



NOV - 5 1998

9 3 4 2 '98 DEC -1 P1 :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 October 29, 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 statements, among others, for the product:

Superior Source Instant Release Head-Ade Helper

“Natural headache formula”

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 statement that you are making for this product suggests that it is intended to treat, prevent, mitigate, or cure diseases, namely, headaches. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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. 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.

Your submission also indicates that, for the product **Superior Source Instant Release Folic Acid/B-6**, you are making the claim “Helps prevent neural tube defects.”

This statement is not a statement of nutritional support subject to 21 U.S.C. 343(r)(6), but is a health claim subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between folate and neural tube defects (see 21 CFR 101.79). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between folate and neural tube defects. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.79 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.79 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, neural tube defects.

97S-0163

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Please contact us if we may be of 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)

f/t:HFS-456:rjm:11/5/98:docname:62120.adv:disc33



CONTINENTAL VITAMIN COMPANY

11/4/98

October 29, 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 lower homocysteine levels
- 2) Helps prevent neural tube defects

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

- 1) Vitamin B6 & Folic Acid
- 2) Folic Acid

Brand name of dietary supplement:

Superior Source Instant Release Folic Acid/B-6

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

William Swan

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

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Also see docket 975-0163



CONTINENTAL VITAMIN COMPANY

October 29, 1998

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11/4/98

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) Natural headache formula

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

- 1) White Willow Bark
Ginkgo Biloba Leaf

Brand name of dietary supplement:

Superior Source Instant Release Head-Ade Helper

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

William Swan

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

Also see docket 975-0163

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