



NDA 21-906/S-003  
NDA 21-251/S-013

**Prior Approval Labeling Supplement**

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

Dear Mr. Votzmeyer:

Please refer to your supplemental new drug applications dated June 27, 2006, received June 28, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for KALETRA<sup>®</sup> (lopinavir/ritonavir tablets and oral solution).

We acknowledge receipt of your submissions dated June 27, 2006, December 12, 2006, and December 15, 2006.

These supplemental new drug applications provide for revisions to the package insert and patient package insert to include drug interaction information when the KALETRA<sup>®</sup> tablet formulation is co-administered with ranitidine or omeprazole.

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.

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 final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and text for the patient package insert submitted on December 15, 2006).

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

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of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions “**FPL for approved supplement NDA 21-251/S-013 and NDA 21-906/S003.**” Approval of these submissions by FDA is not required before the labeling is used.

If you have any questions, call Karen Winestock, Regulatory Project Manager, 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

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Debra Birnkrant  
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