



NDA 21654/S-022

**SUPPLEMENT APPROVAL**

SmithKline Beecham Corp. d/b/a GlaxoSmithKline  
Attention: Willa B. Phyll, Ph.D.  
Senior director, US Regulatory Affairs  
One Franklin Plaza  
200 North 16<sup>th</sup> Street  
Philadelphia, PA 19102

Dear Dr. Phyll:

Please refer to your supplemental new drug application dated September 5, 2008, received September 5, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for LOVAZA<sup>TM</sup> (omega-3-acid ethyl esters) Capsules.

We acknowledge receipt of your submissions dated October 30, 2008 and July 6, 2009.

This "Prior Approval" supplemental new drug application provides for:

1. inclusion of results from two drug-interaction studies with Lipitor<sup>®</sup> and Crestor<sup>®</sup> in the CLINICAL PHARMACOLOGY section (Drug-Drug Interactions subsection) of the package insert, and
2. conversion of the package insert format to conform with the physician's labeling rule (PLR).

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

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)(1)(i)] 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 21654/S-022**."

**PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the

proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

### **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}*

Eric Colman, M.D.  
Deputy Director  
Division of Metabolism and Endocrinology Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosure: Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21654	SUPPL-22	SMITHKLINE BEECHAM	Lovaza (omega 3-acid ethyl esters) Caps

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

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/s/

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ERIC C COLMAN  
09/16/2009