



MAY 27 1999 9 423 '99 JUN -2 P1:22

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 April 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 **Allerplex**:

“...assist the body in defending itself naturally during seasonal challenges.”

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, including the name of the product, suggests that it is intended to treat, prevent, or mitigate a disease, namely, allergies. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims 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. 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 you are making the following claim for the product **Folic Acid-B₁₂**:

“Adequate folate in healthful diets may reduce a woman's risk of having a child with a brain or spinal cord birth defect. As part of a healthy diet, the daily value for folic acid intake is 400 mcg daily.”

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

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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

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)
r/d:HFS-456:RMoore:5/4/99
Revised:GCF-1:ABarnett:5/25/99
f/t:HFS-456:rjm:5/25/99:docname:64912.adv:disc37



6/4/99

April 26, 1999

RECEIVED
5/3/99

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) Adequate folate in healthful diets may reduce a woman's risk of having a child with a brain or spinal cord birth defect. As part of a healthy diet, the daily value for folic acid intake is 400 mcg. daily.*
- (2) Folic acid maintains a healthy heart. The amino acid, homocysteine, has been shown to play a significant role in heart health. Folic acid works to reduce levels of homocysteine in the blood to sustain more acceptable levels.*
- (3) Folic acid helps maintain the healthy structure and function of DNA and cells.*
- (4) These vitamin complexes taken together work to mature and strengthen red blood cells. Another function of these vitamin complexes is in the process of DNA formation and the replication of genetic material.*

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.





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.





RECEIVED
5/3/99

April 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) Allerplex is one of many products Dr. Lee developed to assist the body in defending itself naturally during seasonal challenges.*
- (2) Allerplex aids in maintaining proper pH balance.*
- (3) Allerplex helps maintain a healthy immune system. Among many other important functions, the role of calcium in the diet has also been shown to increase immune efficiency.*
- (4) Allerplex helps maintain healthy function of the sinuses and lungs.*
- (5) Allerplex helps maintain cellular health. The antigenic properties of these nucleoprotein-mineral molecules promote healthy cellular division, growth, repair, and function. The primary purpose of lung PMG™ extract is to support the healthy function of the lungs and upper respiratory system. Adrenal PMG™ extract is an ingredient that is formulated to help maintain the healthy functioning of the adrenal glands.*
- (6) Contains Yakriton, an uncommon bovine liver fat extract that has been shown to help maintain a healthy liver through it's ability to aid in filtering blood.*
- (7) Protomorphogen™ extracts provide nutritional ingredients and support for the corresponding organs in human.*





**Standard
Process®**

These statements are made for a dietary supplement containing the proprietary blend of *tillandsia usneoides*, fenugreek (seed), betaine hydrochloride, soy (bean), bovine lung PMG™ extract, carbamide, carrot (root), oat flour, bovine adrenal PMG™ extract, bovine liver fat extract (Yakriton), alfalfa flour, dried alfalfa juice, bovine bone, dried buckwheat (leaf) juice, defatted wheat (germ), bovine kidney, veal bone, soy bean lecithin, peanut (bran), mixed tocopherols, and carrot oil. Other ingredients include gelatin, calcium lactate, magnesium citrate, potassium bicarbonate, water, calcium stearate, natural colors, ascorbic acid, and vitamin A palmitate. The name of the product is Allerplex™.

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

Sincerely yours,

Ann Holden
Standard Process Inc.

