



FEB - 4 2002

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Ms. Ann Holden
Standard Process, Inc.
1200 West Royal Lee Drive
P.O. Box 904
Palmyra, Wisconsin 53156-0904

Dear Ms. Holden:

This is in response to your letter of November 15, 2001 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 claims, among others, for the product **For-Til B12^o**:

“...support normal glucose and cholesterol at normal levels with a well balanced diet.”

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 this product suggests that it is intended to treat, prevent, or mitigate diseases, namely hypercholesterolemia and disorders of blood sugar regulation. 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.

975-0163

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Page 2 - Ms. Ann Holden

Please contact us if you require 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

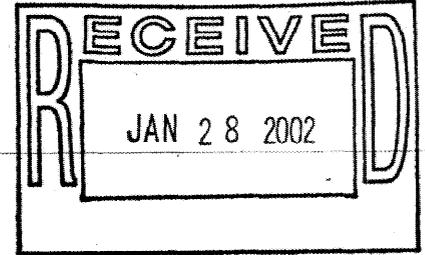
Copies:

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 Compliance, HFR-MW240

November 15, 2001



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. *Tillandsia usneoides* (tillandsia) finds its roots in South American folklore to boost immunity function.
2. Tillandsia has long been used in the form of a tea to support normal glucose and cholesterol at normal levels with a well balanced diet.
3. The compounds found in For-Til B12 help keep the heart and blood vessels healthy.

These statements are made for a dietary supplement containing gelatin, water, natural colors, and calcium stearate. The name of the product is For-Til B12®.

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.



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