DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-438/S-011

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

SUPPLEMENT APPROVAL

Dear Ms. Chin:

Please refer to your supplemental new drug application (NDA) dated September 10, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Innopran XL (propranolol hydrochloride) 80 and 120 mg Extended-Release Capsules.

This supplemental new drug application provides for the addition of the following statement to the **PRECAUTIONS/Drug Interactions** section of the labeling:

> Both digitalis glycosides and beta-blockers slow atrioventricular conduction and decrease heart rate. Concomitant use can increase the risk of bradycardia.

In the **DESCRIPTION** section of the PI (just above the **CLINICAL PHARMACOLOGY** section), the inadvertently added text will be deleted from the SPL submitted on September 10, 2007.

We have completed our review of this application, and it is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon electronic labeling text. We will transmit the SPL version of the labeling submitted on September 10, 2007 (after deletion of) to the National Library of Medicine for public dissemination.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

Marketing the product with labeling that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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, please call Dan Brum, Pharm.D., Regulatory Project Manager, at (301)796-0578.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc: Enclosed Labeling Text

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

/s/

Norman Stockbridge

1/2/2008 10:21:48 AM