DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-695/S-001

Reliant Pharmaceuticals, Inc.
Attention: Robert Mandetta
Director, Regulatory Affairs
110 Allen Road
Liberty Corner, NJ 07938

Dear Mr. Mandetta:

Please refer to your supplemental new drug application dated December 22, 2004, received December 23, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Antara (fenofibrate) Capsules.

We acknowledge receipt of your submissions dated January 18, February 2 and 10, March 2, 16, and 29, August 12 and 18, September 19 and 22, and October 13(email), 14, and 19, 2005.

This supplemental new drug application provides for the use of Antara without regard to meals.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling including the minor editorial revision indicated in the enclosed labeling. This revision modifies the **HOW SUPPLIED** section from: "Antara (fenofibrate) Capsules is available in three strengths" to read: "Antara (fenofibrate) Capsules are available in two strengths."

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert), including the minor editorial revision. This revision is a term of the approval of this application.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs*. 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 this submission "**FPL for approved supplement NDA 21-695/S-001**." Approval of this submission by FDA is not required before the labeling is used.

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:

Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Pat Madara, Regulatory Project Manager, at (301) 796-1249.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
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/

Mary Parks
10/21/2005 04:12:49 PM
for Dr. Orloff