DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-654/S-023

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

SUPPLEMENT APPROVAL

Dear Phyall:

Please refer to your supplemental new drug application dated December 3, 2009, received December 3, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lovaza (omega-3-acid ethyl esters) Capsules.

This supplemental new drug application provides for conversion of the package insert to the Physician Labeling Rule (PLR) format. In addition, a Postmarketing subsection has been added to the ADVERSE REACTIONS section to add "anaphylactic reaction" and "hemorrhagic diathesis".

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert, text for the patient package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 21-654/S-023**."

LETTERS TO HEALTH CARE PROFESSIONALS

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

MedWatch
Food and Drug Administration
5600 Fishers Lane; Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (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, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert/Patient Information

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

4/20/2009 10:07:19 AM

Eric Colman for Mary Parks