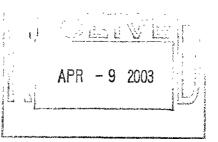


2016 03 APR 15 P1 57

March 25, 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

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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. ("Sundown"), located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487, has marketed a dietary supplement under the Sundown brand name bearing the following statements(s) on the label and/or in the labeling:

<u>Cholesterol Free Fish Oil</u>: ...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 Sundown has substantiation that the statement is truthful and not misleading. Pursuant to 101.93 (a)(1), two copies of this notification are enclosed.

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Cordially,

Rebran Son Dr. uke

Deborah Shur Trinker, Esq. Senior Vice President Regulatory Affairs

Enclosures

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