

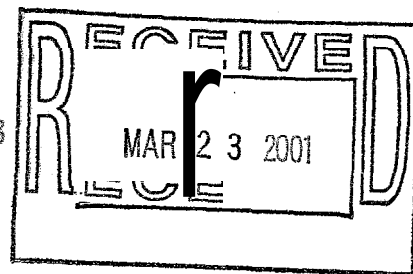


tel 801-345-9800 • fax 801-345-9899

www.pharmanex.com

By Federal Express  
75 West Center, Provo, Utah 84601-4483

3921 '01 MAY 10 P3:23



March 21, 2001

Office of Special Nutritional Products Labeling and Dietary Supplements  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration HFS 811  
200 c St. SW  
Washington, DC 20204

RE: Notification for Certain types of Statements on Dietary Supplements

Dear Sir or Madam:

As required by Section 403(r)(6)(c) of the Food, Drug and Cosmetic Act, Pharmanex, LLC, 75 West Center, Provo, Utah 84601, intends to market a dietary supplement product with the following label and marketing statements of nutritional support:

Product identified as Prostate Formula with the following label statements:

- Supports healthy prostate function
- Maintains healthy prostate structure
- Provides long-term prostate cell and DNA protection against free radical damage
- Included in the formula's line-up of antioxidants are Pharmanex's potent green tea extract, Tegreen 978 (standardized to deliver 97% polyphenols) combined with lycopene and selenium -all effective in neutralizing free radicals which help maintain healthy prostate tissues and DNA structures.
- Saw Palmetto, Selenium, Lycopene, and Tegreen 978 are combined to create a unique formula that provides superior prostate health.
- A dietary supplement for adult men who want to maintain normal prostate function.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, LLC has substantiation that these statements are truthful and not misleading.

Sincerely,

Win Duersch  
Sr. Director of Global Technical Services

975 0162

LET 7540

75095