

# E c o Nutrients I n c .

April 17, 2001

Via UPS Next Day Air  
Dr. Elizabeth Yetley  
Office of Special Nutritionals (HFS-450)  
Food and Drug Administration  
200 C Street, S.W.  
Washington, D.C. 20204

4019 01 MAY 10 P3:28



**Re: Fulfillment of Reporting Obligation - Under 21 U.S.C.# 343(r) and 21 CFR # 101.93**

Dear Dr. Yetley:

Caren Advanced Nutraceuticals, a division of Econutrients, Inc, in accordance with 21 U.S.C. #.343(r) and 21 CFR # 101.93, hereby submits an original and two copies of its notification within thirty days of first marketing its products with the statements presented below. Caren Advanced Nutraceuticals, a division of Econutrients Inc., retains scientific documentation supporting the statements.

- Supplement Brand Name**  
Undecenoic Acid  
**Supplement Iwredients**  
Undecenoic Acid & Extra Virgin Cold Pressed Olive Oil  
**Text of Statements of Nutritional Support**  
Supports normal intestinal flora.
- Supplement Brand Name**  
EFA Combination  
**Supplement Iwredients**  
Mixed Tocopherols, Borage Oil, Gamma Linolenic Acid, Fish Oil, EPA & DHA.  
**Text of Statements of Nutritional Support**  
Essential Fatty Acids help circulation, healthy joint function, and healthy bones.
- Supplement Brand Name**  
Super EPA  
**Supplement Iwredients**  
Natural Vitamin E, Fish Oil, EPA & DHA.  
**Text of Statements of Nutritional Support**  
Omega 3 essential fatty acids help maintain healthy circulation, healthy joint function and healthy bones.

In accordance with 21 USC # 343(r)(6) and 21 CFR # 101.93(c), the above statements of nutritional support will be followed by an asterisk that will be cross-referenced to another asterisk on the very same panel or page next to which the following statement will appear in a box in bold face type: **"This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent disease.?"**

We have also included a sample certificate that must accompany the statement of nutritional support tiling notice. Please feel free to contact us if you have any questions.

Respectfully submitted,

*Ann Brayfield*  
Ann Brayfield, President  
Caren Advanced Nutraceuticals

1. The address of Econutrients/Caren Advanced Nutraceuticals is Econutrients, 40 East Main Street, PMB 202, Newark, DE 19711.

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# Eco Nutrients Inc.

## Certification

I, Ann Brayfield, President of Caren Advanced Nutraceuticals/Econutrients, Inc hereby certify that the information contained in the foregoing notice is complete and accurate and that Caren Advanced Nutraceuticals has Substantiation that the statements are truthful and not misleading.

Executed on: 4-17-2001

Ann Brayfield  
Ann Brayfield