



NDA 217719

**COMPLETE RESPONSE**

Laurus Generics, Inc.  
U.S. Agent for Laurus Labs Limited, India  
Attention: Sharath Koripally  
Senior Director RA, QA & PV  
400 Connell Drive, Suite 5200  
Berkeley Heights, NJ 07922

Dear Mr. Koripally:

Please refer to your new drug application ( (b) (4) )

or the following drug product:

- Darunavir and Ritonavir Tablets, (b) (4) .

We acknowledge receipt of your major amendment dated (b) (4) , which extended the goal date by three months.

We have completed our review of this application, as amended, and have determined that we cannot tentatively 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.

**PRODUCT QUALITY**

(b) (4)

(b) (4)

(b) (4)



### **PRESCRIBING INFORMATION**

We reserve comment on the proposed labeling until the application is otherwise adequate. We encourage you to review the labeling review resources on the Prescription Drug Labeling Resources<sup>3</sup> and Pregnancy and Lactation Labeling Final Rule<sup>4</sup> websites, including regulations and related guidance documents and the Selected Requirements for Prescribing Information (SRPI) – a checklist of important format items from labeling regulations and guidances.

### **CONTAINER LABELING**

We reserve comment on the proposed labeling until the application is otherwise adequate.

### **ADDITIONAL COMMENT**

We have the following recommendation that is not an approvability issue:

(b) (4)



the in-use stability studies

(b) (4)

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<sup>3</sup> <https://www.fda.gov/drugs/laws-acts-and-rules/prescription-drug-labeling-resources>

<sup>4</sup> <https://www.fda.gov/drugs/labeling-information-drug-products/pregnancy-and-lactation-labeling-drugs-final-rule>

**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*.

The product may not be distributed until you have been notified in writing that this application is tentatively approved.

If you have any questions, please contact

(b) (4)

Sincerely yours,

*{See appended electronic signature page}*

(b) (4)

Center for Drug Evaluation and Research

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**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.**  
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/s/  
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(b) (4)

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