NDA 21-494/S-001

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

Dear Ms. Chin:

Please refer to your supplemental new drug application dated September 20, 2004 received September 21, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Axid® (nizatidine) Oral Solution, 15 mg/mL.

We acknowledge receipt of your submissions dated September 30, 2004 and October 18, 2004.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a new 120 mL (4 fl. oz.) package presentation. In addition, you have updated the INDICATIONS section to correct an editorial error.

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 text.

The final printed labeling (FPL) must be identical to enclosed labeling (package insert, immediate container label, and carton label) and the submitted electronic labeling (package insert, immediate container label, and carton label) submitted September 30, 2004.

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 this submission "**FPL for approved supplement\ NDA 21-494/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 mock-up form, not final print. Send one copy to this Division and two copies of both the promotional materials and 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 Mr. Giuseppe Randazzo, Project Manager at (301) 827-1602

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Acting Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure:

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Kathy Robie-Suh
3/21/05 04:07:37 PM
signing for Dr. Joyce Korvick