



SEP 26 2000 5 639 '00 OCT -3 P2:33

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 August 30, 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 Standard Process, Inc. is making the following claim, among others, for the product **SuperEff<sup>®</sup>**:

“...help maintain healthy cholesterol...and help maintain proper blood flow”

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 suggest that it is intended to treat, prevent, or mitigate disease<sup>1</sup>. 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

<sup>1</sup>See the discussion on the claim “inhibits platelet aggregation” in paragraph 41 in the preamble to the final rule published in the January 6, 2000 Federal Register (65 FR 1000 at 1016).

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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 Office, Office of Compliance, HFR-MW340

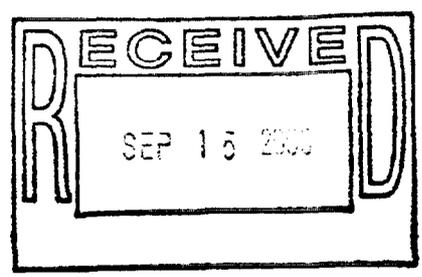
cc:

HFA-224 (w/incoming)  
HFA-305 (docket 97S-0163)  
HFS-22 (CCO)  
HFS-800 (r/f, file)  
HFS-811 (file)  
HFD-40 (Behrman)  
HFD-310  
HFD-314 (Aronson)  
HFS-605  
HFV-228 (Benz)  
GCF-1 (Dorsey, Nickerson)  
f/t:HFS-811:rjm:9/20/00:docname72469.adv:disc50

72469

August 30, 2000

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) The body uses EFAs to manufacture hormone-like substances called prostaglandins that work as chemical messengers and help to regulate many different physiological processes.
- (2) Among many other positive influences, EFAs help transmit nerve impulses throughout the central and peripheral nervous systems and support learning and memory functions in the brain. Phospholipids are intimately involved in many processes in both the central and peripheral nervous systems. They contribute to the appropriate surface charges of nerve cells, help regulate brain activity, and have a direct effect on neurotransmitters. The tocopherols found in Super-Eff help to maintain the stability of the essential fatty acids.
- (3) Supports a healthy nervous system.
- (4) Essential fatty acids assist in the timely transmission of nerve impulses and are needed for the appropriate development and functioning of the brain. EFAs enhance the brain's ability to learn and store learned messages to memory. Phospholipids are actively involved with intricate chemical processes in both the central and peripheral nervous systems.
- (5) Maintains cellular health.
- (6) All living cells require EFAs to repair themselves or to produce new cells.
- (7) Promotes healthy blood.
- (8) EFAs help maintain healthy cholesterol and triglyceride levels in the blood and help maintain proper blood flow. Phospholipids are able to dissipate other lipids found in the



gastrointestinal tract and in the bloodstream. Without phospholipids, other lipids would mix with water and clump together in the body.

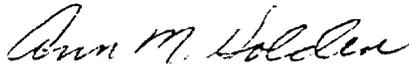
(9) Encourages healthy skin and hair.

(10) The body requires essential fatty acids to keep both skin and hair healthy. Linoleic acid (polyunsaturated fatty acid) promotes healthy skin. Fatty acids are often beneficial in addressing the symptoms of different types of minor skin irritations like common teenage acne. They help to maintain the permeability of the skin's capillaries to support proper water retention and hydration.\*

These statements are made for a dietary supplement containing a proprietary blend of carbamide, *Tillandsia usneoides*, bovine liver fat extract, flaxseed oil extract, and mixed tocopherols. Other ingredients include gelatin, water calcium stearate, and natural colors. The name of the product is Super-Eff<sup>®</sup>.

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.

