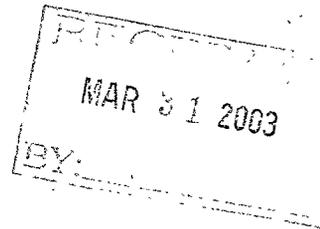




Whole Food Supplements

1985 '03 APR 15 P1:55

March 19, 2003



Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy.
College Park, MD 20740

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) Palmettoplex is made up of three different botanicals that are well-known for supporting the prostate gland.
- (2) These botanicals, combined with other whole food sources, join forces with prostate PMG™ extract to provide strong and natural male genitourinary system support.
- (3) The whole food and herbal ingredients in Palmettoplex provide the following nutritional and tertiary functional benefits: Saw Palmetto Berry Extract and Powder contains nine different fatty acids, diterpenes, triterpenes, sesquiterpene, and alcohols to help support healthy androgenic activity.
- (4) Prostate PMG™ extract provides cells with the specific raw materials to support their natural restoration, repair, and regeneration function.
- (5) Stinging Nettle Root contains polysaccharides, one lectin, multiple phenolic compounds, linear hydroxyl acids, dimeric compounds, and sterols to help support urinary health and is obtained by a methanol extract which has been shown to be more effective in delivering the compounds found in stinging nettle root to the body.
- (6) Pygeum contributes phytosterols, pieces of long-chain fatty acids, triterpenes and linear alcohols and their esters to support a healthy genitourinary tract.

97S 0162

LET

11726



Whole Food Supplements

- (7) Zinc Liver Chelate contains zinc that is chelated to bovine liver to maintain healthy zinc levels in prostate tissue.
- (8) Tomato Powder (Lycopene) stimulates and strengthens immune function and helps protect cells from oxidative damage.
- (9) Three amino acids – Alanine, Glutamine, and Glycine helps support proper urinary tract function and prostate health and these amino acids are found in prostate fluid.
- (10) Each ingredient offers its nutrients and synergistic cofactors to provide efficacious nutritional support to the male genitourinary physiologic structures.
- (11) The whole food and herbal ingredients in Palmettoplex provide a natural alternative for helping the prostate gland and urinary tract function properly and stay healthy.
- (12) The botanical and whole food ingredients found in Palmettoplex offer a natural formula created specifically to support a healthy prostate gland by: providing prostate cell determinants to help support and maintain healthy tissue,
- (13) encouraging healthy cell cycling,
- (14) decreasing cellular oxidative damage,
- (15) and improving bladder elasticity.

These statements are made for a dietary supplement containing a proprietary blend of bovine prostate PMG™ extract, glutamic acid, tomato (fruit) powder, alanine, and glycine. Other ingredients include maltodextrin, gelatin, zinc liver chelate, water, silica, honey, colors, calcium stearate, and corn starch. The name of the product is Palmettoplex™.

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.

