

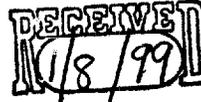


6111 Broken Sound Parkway NW  
Boca Raton, FL 33487-3693  
(561) 241-9400  
Fax (561) 995-5188

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December 30, 1998

VIA US MAIL



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 6111 Broken Sound Parkway, N.W., Boca Raton, Florida has marketed within the past thirty (30) days a dietary supplement under the Sundown brand name bearing the following statement(s) on the label and/or in the labeling:

Neurosharp PTI-00703 Cat's Claw: [It] promotes mental alertness and inhibits brain amyloid deposit formation.\*\* Neurosharp is the exclusive, in vitro tested advanced formula containing Cat's Claw PTI-00703\*\* and standardized Ginkgo Biloba Extract. Healthy brain function involves the transmission of messages by healthy nerve cells. Neurosharp promotes mental alertness by enhancing circulation. .

\*\*In vitro studies suggest that Neurosharp Cat's Claw with PTI-00703 inhibits the formation of brain amyloid deposits.

[Ginkgo Biloba's] distinctive fanshaped leaves contain compounds which promote oxygenation and blood flow in the brain.

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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