

Warner-Lambert Company
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Edward J. Tapper, MD
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October 1, 1998

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St., SW
Washington, D.C. 20204

RECEIVED
10/8/98

Re: Section 403(r)(6) Notification

Dear Sir or Madam:

Pursuant to Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act and Food and Drug Administration regulations at 21 CFR 101.93, this letter serves as notification that, less than 30 days ago, Warner-Lambert Company commenced marketing Quanterra Prostate, which contains the ingredient Saw Palmetto, and the label of which bears statements of nutritional support.

The statements of nutritional support are as follows:

Principal Display Panel

"Helps Maintain Healthy Urinary Flow"
"Supports Male Prostate Health"

Back Panel

"Supports urinary flow and prostate health."
"Saw Palmetto extracts such as Quanterra PROSTATE have been clinically proven by doctors to effectively maintain urinary flow and support prostate health."

The undersigned certifies his good faith belief that the information contained in this notice is complete and accurate, and that Warner-Lambert Company has substantiation that the statements are truthful and not misleading.

Thank you for your attention to this matter.

Sincerely,

Edward J. Tapper, MD
Vice President, Medical and Regulatory Affairs
Warner-Lambert Consumer Healthcare

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