



NDA 21-251/S-014
NDA 21-906/S-004

Abbott Laboratories
Attention: Raymond Votzmeyer
Associate Director, Global Pharmaceutical Regulatory Affairs
200 Abbott Park Road
Dept. RA76/Building AP30-1NE
Abbott Park, IL 60064-6157

Dear Mr. Votzmeyer:

Please refer to your supplemental new drug applications dated September 26, 2006, received September 27, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Kaletra[®] (80 mg lopinavir/20 mg ritonavir) Oral Solution and Kaletra[®] (200 mg lopinavir/50 mg ritonavir) Tablets.

We acknowledge receipt of your submissions dated February 6, 2007.

These supplemental new drug applications provide for revisions to the package insert, patient package insert and container labeling dispensing information to include an alternate container closure system and additional storage information.

We have 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 indicated in the enclosed labeling.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert) and to the immediate container labeling submitted on February 6, 2007.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions “**FPL for approved supplements NDA 21-906/S-004 and NDA 21-251/S-014.**” Approval of these submissions by FDA is not required before the labeling is used.

NDA 21-251/S-014

NDA 21-906/S-004

Page 2

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 these NDAs and a copy to the following address:

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

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, Regulatory Project Manager, at (301) 796-0834.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant
Director
Division of Antiviral Products
Office of Antimicrobial Products

Enclosures: 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
3/2/2007 01:54:37 PM