DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-654/S-015

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 June 5, 2007, received June 6, 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 submission dated August 22, 2007, containing revised bottle labels to include the new tradename.

This supplemental new drug application provides for the addition of a new drug product manufacturer (Accucaps, Inc.) and revised bottle labels to reflect this change.

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 attached final printed labeling (FPL) submitted on August 22, 2007.

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: 4-count sample bottle label
28-count sample bottle label
60-count commercial bottle label
120-count commercial bottle label

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/s/

Eric Colman
12/6/2007 03:27:13 PM
Eric Colman for Mary Parks