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September 1, 1998

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

RECEIVED
9/3/98

Dear Sirs:

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 and in accordance with the requirements of 21 CFR 101.93, that Rexall Showcase International, Inc. located at 853 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 within the past 30 days marketed a dietary supplement bearing the following additional statement(s) on the label and/or in the labeling:

Men's Formula PLUS: [It is] nutritionally formulated to support prostate health. [It] has been created as an integral part of a nutritional program to support prostate and urinary tract health. Scientifically formulated with Cernitin and Calcium Glucarate, a patented ingredient, in combination with a unique proprietary blend of beneficial herbs and nutrients, [it] supports the body's natural immune function and cellular health.

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Deborah Shur Trinker

Deborah Shur Trinker
Vice President of Regulatory Affairs
and Corporate Counsel

Enclosure

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INTERNATIONAL CORPORATE HEADQUARTERS
853 Broken Sound Parkway NW, Boca Raton, FL 33487-3694 • (561) 241-9400
FAX (561) 995-5188