CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-226/S-002

21-251/S-002

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-226/S-002
NDA 21-251/S-002

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:

Please refer to your supplemental new drug applications dated January 2, 2001, received January 3, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Kaletra™ (lopinavir/ritonavir) 133.3/33.3 mg Capsules and 80/20 mg/mL Oral Solution. We also acknowledge receipt of your amended submissions dated January 30, 2001.

These supplemental new drug applications provide for changes in the oral volumes listed in the pediatric dose recommendation table contained in the DOSAGE AND ADMINISTRATION section of the Package Insert. The changes are intended to make the oral volumes closer to the recommended mg/kg doses for children of different weight ranges.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the amended submitted draft labeling (package insert submitted January 30, 2001).

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 21-226/S-002, 21-251/S-002." Approval of these submissions by FDA is not required before the labeling is used.

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If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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

/s/

Debra Birnkrant
3/13/01 04:04:15 PM
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