

Memorandum

MAY 1 2006

Date:

From: Consumer Safety Officer, Division of Dietary Supplement Programs, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: CVT-E002 (*Panax quinquefolius*)

Firm: CVT Technologies Inc.

Date Received by FDA: 01/18/2006

90-Day Date: 04/18/2006

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

____Victoria Lutwak____

19955-0316

RPT 331



APR 17 2006

Patrick W. Noonan
Warner Center Plaza, suite 840
21800 Oxnad Street
Woodland Hills, MD. California, 91367

Dear Mr Noonan:

This is to inform you that the notification you submitted, on behalf of you client CV Technologies, dated January 18, 2006, 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 January 18, 2006. Your notification concerns the substance called " CVT-E002 " a dried powder extract form Panax quinquefolius L that you intend to market as a new dietary ingredient.

According to the notification you stated the following suggested conditions of use for CVT-E002 is 400 mg per day consumed as two gelatin (bovine or porcine origin) capsules each containing of 200 mg of CVT-E002 (your web site recommends a significant higher dose). CVT-E002 is recommended for adults and children 12 years or older for the specific intended use of strengthening the immune system. You also stated that individuals with serious health conditions, individuals taking other medications, pregnant women, lactating women and those with allergies to ginseng should consult a health care professional before using the product.

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 section 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 21U.S.C. 342(f)(1)(B) 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.

In accordance with 21 CFR 190.6(c), FDA must acknowledge its receipt of a notification for a new dietary ingredient. For 75 days after the filing date, your client must not introduce or deliver for introduction into interstate commerce any dietary supplement that contains the new dietary ingredient that is the subject of this notification.

Please note that acceptance of this notification for filing is a procedural matter, and thus, does not constitute a finding by FDA that the new dietary ingredient or supplement that contains the new dietary ingredient is safe or is not adulterated under 21 U.S.C. 342. FDA is not precluded from taking action in the future against any dietary supplement containing your new dietary ingredient if it is found to be unsafe, adulterated, or misbranded.

Your notification will be kept confidential for 90 days after the filing date of January 18, 2006. After the 90-day date, the notification will be placed on public display at FDA's Division of Docket Management 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.

If you have any questions concerning this matter please contact Linda Pellicore, Ph.D., at (301) 436-237

Sincerely yours,

Linda S. Pellicore
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



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

5100 Paint Branch Parkway
Food and Drug Administration
College Park, Maryland 20740

W. Patrick Noonan
Warner Center Plaza, Suite 840
21800 Oxnard Street
Woodland Hills, California 91367

APR 3 2006

Dear Mr. Noonan:

This is to inform you that the notification you submitted, on behalf of your client CV Technologies, dated January 18, 2006, 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 January 18, 2006. Your notification concerns the substance called " CVT-E002 " a dried powder extract from *Panax quinquefolius L* that you intend to market as a new dietary ingredient.

According to the notification you stated the following suggested conditions of use for CVT-E002 is 400 mg per day consumed as two gelatin (bovine or porcine origin) capsules each containing of 200 mg of CVT-E002 (your web site recommends a significant higher dose). CVT-E002 is recommended for adults and children 12 years or older for the specific intended use of strengthening the immune system. You also stated that individuals with serious health conditions, individuals taking other medications, pregnant women, lactating women and those with allergies to ginseng should consult a health care professional before using the product.

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 section 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) 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.

This letter is to alert you within the 75-day notification period that FDA intends to complete its evaluation within a few weeks and send you a response to your notification. Please note that a lack of a response to a notification within the 75-day timeframe does not constitute a finding by the agency that the ingredient or a product that contains the ingredient is safe or is not adulterated under 21 U.S.C. 342. See 21 C.F.R. 190.6(f).

If you have any questions concerning this matter, please contact Linda S. Pellicore, Ph.D. at (301) 436-2375.

Sincerely yours,

Linda S. Pellicore

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

LAW OFFICES

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January 12, 2006

Via Federal Express

Office of Nutritional Products, Labeling,
And Dietary Supplements (HFS-820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740-3835

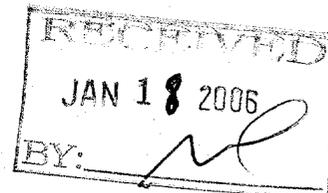
Re: New Dietary Ingredient Notification:
CVT-E002

Dear Sir or Madam:

Enclosed please find an original and two copies of the 75 day pre-market notification for the dietary ingredient CVT-E002 (proprietary American ginseng extract comprised primarily of poly-furanosyl-pyranosyl-saccharides) as required by Section 413(a)(2) of the Food, Drug, and Cosmetic Act (FDC Act) and regulation issued by the Food and Drug Administration (FDA) at 21 CFR Section 190.6.

Please note that pursuant to 21 CFR Section 20.61, we request that Sections 2, 3, and 6 which contain a description of the dietary ingredient, manufacturing processes, product specifications, analytical testing procedures, history of use discussion which contains proprietary data, and unpublished clinical studies included as Attachments 7, 9, 10, 11, 12, and 15 be considered confidential information.

CVT-E002 is a patented and proprietary multi-component dried (powder) extract derived from the root of cultivated botanical source material North American ginseng (*Panax quinquefolius* L., Fam. Araliaceae). The submission contains a table of contents that will allow quick reference to the attached documents and scientific studies. Within



2006-326

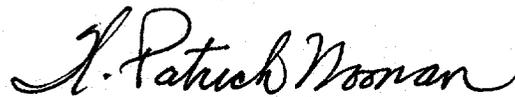
Office of Nutritional Products, Labeling,
And Dietary Supplements (HFS-820)
January 12, 2006
Page 2

W. PATRICK NOONAN, P.C.

50 days after receipt of our 75-day pre-market notification by FDA, we intend to call the agency to discuss the review status of the notification.

We appreciate your attention to this submission. If you should have any questions regarding the notification, please contact me immediately.

Sincerely,

A handwritten signature in black ink that reads "W. Patrick Noonan". The signature is written in a cursive, flowing style.

W. Patrick Noonan

Enclosures