



NDA 210168

**COMPLETE RESPONSE**

Cipla USA, Inc.  
Attention: Michele Crawley  
U.S. Agent for Cipla Limited, India  
10 Independence Boulevard  
Suite 300  
Warren, NJ 07059

Dear Ms. Crawley:

Please refer to your new drug application (NDA) (b) (4)  
(b) (4)  
for Abacavir, Lamivudine, Lopinavir, and Ritonavir Oral  
Granules, (b) (4).

We acknowledge receipt of your amendment dated (b) (4), which  
constituted a complete response to our (b) (4), action letter.

We have completed our review of this application, as amended, and have determined that we cannot approve this application in its present form. We have described our reasons for this action below and, where possible, our recommendations to address these issues.

**FACILITY INSPECTIONS**

During a recent surveillance inspection of the (b) (4)  
(b) (4) manufacturing facility for this application, our field investigator conveyed deficiencies to the representative of the facility. Satisfactory resolution of these deficiencies is required before this application may be approved.

**ADDITIONAL COMMENTS**

(b) (4)

(b) (4)

Additionally provide experimental details,

(b) (4)

**OTHER**

Within one year after the date of this letter, you are required to resubmit or take other actions available under 21 CFR 314.110. If you do not take one of these actions, we may consider your lack of response a request to withdraw the application under 21 CFR 314.65. You may also request an extension of time in which to resubmit the application.

A resubmission must fully address all the deficiencies listed in this letter and should be clearly marked with "**RESUBMISSION**" in large font, bolded type at the beginning of the cover letter of the submission. The cover letter should clearly state that you consider this resubmission a complete response to the deficiencies outlined in this letter. A partial response to this letter will not be processed as a resubmission and will not start a new review cycle.

You may request a meeting or teleconference with us to discuss what steps you need to take before the application may be approved. If you wish to have such a meeting, submit your meeting request as described in the draft guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products*.

If you have any questions, please call

(b) (4)

Sincerely,

*{See appended electronic signature page}*

(b) (4)

-----  
**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
-----

/s/  
-----

(b) (4)

03/22/2024 11:33:23 AM