



Dec 03, 1996

Dr. Elizabeth A. Yetley
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration - HFS-455
200 C Street SW
Washington, DC 20204

Dear Dr. Yetley,

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act of statements of nutritional support which have been made on the label and/or in the labeling in connection with the marketing of the dietary supplement "ProstaCare". We estimate that ProstaCare will start being sold with these statements of nutritional support on or around December 16, 1996. The statements of nutritional support are as follows :

- Nature's balanced prostate comfort formula
- helps manage prostate enlargement, a common condition in men above the age of 50
- helps in relieving urinary discomfort of prostate congestion and normalizes urine flow.

Very truly yours,

Ayurvedic Concepts Ltd.,
Dr. Philip A. Duterme, Chief Executive Officer

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