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Patti Ann Kelly, Ph.D.
Director of Scientific and Regulatory Affairs
Vitamin Shoppe Industries, Inc.
4700 West Side Avenue
North Bergen, New Jersey 07047

Dear Dr. Kelly:

This is in response to your letter of September 15, 2000 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 you are making the following claim, among others, for the product **Folic Acid** (VS# 1148, 1149, and 1527): "Deficiencies of folic acid have been linked to some forms of birth 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 for folate and neural tube defects 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, making a claim that is not 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.

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

975-0163

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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, New Jersey District Office, Office of Compliance, HFR-MA240

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (file, r/f)
HFS-810
HFS-811 (file)
HFD-310
HFD-314 (Aronson)
HFS-605
HFV-228 (Betz) --
GCF-1 (Dorsey, Nickerson)
f/t:HFS-811:rjm:9/28/00:docname:72618.adv:disc51

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September 15, 2000

Rec'd
SEP 26 2000

Dr. Robert Moore
Branch Chief (HFS-811)
Dietary Supplements Branch
Food and Drug Administration
200 C Street S.W.
Washington D.C. 20204

Re: FDCA 403(r)(6) Notification

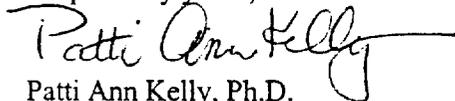
Dear Dr. Moore:

Pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 343(r)(6), and implementing Food and Drug Administration regulation, 21 C.F.R. 101.93 (62 Fed. Reg. 49886 (Sept 23, 1997)), Vitamin Shoppe Industries Inc. submits this notification that statements are included in labeling its dietary supplements, as attached.

Vitamin Shoppe Industries Inc. at 4700 Westside Avenue, North Bergen, New Jersey is the distributor of the dietary supplements.

The undersigned certifies that the information contained in this notice is complete and accurate, and that the notifying firm has substantiation that each statement is truthful and not misleading.

Respectfully yours,



Patti Ann Kelly, Ph.D.
Director of Scientific and Regulatory Affairs
Vitamin Shoppe Industries Inc.

<u>Product Names</u>	<u>VS#</u>	<u>Ingredients</u>	<u>Structure/Function Statements</u>
No-Flush Niacin	1310, 1311	Hexaniacinate	1) Hexaniacinate is metabolized in the body to niacin and inositol.
Niacinamide Yeast Free	1532, 1533	Niacinamide	1) Niacinamide is a major form of niacin in the blood, participating in the metabolism of fats and supports the health of the nervous system.
Folic Acid	1148, 1149 1527	Folic Acid	1) Folic acid, along with Vitamin B-6 and B-12 promote a healthy cardiovascular system. 2) Folic acid is vital to the development of the nervous system in a growing fetus. 3) Deficiencies in folic acid have been linked to some forms of birth defects.
Co Enzyme Q10	1088, 1089 1090 1230 1276,1277 1260, 2134 2135	Coenzyme Q10	1) Coenzyme Q10 is a nutrient required by every cell in the body for energy support.

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