



December 15, 1999

RECEIVED
12/27/99

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) Protomorphogen™ extracts are designed to promote healthy functioning of the glands to maintain the body's natural balance.
- (2) Promotes efficient carbohydrate and sugar metabolism.
- (3) Paraplex is formulated to help maintain the healthy functioning of the pancreas and the adrenal, pituitary, and thyroid endocrine glands. Paraplex combines the Protomorphogen™ extracts from these corresponding bovine glands to help support the balanced functioning of endocrine glands and organs in regard to appropriate carbohydrate and sugar metabolism.
- (4) Supports balanced function of the pancreas, adrenal, pituitary, and thyroid glands.
- (5) Maintains a healthy functional relationship between these important organs and glands.
- (6) Combines the Protomorphogen™ extracts of bovine pancreas, adrenal, pituitary, and thyroid glands to promote proper carbohydrate and sugar metabolism.
- (7) Paraplex provides nutritional ingredients and support for the balanced function of the pancreas, adrenal, pituitary, and thyroid glands.

These statements are made for a dietary supplement containing a proprietary blend of magnesium citrate, bovine pancreas PMG™ extract, dried alfalfa juice, nutritional yeast, porcine duodenum, bovine adrenal PMG™ extract, bovine pituitary PMG™ extract, bovine thyroid PMG™ extract (processed to remove its thyroxine), defatted wheat (germ), and dried

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buckwheat (leaf) juice. Other ingredients include calcium lactate, cellulose, and calcium stearate. The name of the product is Paraplex®.

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.

