DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-853
NDA 21-654/S-016

Reliant Pharmaceuticals, Inc.
Attention: Gerlee Thomas
Manager, Regulatory Affairs
110 Allen Road
Liberty Corner, NJ 07938

Dear Ms. Thomas:

Please refer to your new drug application (NDA 21-853) dated January 9, 2004, received January 12, 2004, and your supplemental new drug application (NDA 21-654/S-016) dated June 12, 2007, received June 12, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Omacor (omega-3-acid ethyl esters) Capsules, 1 gram.

We acknowledge receipt of your submissions dated December 11, 2006, March 23, May 3 and 29, June 4 and 12(e-mail), 2007.

The December 11, 2006 submission constituted a complete response to our November 10, 2004 action letter for NDA 21-853.

This new drug application (NDA 21-85[illegible] provides for information on the use of Omacor as an add-on to HMG-CoA reductase inhibitor therapy in patients with persistent high triglycerides despite HMG-CoA reductase inhibitor therapy. The supplemental application provides for the addition of this information to the approved labeling for NDA 21-654.

We completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved NDA 21-853 and NDA 21-654/S-016**." Approval of these submissions by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly 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

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original NDA 21-654 for this drug product, not to this NDA. **In the future, do not make submissions to this NDA except for the final printed labeling requested above**.

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

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
6/12/2007 04:03:14 PM
Eric Colman for Mary Parks