DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-917/S-024

Dr. Reddy's Laboratories, Inc.
Attention: Kumara Sekar
200 Somerset Corporate Blvd, 7th Floor
Bridgewater, NJ 08807

SUPPLEMENT APPROVAL

Dear Dr. Sekar:

Please refer to your new drug application (NDA) for Sectral (acebutolol hydrochloride) 200 and 400 mg Capsules.

We acknowledge receipt of your submission dated July 3, 2007.

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

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

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.

In the SPL version you submitted on July 3, 2007, under the WARNINGS section of the package insert, please correct the spelling of the word "Withdrawal" (i.e. "Exacerbation of Ischemic Heart Disease Following Abrupt Withdrawl"). As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling text for the package insert. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 18-917/S-024."

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

9/6/2007 05:19:05 PM