

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

***APPLICATION NUMBER:***

**21-695**

**APPROVAL LETTER(S)**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-695

Reliant Pharmaceuticals, Inc.  
Attention: Paulette F. Kosmoski  
Senior Director, Regulatory Affairs  
110 Allen Road  
Liberty Corner, NJ 07938

Dear Ms. Kosmoski:

Please refer to your new drug application (NDA) dated December 1, 2003, received December 4, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Antara (fenofibrate) Capsules, 43 mg, 87 mg, and 130 mg.

We acknowledge receipt of your submissions dated January 26, and 29, April 2, 26, and 27, May 14, June 14, July 6, and 7, August 6, 16, and 30, September 3, 24, and 30(2), October 6, and 29, 2004.

This new drug application provides for the use of Antara (fenofibrate) Capsules as adjunctive therapy to diet to reduce elevated LDL-C, Total-C, Triglycerides and Apo B, and to increase HDL-C in adult patients with primary hypercholesterolemia or mixed dyslipidemia (Fredrickson Types IIa and IIb). Antara is also indicated as adjunctive therapy to diet for treatment of adult patients with hypertriglyceridemia (Fredrickson Types IV and V hyperlipidemia).

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert submitted October 6, 2004, and the immediate container labels submitted October 29, 2004). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-695.**" Approval of this submission by FDA is not required before the labeling is used.

In addition, submit the content of labeling in electronic format as described in 21 CFR 314.50(l)(5) and in the format described at the following website: <http://www.fda.gov/oc/datacouncil/spl.html>.

All communications regarding this application that contain electronic media or a combination of electronic and paper media should be addressed as follows:

U.S. Postal Service/Courier/Overnight Mail:  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Central Document Room  
5901-B Ammendale Rd.  
Beltsville, Md. 20705-1266

Paper communications regarding this application that **DO NOT** contain electronic media should be addressed as follows:

U.S. Postal Service/Courier/Overnight Mail:  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Metabolic and Endocrine Drug Products, HFD-510  
Attention: Division Document Room, 8B45  
5600 Fishers Lane  
Rockville, Maryland 20857

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:

Division of Drug Marketing, Advertising, and Communications, HFD-42  
Food and Drug Administration  
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) 827-6416.

Sincerely,

*{See appended electronic signature page}*

David G. Orloff, M.D.  
Director  
Division of Metabolic and Endocrine Drug Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosure: package insert, bottle labels (9)