DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-654/S-014

Reliant Pharmaceuticals, Inc.
Attention: Mary Chin
Senior Manager, Regulatory Affairs
110 Allen Road
Liberty Corner, NJ 07938

Dear Ms. Chin:

Please refer to your supplemental new drug application dated May 25, 2007, received May 29, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for LOVAZA (omega-3-acid ethyl esters) Capsules.

We acknowledge receipt of your submissions dated July 2 and October 24, 2007.

This "Changes Being Effected" supplemental new drug application provides for a revised Patient Package Insert (PPI).

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on October 24, 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 & Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Revised PPI (4251P-00; 14252100-P, Revised: July 2007)

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/s/

Eric Colman
11/7/2007 01:29:14 PM
Eric Colman for Mary Parks