



6111 Broken Sound Parkway NW  
Boca Raton, FL 33487-3693  
(561) 241-9400  
Fax (561) 995-5188

1237 '99 FEB -2 P3:37

December 29, 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

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 Sundown, Inc. located at 851 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Sundown brand name and bears the following statement(s) on the label and/or in the labeling:

Cernitin AF: [It] helps control nighttime urinary frequency. [It] offers men a safe and effective nutritional approach to prostate health through multiple mechanisms of action: by supporting smooth muscle function surrounding the urinary tract; and by promoting prostate function for healthy urinary flow. Cernitin AF, a unique combination of Cernitin, standardized Beta Sitosterol and Saw Palmetto, is designed to provide nutritional support for prostate and urinary health. The ingredients in Cernitin AF help support smooth muscle tissue function. Cernitin AF supports and helps promote healthy prostate and urinary function.

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  
Vice President of Regulatory Affairs  
and Corporate Counsel

Enclosure

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