



JUN - 4 1999

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Ms. Ann Holden
Standard Process, Inc.
1200 West Royal Lee Drive
Palmyra, Wisconsin 53156

Dear Ms. Holden:

This is in response to your letter of May 26, 1999 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 Standard Process, Inc. is making the following claim, among others, for the product **Folic Acid B₁₂**:

“...significant protection from developing a neural tube defect during pregnancy”

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,

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

975-0163

LET 278

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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, Minneapolis District Office, Office of Compliance, HFR-MW340

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)

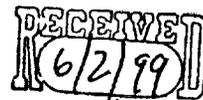
GCF-1 (Dorsey)

f/t:HFS-456:rjm:6/4/99:docname:65434.adv:disc38



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May 26, 1999



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

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) We have chosen and combined the finest in whole food ingredients to bring you Folic Acid B₁₂, helping to maintain your heart and mind as well as offering many other significant benefits.*
- (2) It gives your body what it needs to keep your heart healthy, your cells dividing at a normal rate, and significant protection from developing a neural tube defect during pregnancy.*
- (3) Standard Process Folic Acid B₁₂ helps regulate your metabolism and makes you feel better.*

These statements are made for a dietary supplement containing a proprietary blend of carrot (root), calcium lactate, porcine stomach parenchyma, defatted wheat (germ), bovine spleen, ovine spleen, bovine adrenal Cytosol™ extract, oat flour, and ascorbic acid. Other ingredients include honey, cellulose, folic acid, and cyanocobalamin. The name of the product is Folic Acid-B₁₂.





**Standard
Process®**

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann M. Holden

Ann Holden
Standard Process Inc.

