DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-251/S-040
NDA 21-906/S-033

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Abbott Laboratories
Attention: Mary Konkowski
Associate Director, Regulatory Affairs, Pharmaceutical Products Group
200 Abbott Park Road
Dept PA76/BLDG AP30-1E
Abbott Park, IL 60064

Dear Ms. Konkowski:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 28, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Kaletra® (lopinavir/ritonavir) tablets and oral solution.

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated March 28, 2011.

These supplemental new drug applications propose to eliminate the requirement for the Kaletra®REMS.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Kaletra® (lopinavir/ritonavir) tablets and oral solution was originally approved on April 6, 2009 and the most recent REMS modification was approved on February 24,,2011. The REMS consists of a Medication Guide, and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Kaletra® (lopinavir/ritonavir) tablets and oral solution.

We have determined that a REMS is no longer necessary to ensure that the benefits of Kaletra® outweigh its risks. We have determined that it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of the drug outweigh the risks. Therefore, a Medication Guide is no longer required as part of the REMS for Kaletra®. Therefore, we agree with your proposal and a REMS for Kaletra® is no longer required.

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

REPORTING REQUIREMENTS

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 Linda C. Onaga, Regulatory Project Manager, at (301) 796-0759.

Sincerely,

{See appended electronic signature page}

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

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

/s/

KENDALL A MARCUS
05/06/2011