

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-226/S-002**

**21-251/S-002**

**CORRESPONDENCE**



NDA 21-226  
NDA 21-251

Abbott Laboratories  
Attention: Rebecca A. Welch  
Associate Director, PPD, Regulatory Affairs  
D-491/ AP6B-1SW  
100 Abbott Park Road  
Abbott Park, IL 60064-6108

Dear Ms. Welch:

We acknowledge receipt of your May 4, 2001 submission containing final printed labeling in response to our March 13, 2001 letter approving your supplemental new drug application for Kaletra™ (lopinavir/ritonavir) 133.3/33.3 mg Capsules and Kaletra™ (lopinavir/ritonavir) 80/20 mg/mL Oral Solution.

We have reviewed the labeling that you submitted in accordance with our March 13, 2001 letter and we find it acceptable.

If you have any questions, call Sean J. Belouin, R.Ph, Regulatory Project Manager, at 301-827-2335.

Sincerely,

*{See appended electronic signature page}*

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

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this page is the manifestation of the electronic signature.**

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/s/

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Debra Birnkrant  
6/6/01 12:48:19 PM  
NDA 21-251 SLR 002/NDA 21-226 SLR 002



Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Drug Evaluation IV

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**FACSIMILE TRANSMITTAL SHEET**

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**DATE:** January 16, 2001

<b>To:</b> Rebecca A. Welch	<b>From:</b> Sean J. Belouin, R.Ph
<b>Company:</b> Abbott Laboratories, Pharmaceutical Products Div.	Division of Antiviral Drug Products
<b>Fax number:</b> (847) 937-8002	<b>Fax number:</b> (301) 827-2523
<b>Phone number:</b> (847) 937-8971	<b>Phone number:</b> 301-827-2481
<b>Subject:</b> Pediatric dosing	

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**Total no. of pages including cover:** 2

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**Comments:**

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**Document to be mailed:**             YES             NO

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## Attachment

In addition to your proposed changes, please add the following underlined text (retaining the bold font) to the paragraph preceding the dosing tables:

“In children 6 months to 12 years of age, the recommended dosage of KALETRA oral solution is 12/3 mg/kg for those 7 to <15 kg and 10/2.5 mg/kg for those 15 to 40 kg (approximately equivalent to 230/57.5 mg/m<sup>2</sup>) twice daily taken with food, up to a maximum dose of 400/100 mg in children >40 kg (5.0 mL or 3 capsules) twice daily. **It is preferred that the prescriber calculate the appropriate milligram dose for each individual child ≤ 12 years old and determine the corresponding volume of solution or number of capsules. However, as an alternative,** the following table contains dosing guidelines for KALETRA oral solution based on body weight. When possible, dose should be administered using a calibrated dosing syringe.”

/s/

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Sean Belouin  
1/16/01 10:33:25 AM  
CSO