

0880 5 DEC 19 P1:48

13 December 2005

Division of Dockets Management  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852  
USA

### **CITIZEN PETITION**

The undersigned submits this **petition** under 21 CFR §10.30 of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to take the administrative action of clarifying, in writing, an FDA letter received in response to a pre-market notification.

#### *A. Action Requested*

1. This petition respectfully requests the Commissioner to take the administrative action of clarifying, in writing, whether or not the dietary supplement VI-28™, as detailed in the pre-market notification filed 18 August 2005, upon importation into the United States, shall be deemed adulterated under 402(f) based on reasoning provided in the FDA's letter to petitioner mailed October 13, 2005.

#### *B. Statement of Grounds*

1. Reasons for filing this petition

A FDA communication, dated October 13, 2005, was received in writing with regard to a pre-market notification filed on 18 August 2005 under 21 U.S.C.

2005P-0495

CPI

350b. The manufacturer had serious contentions with the FDA communication as a matter of law, however there was no instruction as to whether the manufacturer could respond to this communication, how the manufacturer should respond to this communication, or whether this communication was a "final agency action". Because the implications made by this communication severely affect the rights of the manufacturer, this petition has been filed.

## 2. Facts

### a) Procedural Summary

A pre-market notification was filed on 18 August 2005 in accordance with 21 U.S.C. 350b(2)<sup>1</sup> for the new dietary ingredients (NDIs) *Radix Ginseng*, *Cornu Cervi Pantotrichum*, *Fructus Cnidii*, *Semen Cuscutae*, and *Kaempferiae Rhizoma*, such ingredients being contained in the dietary supplement trademarked VI-28<sup>TM</sup>. Because the FDA has not provided any guidance on filing procedures for a dietary supplement containing multiple NDIs, the ingredients were provided in one filing, and presented on separated documents. A copy of the filed notification is submitted herewith (Attachment A).

Following an oral request by Ms. Victoria Lutwak of the Division of Dietary Supplement Programs (the Division), additional information was submitted, in writing, providing the address of the Notifier and an explanation to one reference submitted by the Notifier (Attachment B).

---

<sup>1</sup> 108 Stat. L. at 4331 (1994).

A letter with regard to the pre-market notification was received from the Division on October 13, 2005 (Attachment C). In the letter, the Division stated that,

“... your submission does not provide an **adequate basis** to conclude that “VI-28” when used under the conditions recommended or suggested in the labeling ... **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 a 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).”<sup>2</sup> (emphasis ours)

b) The subject matter of the previous filing

The pre-market notification previously filed was drawn to the ingredients *Radix Ginseng*, *Cornu Cervi Pantotrichum*, *Fructus Cnidii*, *Semen Cuscutae*, and *Kaempferiae Rhizoma*. Information on the ingredients included scientific articles, non-peer reviewed literature, and information on similar products.

The pre-market notification also included the **conditions of use** for the dietary supplement VI-28<sup>TM</sup>, and the **amount** of each ingredient included in each serving size.

It is unknown to the manufacturer of VI-28<sup>TM</sup> whether the ingredients have been marketed in the U.S. prior to 1994. The ingredients *Radix Ginseng*, *Fructus Cnidii*, *Kaempferiae Rhizoma*, and *Semen Cuscutae* are understood by the

---

<sup>2</sup> Letter dated October 13, 2005 from Linda S. Pellicore for Susan J. Walker, M.D. to Robert M. DeWitty, Esq.

manufacturer to be botanicals. The ingredient *Cornu Cervi Pantotrichum* is not a botanical. The Latin binomials and publishing authors for the botanical ingredients are:

---

|                     |                                  |
|---------------------|----------------------------------|
| Radix Ginseng       | <i>Panax ginseng</i> (C.A. Mey)  |
| Fructus Cnidii      | <i>Cnidium monnieri</i> (L.)     |
| Semen Cuscutae      | <i>Cuscutae chinensis</i> (Lam.) |
| Kaempferiae Rhizoma | <i>Kaempferia galanga</i> (L.)   |

---

## 2. Restatement of current dietary supplement law and regulation

### a) A Dietary Supplement

Under the Federal Food, Drug, and Cosmetic Act (FDCA), dietary supplements are currently regulated primarily by the provisions set forth in the Dietary Supplement and Health Education Act of 1994 ("DSHEA").<sup>3</sup> A dietary supplement under DSHEA is defined as "... a product intended to supplement the diet that ... contains one or more of the following dietary ingredients ... (c) a herb or other botanical; ... (e) a dietary substance for use by man to supplement the diet by increasing the total dietary intake ...".<sup>4</sup> Applied to VI-28<sup>TM</sup>, it is clear VI-28<sup>TM</sup> is a dietary supplement as it is intended to supplement the diet, and it contains botanicals (*Radix Ginseng*, *Fructus Cnidii*, *Semen Cuscutae*, and *Kaempferiae Rhizoma*), and a substance for use by man to supplement the diet by increasing the total dietary intake (*Cornu Cervi Pantotrichum*). Thus, VI-28<sup>TM</sup> falls under the provisions of DSHEA.

---

<sup>3</sup> 108 Stat. L. 4325; Pub. L. 103-417 (1994).

<sup>4</sup> 108 Stat. L. at 4327; 21 U.S.C. § 321 (ff).

b) Adulteration under dietary supplement law

Dietary ingredients to be included in a dietary supplement may either be “new” or “old”. A NDI is defined under DSHEA as being a dietary ingredient that was “... not marketed in the United States before October 15, 1994 ...”.<sup>5</sup> Dietary supplements that contain NDIs are deemed adulterated under section 402(f) of the FDCA.

However, the classification of a dietary supplement as adulterated under section 402(f) may be averted if, in one instance, the manufacturer:

“... provides the Secretary with information ... which is the basis upon which the manufacturer ... has concluded ... a dietary supplement containing the ingredient [the NDI] will **reasonably be expected to be safe**”.<sup>6</sup> (emphasis ours)

This instance has been deemed a “Pre-market Notification” by the FDA.<sup>7</sup>

If the manufacturer does not satisfy one of two instances, the dietary supplement is adulterated under 402(f) as,

“... [it] is 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** ...”<sup>8</sup> (emphasis ours)

In the instant case, VI-28<sup>TM</sup>, while containing NDIs, averts the classification of “adulterated” because the manufacturer satisfied one instance by

<sup>5</sup> Id. at 4331-2; 21 U.S.C. § 350b(c).

<sup>6</sup> Id.; 21 U.S.C. 350b(a)(2).

<sup>7</sup> 21 CFR 190.6.

<sup>8</sup> Id.; 21 U.S.C. §350b (a)

previously supplying the Secretary with evidence it used to conclude that the NDIs in VI-28<sup>TM</sup> offered a reasonable expectation of safety.

i. *Satisfying Pre-market Notification instance: Regulatory process*

Under 21 CFR 190.6, the pre-market notifications ("notifications") for NDIs should contain the "... name ... of the new dietary ingredient ... including the Latin binomial name (including the author of any herb or other botanical)".<sup>9</sup> As shown in this petition, the names of the dietary ingredients have been given, and the Latin binomials including the authors have been given for the botanicals. This information was also previously provided in the notification.

The levels or amount of the dietary ingredient in the supplement should be included in the notification.<sup>10</sup> In the instant case, the levels of the various ingredients are provided. This information was also previously provided in the notification. It should be noted that the levels used are deemed trade secrets by the manufacturer.

Information to be submitted to the Secretary is permitted to vary in quality and quantity. As the FDA stated,

"... the manufacturer is not required to do a complete literature search. It is required only to provide "the basis on which it has concluded a dietary supplement containing such dietary ingredient will **reasonably be expected to be safe** ... That is all

---

<sup>9</sup> 21 CFR 190.6(b)(2).

<sup>10</sup> The FDA stated "This provision is necessary to ensure that a manufacturer has considered information that directly bears on the safety of the new dietary ingredient of interest", 62 Fed. Reg. 49887 (1997).

the regulation requires.”<sup>11</sup>

The evidence to be submitted need only be that which led the manufacturer to the conclusion of a “reasonable expectation of safety”.<sup>12</sup> The FDA may review such conclusion,<sup>13</sup> however the pre-market notification process is not subject to substantive regulations.<sup>14</sup> The instance is satisfied following the manufacturer’s submission of evidence showing how and why he concluded the dietary supplement containing the new dietary ingredient to offer a “reasonable expectation of safety”. This instance is not subject to an “Approval” from the

---

<sup>11</sup> 62 Fed. Reg. 49888; 21 CFR 190.6 requires “... b) The notification required by paragraph (a) of this section shall include:

(1) The name and complete address of the manufacturer or distributor of the dietary supplement that contains a new dietary ingredient, or of the new dietary ingredient;

(2) The name of the new dietary ingredient that is the subject of the premarket notification, including the Latin binomial name (including the author) of any herb or other botanical;

(3) A description of the dietary supplement or dietary supplements that contain the new dietary ingredient including:

(i) The level of the new dietary ingredient in the dietary supplement; and

(ii) The conditions of use recommended or suggested in the labeling of the dietary supplement, or if no conditions of use are recommended or suggested in the labeling of the dietary supplement, the ordinary conditions of use of the supplement;

(4) The history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe, including any citation to published articles or other evidence that is the basis on which the distributor or manufacturer of the dietary supplement that contains the new dietary ingredient has concluded that the new dietary supplement will reasonably be expected to be safe. Any reference to published information offered in support of the notification shall be accompanied by reprints or photostatic copies of such references. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation; and

(5) The signature of the person designated by the manufacturer or distributor of the dietary supplement that contains a new dietary ingredient.

<sup>12</sup> 62 Fed. Reg. 49888.

<sup>13</sup> Id.

<sup>14</sup> Id.

FDA, but simply an acknowledgment that such information has been placed on the FDA docket.<sup>15</sup>

In the instant case, the manufacturer should have received acknowledgment of the notification being placed on the FDA docket, but such was not forthcoming.

ii. *Adulteration under 402(f)*

Under DSHEA, a food is adulterated if "... it is a dietary supplement or contains a dietary ingredient that ... is 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.**"<sup>16</sup>

(emphasis added). Regarding application of adulteration to such product,

"... the United States shall bear the burden of proof of each element to show that a dietary supplement is adulterated."<sup>17</sup>

To procedure, DSHEA asserts

"... Before the Secretary may report to a United States attorney a violation of paragraph (1)(A) ... the person against whom such proceeding would be initiated shall be given appropriate notice and the opportunity to present views, orally and in writing ..."<sup>18</sup>

---

<sup>15</sup> Following submission of a notification, the FDA provides the following language in a letter to the notifiers: "In accordance with the requirements of Section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day notification ...should be placed on public display in Docket 95S-0316 ...".

<sup>16</sup> 108 Stat. L. at 4328; 21 U.S.C. 342(f)(1)(B).

<sup>17</sup> *Id.*; 21 U.S.C. 342(f)(2).

<sup>18</sup> *Id.*

Viewing adulteration for a dietary supplement containing a NDI in view of the pre-market notification instance, it is believed that once the manufacturer has filed and provided evidence in a notification, he has met his burden, and thus averted the "adulteration" classification. Accordingly, his dietary supplement should not be subject to the provisions of 402(f) at the onset. Because the United States has the burden under 402(f) to prove the elements of adulteration, the manufacturer's initial burden can only be overturned upon some evidence provided by the FDA that questions the risk of illness or injury arising from use of the dietary supplement containing the NDI. If the FDA's evidence to the dietary supplement cannot be contradicted by the manufacturer through the submission of oral or written views, the supplement shall henceforth be deemed adulterated. **It does not appear as though the FDA can merely rely upon the evidence submitted by the manufacturer as being inadequate in and of itself.** At the very least, the FDA should be required to contradict the evidence submitted by the manufacturer by specific reference. Mere wholesale classification of evidence as "inadequate" does not show that the FDA has actually reviewed the manufacturer's evidence nor considered the level of NDI used in the supplement, and likely does not satisfy the statute. Additionally, wholesale classification of the manufacturer's evidence as "inadequate" would require the manufacturer to meet two burdens in his pre-market notification filing:

- 1) showing that the NDIs present a "reasonable expectation of safety";
- and

2) proving the "adequacy" of the information to show the NDIs do not present a significant or unreasonable risk of illness or injury.

The first burden is met by the manufacturer upon submission of the notification and evidence. Before it is required to address the second burden, the FDA should present specific evidence as to how and why the NDIs may present a significant or unreasonable risk of illness or injury. After the FDA's presentation of evidence, the manufacturer, under 402(f), is notified and given an opportunity to respond orally or in writing. If the FDA merely provides conjecture without evidence as to how and why the NDIs may present a significant or unreasonable risk of illness or injury, it has not met its burden under 402(f). The manufacturer should not be required to reply to mere conjecture with concrete data.

Furthermore, a determination that there is inadequate information requires a proceeding in which the manufacturer is notified and allowed to present views, orally or in writing, more than likely contradicting the FDA's assertion of inadequate information to provide assurance against significant or unreasonable risk of illness or injury. If a determination of adulteration under 402(f) is made **after submission of the pre-market notification**, and before the manufacturer has been notified and given an opportunity to contradict the FDA's evidence orally or in writing, his due process rights under the Fifth Amendment are likely being violated.

In Zotos International, Inc. v. Kennedy,<sup>19</sup> the plaintiff brought suit to challenge the FDA's denial of trade secret protection for its chemical-based cosmetic formula. In holding that the FDA failed to accord the manufacturer due

---

<sup>19</sup> 460 F. Supp. 268 (1978).

process rights by not disclosing the facts and assumptions upon which it relied prior to issuance of a final order, the court stated

“... before issuance of a final order a petitioner must have some means of engaging in a reasonably focused dialogue with the agency concerning the major points at issue and an opportunity to address the agency’s position and information on which it rests must be afforded, whether by written or spoken word ...”<sup>20</sup>

In the instant case, it is believed that a determination of adulteration for VI-28<sup>TM</sup> possessing the indicated NDIs should not have been made without the presentation of evidence by the FDA which questions the NDIs as posing a significant or unreasonable risk of illness or injury. If the FDA desired to make a determination of adulteration for VI-28<sup>TM</sup> under 402(f), the petitioner should be notified and have the opportunity to present his views, orally or in writing, to contest the FDA’s evidence and assertions. By declaring VI-28<sup>TM</sup> to be adulterated under 402(f) without the presentation of evidence, without notifying the manufacturer, or allowing the manufacturer an opportunity to present views, the FDA circumvented the plain-letter of the statute, as well as the interpretation provided to FDA procedures by the federal courts. Because it is prohibited to introduce an adulterated product into interstate commerce,<sup>21</sup> and if such product is introduced, it may be subject to condemnation,<sup>22</sup> seizure,<sup>23</sup> and destruction,<sup>24</sup> the property interests of the manufacturer are at issue. Thus, a determination of adulteration that is not in accordance with the statute is a violation of the due process rights of the manufacturer.

---

<sup>20</sup> Id. at 278.

<sup>21</sup> see, 21 U.S.C. §331 (a) and (v).

<sup>22</sup> 21 U.S.C. 334(a)(1).

<sup>23</sup> 21 U.S.C. 334(b).

<sup>24</sup> 21 U.S.C. 334(d)(1).

### 3. Analysis of FDA communication mailed October 13, 2005

In the FDA's communication, the FDA held that the "... information in ... [the] submission [did] not provide an **adequate basis** to conclude that VI-28 when used under the conditions recommended or suggested in the labeling ... will reasonably be expected to be safe." (emphasis added)<sup>25</sup> In support of their position, the FDA asserted it was "... unable to identify any of the new dietary ingredients that will be used to make VI-28", the notification did not specify which species within the genus *Cervus* will be the source of the ingredient *Cornu Cervi Pantotrichum*, and it was not stated which part of the plant or how the raw plant material will be processed for any of the four botanical ingredients of VI-28.

Further, the FDA stated the notification did not describe the manufacturing process used to combine the NDIs or information about the safety of the NDIs in the supplement VI-28. It is our contention that because the FDA's requirement that the information be "adequate" was improper, the support used by the FDA was beyond that allowed by the statute and did not adhere to current FDA regulations, the FDA has not proposed or published new or modified regulations, and the FDA concluded the dietary supplement was adulterated without notifying the manufacturer or providing an opportunity to respond orally or in writing, the FDA's letter was an improper violation of the FDCA in general, DSHEA, and the due process clause of the Fifth Amendment.

a) Requirement of "adequacy" improper at Pre-market Notification stage

---

<sup>25</sup> Attachment C at page 2.

As indicated, the FDA asserted that the information submitted did not "provide an adequate basis to conclude" VI-28 will reasonably be expected to be safe. The application of the "adequate basis" standard at this point is improper. DSHEA clearly states that the manufacturer should present evidence supporting his conclusion as to why the dietary supplement containing the NDI presents a "reasonable expectation of safety". By requiring the information to be "adequate" the FDA has modified 21 U.S.C. 350b(a)(2) ("pre-market notification instance"), and their own regulations by setting a standard that the evidence (information) must reach to be higher than that in the statute. By the FDA's own comments, the evidence to be submitted may vary in quality and quantity.<sup>26</sup> The standard of the evidence to be submitted by the manufacturer need only show how and why he was able to determine the NDIs offer a "reasonable expectation of safety".<sup>27</sup> There is no verbal equivalent in 21 U.S.C. 350b to the term "adequate". By inserting this standard, the FDA has unconstitutionally taken on the role as legislator, modifying the law as it deems suitable.<sup>28</sup>

In the instant case, the manufacturer supplied evidence to the Secretary establishing how and why he came to the conclusion that VI-28 containing the NDIs *Radix Ginseng*, *Cornu Cervi Pantotrichum*, *Fructus Cnidii*, *Semen Cuscutae*, and *Kaempferiae Rhizoma* offers a reasonable degree of safety. The manufacturer showed evidence of considering the amounts of the NDIs used in VI-28 by including them in the notification. It is believed the manufacturer had

---

<sup>26</sup> 62 Fed. Reg. 49888

<sup>27</sup> Id.

<sup>28</sup> Contrast this with the FDA's stated comment that "The agency ... in deciding what information needs to be provided, is bound by the standard of the act. It is not free to rewrite the law." (62 Fed. Reg. at 49888).

met his burden under the statute. Whether or not the information is "adequate" can be addressed during proceedings relating to the possibility of VI-28 being an adulterated product.

b) Support provided by the FDA was beyond that allowed by statute and required in 21 CFR 190.6

Under current FDA regulations, the FDA has not defined the level of quality and quantity of evidence to be submitted by manufacturers in pre-market notifications. Instead, the type of evidence to be submitted is based upon that which leads the manufacturer to conclude that the dietary supplement containing the NDI's offers a reasonable degree of safety. As stated in Zotos,

"It is axiomatic that once an agency commits in its regulations to adhering to certain principles or procedures, it cannot violate them."<sup>29</sup>

That the FDA has committed itself to the current regulation, 21 CFR 190.6, is evident in comments made and published.<sup>30</sup> The petitioner is not aware of the FDA proposing new regulations to replace 21 CFR 190.6, or proposed modifications to the current regulations.

In the instant case, the FDA has stated that it was unable to identify the new dietary ingredients used to make VI-28. However, the manufacturer had identified the botanicals by their Latin binomials and corresponding authors in accordance with the regulations.<sup>31</sup> The FDA commented that it was not clear as to what is the source of the ingredient *Cornu Cervi Pantotrichum*. The FDA has

---

<sup>29</sup> Zotos at 275.

<sup>30</sup> see 62 Fed. Reg. 49888 et seq.

<sup>31</sup> see Attachment A.

indicated that we did not provide the species for the ingredient *Cornu Cervi Pantotrichum*, however as this ingredient is not a botanical, the Latin binomial or author were not required by the regulations. Various species of deer antler were provided to show the general nature of the use of deer antler in supplements, and the safety associated with their use. Additionally, it was stated that *Cornu Cervi Pantotrichum* is also known as Pilose Antler. One piece of evidence submitted was directed to Pilose Antler, entitled "Young Pilose Antler-A Precious Crude Drug". The FDA, through an oral request, desired more information on this reference, which was delivered in the letter filed by notifier dated 29 August 2005. In its request, the FDA did not indicate that it was contesting the safety of this NDI when requesting more information.

The FDA also indicated that we did not indicate the part of the plant to be used or how it will be processed. This information was not required to be stated under the current regulations. The manufacturer should not be expected to mind-read or anticipate what the FDA deems necessary if it has not been promulgated and published in current regulations. All the manufacturer can do is follow the regulations made available to it.

FDA has also indicated that the manufacturing process used to combine the NDI's was not provided. Again, such information has not been promulgated for. By providing the amounts of NDI's used in VI-28, the manufacturer has shown that he has considered the amounts when concluding VI-28 offers a reasonable expectation of safety.

The FDA has further indicated that evidence about the safety of the NDI's combined in VI-28 was not provided. Again, the request for such information by FDA goes beyond current promulgated regulations. What type of study should be conducted on VI-28? How long should the study occur for? Where should the studies be conducted? The ambiguity in such a request is outstanding. The FDA has requested information that clearly goes beyond their current regulations, and the intent of the Congress when passing DSHEA,

"DSHEA fulfills that purpose by ... defining dietary supplements [and] directing FDA that they are not to be regulated as drugs or food additives ..."<sup>32</sup>

The standard for drugs should not be used, nor should the standard for food additives be used, so which standards should be used? Regardless of what the answer is, it should not be up to manufacturers to decipher such a riddle.

By relying upon regulations that have not been formally proposed and published, interested parties are "operating in the dark". If the FDA decides to implement regulations without informing interested parties what those regulations are, such would be a clear violation of fairness. The FDA could supposedly implement the unpublished regulations against some, but not implement them against others. Those who were subject to the unpublished regulations would be required to expend large sums to satisfy regulations unknown to them or to others. Simultaneously, those that are not subject to the unpublished regulations would clearly have an unfair advantage by not being required to expend resources to overcome the unpublished regulations. If the FDA desires new regulations,

---

<sup>32</sup> Pharmanex v. Shalala, 35 F. Supp.2d 1341 (1999).

procedure must be followed under Administrative Procedure Act.<sup>33</sup> At present date, all manufacturers can do is follow what has been published and what the FDA deems as being their current regulatory procedure. The manufacturer of VI-28 has done just that, satisfying the FDA's current published regulations. To subject him to regulations of which are unpublished would subject him to "arbitrary and capricious" findings by the FDA, and possibly discriminatory treatment.

c) The FDA has not proposed nor promulgated modified or new regulations

The manufacturer notes that current regulations as they relate to pre-market notifications for dietary supplements are promulgated in 21 CFR 190.6. These regulations were relied upon when filing the notification. The FDA has not proposed new or modified regulations, nor has it published new regulations. The notifier was not made aware of any changes to 21 CFR 190.6, thus the application of new or modified regulations that are not published or made known to interested third parties is a violation of administrative procedure, and possibly constitutional violations.

d) FDA's conclusion of adulteration violates of due process rights

In it's communication, the FDA concluded that VI-28 may be adulterated under 21 U.S.C. 342(f)(1)(B). It is believed this conclusion is a violation of the manufacturer's due process rights as the FDA has failed to notify the manufacturer of a proceeding to determine adulteration, and has not provided the

---

<sup>33</sup> 5 U.S.C. §561 et seq.

manufacturer an opportunity to present views, orally or in writing, to contradict the FDA's conclusion.

The manufacturer satisfied its burden under DSHEA by submitting a pre-market notification. In its letter, the FDA concluded that the dietary supplement may be adulterated under FDCA. However, the FDA did not communicate the evidence it relied upon in making its determination. Merely stating an inability to identify a new dietary ingredient likely does not support a case for adulteration under 402(f). The FDA did not present any case of harm when using the NDIs, nor any information or question on illness arising from use of the NDIs. In fact, the FDA did not provide one scintilla of evidence or even mere conjecture questioning the safety of the NDIs. The manufacturer is unaware why the FDA was not able to identify the ingredients; the amounts were given for each NDI, the Latin binomials and authors were provided for all botanicals, and evidence was submitted for each NDI.

The FDA did not accord the manufacturer an opportunity to respond to FDA evidence, orally or in writing. As the manufacturer's property interest are at issue due to the fact its product may be condemned, seized, and destroyed, upon entering interstate commerce, the FDA's determination is a violation of the manufacturer's due process rights.

The petitioner takes note of the specific language used by the FDA in its communication that the product "... **may** be adulterated under 21 U.S.C. 342(f)(1)(B) ..." (emphasis added). The FDA may intend this to mean adulteration is not definite, but it does not give the manufacturer any idea of how

its product would be affected. As the manufacturer imports its product into the U.S., it is subject to Prior Notice as administered by the U.S. Customs and Border Protection (CBP) agency.<sup>34</sup> To satisfy the Prior Notice, the FDA works with the CBP to address imported foods (including dietary supplements). Whereas in the communication the FDA asserts that the product may be adulterated, upon the submission of Prior Notice, **Will the FDA inform the CBP that VI-28 is adulterated, and then subject it to seizure and detention? or Will the FDA inform the CBP that the manufacturer has filed the pre-market notification and therefore is not subject to detention or seizure?** The manufacturer cannot make a determination either way, and thus is at a severely unfair disadvantage, and potential loss of his property. The inability to determine if the goods will be detained, seized, and destroyed does not give sufficient notice in sufficient time to the manufacturer. As stated in Zotos,

“...it is ... fundamental that notice be given and that it be timely and clearly inform the individual of the proposed action and the grounds for it. Otherwise, the individual likely would be unable to marshal evidence and prepare his case so as to benefit from any hearing that was provided”<sup>35</sup>

If the manufacturer ships VI-28 to the U.S. for importation, and the FDA informs CBP that the goods are adulterated under 402(f) for the reasons stated in their communication, resulting in detainment, the manufacturer has no other choice but to destroy the goods or incur the expense of shipping them back to their origination. Thus, the use of the FDA's language of “may” in their communication still leads to the violation of the due process rights of the manufacturer.

---

<sup>34</sup> Pub. L. 107-188 (2002).

<sup>35</sup> Zotos at 274.

*C. Environmental Impact*

A. The petitioners herein make a claim of categorical exclusion under 21 CFR §25.30.

*D. Economic Impact*

*(to be submitted if requested by the Commissioner)*

*E. Certification*

The undersigned certifies, that, to the best knowledge and belief to the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Signed:



Name of petitioner: Robert M. DeWitty, Esq. on behalf of

Vigconic (International) Ltd.

Mailing Address: 111 S. Calvert Street, Ste. 2700, Baltimore, Maryland 21202

Telephone Number: 410-539-6969 (tele)

Fax Number: 410-510-1973 (fax)