



tomorrow's nutrition today

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May 9, 2003

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 Section 403(r)(6) (21 U.S.C. § 343 (r)(6)) of the Federal Food, Drug and Cosmetic Act that Rexall Sundown, Inc. ("Rexall"), located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487, has marketed a dietary supplement under the Naturalist brand name bearing the following statement(s) on the label and/or in the labeling:

Fish Oil 1000 mg: ...a source of omega-3 fatty acids (EPA and DHA), helps promote healthy heart and circulatory function. [It] also helps maintain healthy blood lipid levels already within a normal range and vascular tone. DHA is one of the primary fatty acids in the brain, retina and nerves.

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

Cordially,

Deborah Shur Trinker, Esq.
Senior Vice President
Regulatory Affairs

Enclosures

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