

## 1799 '03 APR -4 P4:31

March 18, 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 that Rexall, Inc. ("Rexall") located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Rexall brand name bearing the following statement(s) on the label and/or in the labeling:

Evening Primrose Oil: [For] hormonal balance. [It] is a source of gamma-linolenic acid (GLA). GLA is an omega-6 fatty acid that helps maintain hormonal balance and has traditionally been used to provide support for PMS. Additionally, GLA is essential to healthy joint function and is important in helping maintain smooth, healthy-looking skin.

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall 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.

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Senior Vice President

Regulatory Affairs

**Enclosures** 

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