DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-654/S-021

GlaxoSmithKline
Attention: Willa B. Phyall, PhD
Director, US Regulatory Affairs
One Franklin Plaza, P. O. Box 7929
Philadelphia, PA 19101

Dear Dr. Phyall:

Please refer to your supplemental new drug application dated October 26, 2007, received October 29, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lovaza (omega-3-acid ethyl esters) Capsules.

This "Changes Being Effected" supplemental new drug application provides for revised labeling to reflect the tradename change from Omacor to Lovaza, and other editorial revisions.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the enclosed final printed labeling (FPL) submitted on October 26, 2007.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, MD
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure:

- Package Insert
- Professional Sample Tray
- 4-count sample bottle labels
- 28-count sample bottle labels
- 60-count commercial bottle labels
- 120-count commercial bottle labels

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Eric Colman
6/3/2008 11:33:38 AM
Eric Colman for Mary Parks