60 mg of Semen Cuscutae per capsule, for a dietary intake of up to maximum 120 mg per day.

This ingredient can be identified as a botanical in accordance with 21 U.S.C. 321(ff).

### III. PRESENT IN FOOD SUPPLY

Semen Cuscutae has likely been present in the United States food supply, most likely in staple crops including soybean, potato, and pumpkin<sup>20</sup>. Specifically, Semen Cuscutae has been known to parasitize such staple crops. While being considered a parasite, it is a likely fact that during harvest, Semen Cuscutae was harvested along with the staple crop, and unknowingly utilized during the production of foods.

Further to its past use, Semen Cuscutae has frequently been known as a medicinal herb that is sold under a variety of names include "Dodder Seed Semen", "Cuscutae" and "Tu Si Zi"<sup>21</sup>.

### IV. HISTORY OF USE/SAFETY EVIDENCE FOR INGREDIENT:

The history of use of Semen Cuscutae can be established from a review of scientific literature. In one study, a dietary supplement, Equiguard<sup>TM</sup>, currently available in the United States, concluded that the ingredients of the dietary supplement were effective in prohibiting the effects of carcinoma<sup>22</sup>. Notably, Equiguard<sup>TM</sup> ingredients include Cuscuta Chinensis Lam. (Semen Cuscutae).

### V. CONCLUSION

The ingredient as used throughout the cited studies (Cuscuta Chinensis Lam.; Cuscuta japonica Choisy) is the same as the ingredient stated herein. Therefore, the proposed ingredient as used in VI-28 can reasonably be expected to be safe.

---

<sup>20</sup> NPAG DATA: Cuscuta Japonica (Japanese Dodder) 11/2001, pp. 5.

<sup>21</sup> Id. at pp. 8.

<sup>22</sup> Hsieh, T et al "Effects of herbal preparation Equiguard on hormone-responsive...", Intern. Jour. of Oncology 20: pp. 681-689 (2002).

Ingredient: Fructus Cnidii

I. INGREDIENT NAME: FRUCTUS CNIDII (Cnidii Monnieri Fructus (***Cnidium monnieri cusson, Matsuda***); Dried Fruits of *Cnidium monnieri*)

II. INTENDED USE AND IDENTIFICATION: Fructus Cnidii is intended for use as an ingredient in the dietary supplement, VI-28. The dietary supplement will contain 60 mg of Fructus Cnidii per capsule, for a dietary intake of maximum 120 mg per day.

This ingredient can be identified as a botanical in accordance with 21 U.S.C. 321(ff).

III. HISTORY OF USE/SAFETY EVIDENCE FOR COMPONENT:

The history of use of Fructus cnidii is established from a review of current products in the U.S. marketplace. Examples of such products include Stamina-Rx, a dietary supplement for "enhancing sexual performance", which contains 25 mg of *Cnidium monnieri* and instructions that use should not exceed 4 tablets in a 24-hour period, for a total dietary intake of 100 mg<sup>23</sup>. Watkins "Male Formula" is currently being sold in the U.S. to aid in optimizing male health. The formula includes a proprietary herbal blend in an amount of 500 mg that includes *Cnidium monnieri*<sup>24</sup>. Vagistatin is a product useful for "cervical dysplasia, HPV, and candidiasis". The ingredients of the supplement include *cnidium* fruit. No information is given as to the amount used or frequency of administration<sup>25</sup>.

Evidence of safety of Fructus cnidii is also shown in the scientific literature. In one study, the anti-inflammatory effects of a dietary supplement were determined upon application to rats. The dietary supplement, *Xuan-Ju*, contains in its ingredients Fructus *cnidii*. The supplement was administered at doses of .20, .40 and .80 g/kg<sup>26</sup>.

IV. CONCLUSION

The ingredient as used throughout the cited studies (Fructus *cnidii*) is the same as the ingredient stated herein. As the cited studies utilize the ingredient in doses similar to used in VI-28, it is believed the proposed use can reasonably be expected to be safe.

---

<sup>23</sup> Available at [www.stamina-rx.com/about.html](http://www.stamina-rx.com/about.html).

<sup>24</sup> Information available at [www.watkinsonline.com](http://www.watkinsonline.com).

<sup>25</sup> Information available at [www.emersonecologics.com](http://www.emersonecologics.com)

<sup>26</sup> Wei J et al. "Anti-Inflammatory effects of an herbal medicine (*Xuan-Ju* agent)...", *Journal of Ethnopharmacology*, 89(1) pp. 139-141 (2003).

## Ingredient: Kaempferiae Rhizoma

I. INGREDIENT NAME: KAEMPFERIAE RHIZOMA (rhizomes of Kaempferia galanga)

II. INTENDED USE AND IDENTIFICATION: Kaempferiae Rhizoma is intended for use as an ingredient in the dietary supplement VI-28. The dietary supplement will contain 30 mg of Kaempferiae Rhizoma per capsule, for a dietary intake of maximum 60 mg per day.

This ingredient can be identified as an extract in accordance with 21 U.S.C. 321 (ff).

### III. HISTORY OF USE/SAFETY EVIDENCE FOR NEW DIETARY INGREDIENT:

The history of use of Kaempferiae Rhizoma is established from a review of various Asian cultures. Kaempferia galanga (**Kaempferia galanga chekur, Vimala**) is cultivated in India, China, Malaysia, Indonesia, and Singapore. It is widely used as a flavoring in food, as well as a health aid. The rhizomes of Kaempferiae Rhizoma have been used to aid in abdominal pain, swelling, and rheumatism<sup>27</sup>.

Evidence of safety for Kaempferiae Rhizoma is also shown in the scientific literature. In one study, the cytotoxicity effect of rhizomes of Kaempferia galangal against EBV genome carrying human lymphoblastoid cells (Raji) was performed. It was determined that Kaempferia galangal exhibited no cytotoxicity effect<sup>28</sup>. In another study, the various constituents of Kaempferiae Rhizoma were determined<sup>29</sup>. Safety information regarding many of the constituents can be found in the literature including cineol (which is major component of sage oil, an ingredient used in the U.S.<sup>30</sup>), borneol<sup>31</sup>, 3-carene (in which dairy farmers during milking are regularly exposed to the compound<sup>32</sup>), kaempferol (in which guinea pig enterocytes were exposed to the compound in concentration of 50-450 microM, and kaempferol was determined to be less toxic<sup>33</sup>), and ethyl cinnamate (EC) (in which it was determined that EC, which is present in red wines as flavor,

---

<sup>27</sup> Othman et al. "Vasorelaxant Effects of Ethyl Cinnamate Isolated from Kaempferia galangal ..", *Planta Med.* 68, pp. 655-657 (2002).

<sup>28</sup> Vimala et al. "Anti-tumor promoter activity in Malaysian ginger. .", *British Journal of Cancer* 80, pp. 110-116 (1999).

<sup>29</sup> Kiuchi et al. "Studies on Crude Drugs effective on Visceral Larva..." *Chemical and Pharmaceutical Bulletin*, 36 (1) pp. 412-415 (1988). Constituents include cineol, borneol, 3-carene, camphene, kaempferol, kaempferide, cinnamaldehyde, p-methoxycinnamic acid, ethyl cinnamate, and ethyl p-methoxycinnamate.

<sup>30</sup> Farhat et al. "Seasonal changes in the composition of the essential oil...", (Abstract), PubMed record no. 11478969.

<sup>31</sup> Id.

<sup>32</sup> Sunesson et al. "Airborne chemical compounds..", (Abstract), PubMed record no. 11354733

<sup>33</sup> Canada et al. "The toxicity of flavonoids..." (Abstract), PubMed record no. 2734797.

may be responsible for the vasorelaxant activity of the rhizome of *Kaempferia galanga*<sup>34</sup>).

#### IV. CONCLUSION

The substance as used throughout the cited studies *KAEMPFERIAE RHIZOMA* (rhizomes of *Kaempferia galanga*) is similar to the component to be used in VI-28 (i.e., they are of the same genus and species). It is believed that the component can reasonably be expected to be safe.

---

<sup>34</sup> Id. at 26.