



NDA 20-945/S-022

NDA 20-659/S-042

Abbott Laboratories
Attention: Mary Konkowski
Manager, Global Pharmaceutical Regulatory Affairs
Dept. PA76/Building AP30-1NE
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Ms. Konkowski

Please refer to your supplemental new drug applications dated December 28, 2007, received December 28, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NORVIR[®] (ritonavir) Soft Gelatin Capsules and NORVIR[®] (ritonavir) Oral Solution.

We acknowledge receipt of your submissions dated January 17, 2008, February 15, 2008, May 14, 2008, June 5, 2008 and June 24, 2008.

These supplemental applications proposed the following changes:

- To update the CLINICAL PHARMACOLOGY, PRECAUTIONS, and ADVERSE REACTIONS, Post-Marketing sections of the package insert with QT/QTc interval and PR interval prolongation information from Study M06-80 and to update the package patient insert with language related to changes in the electrocardiogram and cardiac arrhythmias.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Within 21 days of the date of this letter, submit 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 in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert and patient package insert).

In addition, within 21 days of the date of this letter, amend any pending applications for these NDAs with content of labeling in structured product labeling (SPL) format to include the changes approved in these applications.

The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed the revised product labeling and has determined that it contains significant new risk information relating to your drug product. We are hereby requesting that all promotional materials for your drug product that include representations about your drug product be revised to include the new risk information immediately. These revisions should include prominent disclosure of the important new information described in the WARNINGS and PRECAUTIONS sections that appear in the revised package labeling. Please submit a written response to this request on or before September 5, 2008, stating whether you intend to comply with this request, to the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications by facsimile at (301)796-9878 or at 5901-B Ammendale Road, Beltsville, MD 20705.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Karen Winestock, Chief, Project Management Staff, at (301) 796-0834.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Package Insert
Patient Package Insert

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

/s/

Jeffrey Murray
8/29/2008 12:50:36 PM