

August 24, 2000

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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:

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- (1) The Protomorphogen™ brand extracts found in Symplex M enhance the healthy functioning of the human adrenal, thyroid, and pituitary glands, and reproductive organs.
- (2) These glands support healthy normal hormone production to help regulate cardiovascular and muscle function, central nervous system response to stress, energy production, basal metabolism rate, and protein synthesis.

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, 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.

975-0162



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