



NOV 24 1998 DEC 11 A 6:49

Mr. William Swan  
Continental Vitamin Company, Inc.  
4510 South Boyle Avenue  
Vernon, California 90058

Dear Mr. Swan:

This is in response to your letter of November 20, 1998 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Continental Vitamin Company, Inc. is making the following claims, among others, for the products:

**Instant Release Zinc Lozenjets**

“Helps fight cold and flu symptoms”

**Instant Release Arthritis Helper**

“Herbal supplement for arthritis support”

Your submission also states that you are making claims for a product named **No Shot Instant Release B12/Folic**.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases, namely, cold and flu and arthritis, and in the case of the product “No Shot Instant Release B12/Folic,” that it is intended for use as an alternative to an approved drug product. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA’s Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Your submission also states that you are making claims for a product named **Instant Release Aloe Vera 5000mg**. This product does not meet the statutory definition of a dietary supplement contained in 21 U.S.C. 321(ff), and therefore, can not be marketed as a dietary supplement.

The term "dietary supplement" is defined in 21 U.S.C. 321(ff). 21 U.S.C. 321(ff) provides that the term means a product (other than tobacco) intended to supplement the diet that bears or contains a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above ingredients. 21 U.S.C. 321(ff) further states that dietary supplements are intended for ingestion in a form described in 21 U.S.C. 350(c)(1)(B)(i) or in compliance with 21 U.S.C. 350(c)(1)(B)(ii), are not represented as conventional food or as a sole item of a meal or the dietary, and are labeled as a dietary supplement.

**Instant Release Aloe Vera 5000mg** is not a product "intended for ingestion." As stated above, the definition of dietary supplement in 21 U.S.C. 321(ff) states that a dietary supplement is a product "intended for ingestion." The term "ingestion" has been addressed by the court in United States v. Ten Cartons, Ener-B Nasal Gel, 888 F. Supp. 381, 393-94 (E.D.N.Y.), aff'd, 72 F.3d 285 (2d Cir. 1995), which states:

The ordinary and plain meaning of the term "ingestion" means to take into the stomach and gastrointestinal tract by means of enteral administration. See Stedman's Medical Dictionary (4th Lawyer's Ed. 1976) (defining ingestion as the "introduction of food and drink into the stomach."); Webster's Third New International Dictionary (1976) (defining ingestion as "the taking of material (as food) into the digestive system.")...

The interpretation of the term "ingestion" to mean enteral administration into the stomach and gastrointestinal tract is also supported by the language of the statutory sections immediately preceding and following section 350(c)(1)(B)(ii). Section 350(c)(1)(B)(i) states that the vitamin must be intended for ingestion in tablet, capsule or liquid form. Each of these forms denotes a method of ingestion that involves swallowing into the stomach. Section 350(c)(2) states that a food is intended for ingestion in liquid form under section 350(c)(1)(B)(i) "only if it is formulated in a fluid carrier and is intended for ingestion in daily quantities measured in drops or similar small units of measure." This elaboration of "liquid form" also denotes ingestion by swallowing the fluid.

Therefore, because the term "ingestion" means introduced into the gastrointestinal tract, a product applied to the skin is not subject to regulation as a dietary supplement because it is not "intended for ingestion." Moreover, the claims made for this product, namely that it is intended for use as "first aid for minor skin irritation" and for its

Page 3 - Mr. William Swan

“natural healing properties,” suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act

Please contact us if you require further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.  
Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200  
FDA, San Francisco District Office, Office of Compliance, HFR-PA140

cc:

HFA-224 (w/incoming)  
HFA-305 (docket 97S-0163)  
HFS-22 (CCO)  
HFS-456 (file)  
HFS-450 (r/f, file)  
HFD-310 (BWilliams)  
HFD-314 (Aronson)  
HFS-600 (Reynolds)  
HFS-605 (Bowers)  
GCF-1 (Dorsey, Nickerson)  
f/t:HFS-456:rjm:11/24/98:docname:62446.adv:disc33



CONTINENTAL VITAMIN COMPANY

RECEIVED  
11/23/98

November 20, 1998

Office of Special Nutritional (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. St. S.W.  
Washington, DC 20204

Notice of Descriptive Claim

Text of description claims:

- 1) Helps fight cold and flu symptoms
- 2) Safe for children

Name of dietary ingredient that is the subject of the statements:

- 1) Zinc and Vitamin C

Brand name of dietary supplement:

Instant Release Zinc Lozenjets

I certify that this information presented and contained in this notice is accurate.

  
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Continental Vitamin Company, Inc.  
4510 South Boyle Ave.  
Vernon, CA 90058

62446



CONTINENTAL VITAMIN COMPANY

November 20, 1998

11/23/98

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Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. St. S.W.  
Washington, DC 20204

Notice of Descriptive Claim

Text of description claims:

- 1) Assists calcium absorption
- 2) Helps promote natural energy

Name of dietary ingredient that is the subject of the statements:

- 1) Folic Acid, Vitamin B12
- 2) Folic Acid, Vitamin B12

Brand name of dietary supplement:

No Shot Instant Release B12/Folic

I certify that this information presented and contained in this notice is accurate.

William [Signature] (dd)

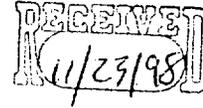
Continental Vitamin Company, Inc.  
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Vernon, CA 90058

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CONTINENTAL VITAMIN COMPANY

November 20, 1998



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Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. St. S.W.  
Washington, DC 20204

Notice of Descriptive Claim

Text of description claims:

- 1) Imparts natural healing properties
- 2) First aid for minor skin irritation

Name of dietary ingredient that is the subject of the statements:

- 1) Aloe Vera
- 2) Aloe Vera (applied to skin)

Brand name of dietary supplement:

Instant Release Aloe Vera 5000mg.

I certify that this information presented and contained in this notice is accurate.

William Suran  
(d)

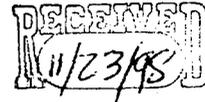
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Washington, DC 20204

Notice of Descriptive Claim

Text of description claims:

- 1) Herbal supplement for arthritis support

Name of dietary ingredient that is the subject of the statements:

- 1) Devils Claw, White Willow Bark, Fever Few, Angelica Root, Chamomile, Sarsaparilla, Ginger

Brand name of dietary supplement:

Instant Release Arthritis Helper

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