

**KNATURE CORPORATION**

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Redmond, WA 98052

Tel: (425) 649-2075; Email: knaturecorp@msn.com

Office of Special Nutritional (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street SW  
Washington, DC 20204

*See'd*  
JAN 21 2005

Jan 12th, 2005

**Notification letter for Statement on Dietary Supplement**

Dear FDA officers:

I am the president of Knature Corporation, who is, among other things, a manufacturer and distributor of dietary supplements, mostly herbal products in the United States. I am writing as per Code of Federal Regulations, Volume 21, Part 101.93, to notify you that we have included a statement on the label or in the labeling of one of our products. The following are the information required in this notification letter:

1. Statement of Purpose:

This is a letter to provide notification of a statement of nutritional support, including the exact wording that appears on the label and labeling for a dietary supplement.

2. Vendor Information:

Name, address, telephone and fax numbers of the manufacturer and distributor for mailing and other communication purposes, are as follows:

Knature Corporation

2489 173rd Pl. NE  
Redmond, WA 98052

Tel: (425)649-2075,

*90704*

97S 0162

LET

*154/68*

*Also see docket 97S-0163*

The above address is also used for consumer inquiries.

3. Product Identification:

The trade name of the product:

**Evening Primrose Oil**

The common and usual name of the product:

None.

A label copy showing all information displayed and provided to consumers is attached.

4. The text of the Structure/Function Statement:

**Evening Primrose Oil is a natural source of Omega-6 fatty acids with a guaranteed level of Gamma Linolenic Acid (GLA). These essential fatty acids are needed to form important prostaglandin that maintain and regulate vital body functions.\***

**EPO helps to promote women's Well-Being. It can provide nutritional support for woman with PMS, Menstruation, Menopause.\***

**EPO helps regulate fat metabolism, inflammatory response, hormones, as well as cardiovascular, immune and central nervous systems.\***

**EPO also maintain blood pressure, sustain healthy skin and support joints.\***

**Vitamin E is added to enhance long term freshness and ensure a more stable product without artificial preservatives.\***

5. Ingredient Statement

This product is a proprietary of botanical. The following is a complete list of dietary ingredients:

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Common Name	Latin Binomial	Part of Plant
Evening Primrose oil	<i>Oenothera biennis</i>	Seed

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6. Intended Use:

This product is intended to be used by person over the age of 14.

Dosage: As a dietary supplement, take 1-2 soft gel, twice daily after meal.

**Warning:** Keep out of reach of children. If you are pregnant or lactating, or taking a prescription medication, consult a physician before using this product. To be kept in a cool and dry place.

7. Statement of Affirmation:

We, as a distributor of the above mentioned product, affirm that we have substantiation that the structure/function statement ( as shown in No. 4 above ) made under 403(6)(r) of the Federal Food, Drug and Cosmetic Act is truthful, not misleading, and scientifically valid and that the product does not present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the label or labeling.

8. Disclaimer:

At the end of each structure/function statement, there is an asterisk that refers to another asterisk placed adjacent to another statement called disclaimer. The disclaimer is placed at the bottom of the same panel or, in adjacent with the structure/function statement, The disclaimer reads:

**The statement has not been evaluated by the Food and Drug Administration.  
This product is not intended to diagnose, treat, cure, or prevent any disease.**

Should there be any question or comment, please contact the Vendor through the information in No. 2 above.

Sincerely,



Dongning Wen  
President

Enclosure

## **Evening Primrose Oil**

**Source of GLA  
Hexane Free  
Naturally Cold Pressed  
Dietary Supplement**

500 mg, 180 softgels

Evening Primrose Oil is a natural source of Omega-6 fatty acids with a guaranteed level of Gamma Linolenic Acid (GLA).

EPO helps to promote women's well-being. It can provide nutritional support for woman with PMS, Menstruation, Menopause.\*

EPO helps regulate fat metabolism, inflammatory response, hormones, as well as cardiovascular, immune and central nervous systems.\*

EPO also maintain blood pressure, sustain healthy skin and support joints.\*

Vitamin E is added to enhance long term freshness and ensure a more stable product without artificial preservatives.\*

\* 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.

Directions: 1-2 softgel, twice daily after meal.

### **Warning:**

Not recommended for male; or female under the age of 15. Consult your physician if you are on any type of medication. Keep out of reach of children.

Distributed by:

Knature Corporation, Redmond, WA98052  
Tel: (425)649-2075.

Manufactured by: Sheng Sheng Pharmaceuticals Ltd., Co., China

Expire Date: Dec, 2009

### **Nutrition Facts**

