



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

DEC 28 1999

1625 '00 JAN -4 P2 04

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 December 15, 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 statement, among others, for the product "Symplex[®]M:"

"...neutralizing autoimmune conditions."

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 claims that you are making for this product suggest that it is intended to treat, cure, prevent, or mitigate disease, in that it is intended to treat, cure, prevent, or mitigate autoimmune diseases and disorders. 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.

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

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Page 2 - Ms. Ann Holden

Copies:

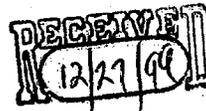
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Minneapolis District Office, Compliance Branch, HFR-MW340

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-456 (r/f, file)
HFS-450 (r/f, file)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-605
HFV-229 (Benz)
GCF-1 (Barnett, Nickerson, Dorsey)
f/t:rjm:HFS-456:12/28/99:68581.adv:disc43



December 15, 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) Glandular products operate on the body's immune system by neutralizing autoimmune conditions.
- (2) His line of Protomorphogen™ extracts was designed to promote healthy functioning of the glands to maintain the body's natural balance.
- (3) Promotes healthy functioning of the adrenal glands.
- (4) Promotes healthy thyroid function.
- (5) By providing the building blocks necessary for proper thyroid gland function, Symplex M supports the thyroid glands' ability to maximize the potential of all food types for energy production and increases the rate of protein synthesis in most tissues.
- (6) Enhances endocrine performance.
- (7) Maintains a healthy functional relationship between these important organs and glands.
- (8) Combines the Protomorphogen™ extracts of bovine orchic, adrenal, pituitary, and thyroid glands to promote proper metabolism and healthy production of the male hormones.
- (9) Symplex M provides nutritional ingredients and support for the male hormones.

68581





These statements are made for a dietary supplement containing a proprietary blend of magnesium citrate, bovine orchic PMG™ extract, bovine adrenal PMG™ extract, bovine pituitary PMG™ extract, and bovine thyroid PMG™ extract (processed to remove its thyroxine). Other ingredients include calcium lactate, cellulose, and calcium stearate. The name of the product is Symplex® M.

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.