



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Rockville, MD 20857

NDA 21-251/S-018  
NDA 21-906/S-007

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

Dear Ms. Konkowski:

Please refer to your supplemental new drug applications dated May 10, 2007, received May 10, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for KALETRA<sup>®</sup> (lopinavir/ritonavir) Oral Solution, 80 mg/20 mg and KALETRA<sup>®</sup> (lopinavir/ritonavir) Tablets, 200 mg/50 mg.

We acknowledge receipt of your submissions dated May 18, 2007, August 21, 2007 September 13, 2007, September 28, 2007, November 6, 2007 and November 7, 2007. We also acknowledge receipt of your November 8, 2007 electronic mail correspondence that contained the latest version of the labeling.

These supplemental new drug applications provide for the use of a lower strength KALETRA Tablet, 100 mg lopinavir/25 mg ritonavir, to be used for twice daily dosing in pediatric patients weighing greater than 15 kg. Information related to the 100 mg lopinavir/25 mg ritonavir tablet for the PEPFAR program was also included in this submission.

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.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

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, text for the patient 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 21-906/S007 and NDA 21-251/S018.

NDA 21-906/S-007

NDA 21-251/S-018

Page 2

Submit final printed container labels that are identical to the immediate container labels submitted on November 28, 2007 (U.S. marketed product) and November 6, 2007 (PEPFAR marketed product), as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 21-906/S007.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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  
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, 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

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/

-----  
Debra Birnkrant  
11/9/2007 02:34:07 PM  
NDA 21-251, 21-906