

Tuesday, January 14, 2003

Barlean's Organic Oils, LLC 4936 Lake Terrell Road Ferndale, WA 98248 Attention: Jim Springer

Office of Nutrition Products, Labeling and Dietary Supplements Center for Food Safety and Applied Nutrition U. S. Food and Drug Administration 5100 Paint Branch Parkway Harvey W. Wiley Building HFS-810 College Park, MD 20740

RE: Section 403(r)(6) Dietary Supplement Notification

To Whom It May Concern:

Pursuant to Section 403(r)(6 of the Federal Food, Drug and Cosmetic Act (FFDCA) we are notifying the Food and Drug Administration (FDA) that we have introduced into interstate commerce a dietary supplement that contains a structure/function claim. We are providing the following information as required by 21 CFR 101.93(a)(2):

1. Name and Address pf the Manufacturer:

Barlean's Organic Oils, 4936 Lake Terrell Rd., Ferndale, WA 98248

2. Text of the Statements:

Evening Primrose Oil has long been revered for providing relief from symptoms associated with PMS and menopause such as cramps, hot flashes, breast tenderness and moodiness.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

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4936 Lake Terrell Road • Ferndale, WA 98248 • 800-445-3529 Fax 800-551-9879 • http://www.barleans.com

3. Name of the Dietary Ingredient

Gamma Linolenic Acid (derived from the Evening Primrose flower - Oenothera Macrocarpa)

4. Name of Dietary Supplement

**Barlean's Organic Evening Primrose Oil** 

I certify that the information contained in the notice is complete and accurate and that Barlean's Organic Oils has substantiation that the statements are truthful and not misleading.

If you have any question on this or other matters, please contact us.

Very truly yours,

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For Bruce Barleun

**Jim Springer**