DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-152/S-032

Ranbaxy Laboratories Limited
Attention: Usha Sankaran
US Agent for Ranbaxy Laboratories Limited
600 College Road East
Princeton, NJ 08540

Dear Ms. Sankaran:

Please refer to your supplemental new drug application dated April 23, 2009, received April 24, 2009, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Isoptin SR (verapamil HCL) 120 mg, 180 mg, and 240 mg Sustained Release Tablets.

This "Changes Being Effected" supplemental new drug application provides for changes to the **PRECAUTIONS/Drug Interactions** and the **HOW SUPPLIED** sections of the label. The following changes have been made:

1. In **PRECAUTIONS/Drug Interactions**, the following has been added:

   Telithromycin: Hypotension and bradyarrhythmias have been observed in patients receiving concurrent telithromycin, an antibiotic in the ketolide class of antibiotics.

2. In **HOW SUPPLIED**, the manufacturer has been changed from:

   Abbott Laboratories
   North Chicago, IL 60064 USA

   To:

   Halo Pharmaceutical Inc.
   Whippany, NJ 07981, USA

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 labeling.

CONTENT OF LABELING

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 19-152/S-032**."

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
Suite 12B05
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, please call:

Lori Anne Wachter, RN, BSN
Regulatory Project Manager
(301) 796 3975

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD
Deputy Director for Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Agreed-upon Labeling

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

/s/

Mary Southworth

7/1/2009 12:02:42 PM