

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**209481Orig1s000**

**OTHER ACTION LETTERS**



NDA 209481

**COMPLETE RESPONSE**

Mylan Laboratories Limited  
c/o Mylan Pharmaceuticals Inc.  
Attention: Anil Sachdeva  
Senior Director, Regulatory Affairs  
781 Chestnut Ridge Road, P.O. Box 4310  
Morgantown, WV 26504-4310

Dear Mr. Sachdeva:

Please refer to your New Drug Application (NDA) dated July 20, 2016, received July 20, 2016, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Vancomycin Hydrochloride for Injection USP, 250 mg/vial, 750 mg/vial, 1.25 g/vial and 1.5 g/vial.

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 reason for this action below and, where possible, our recommendations to address these issue.

**FACILITY INSPECTIONS**

During a recent inspection of the [REDACTED] (b) (4) and Mylan Laboratories Ltd. (FEI 3008255419), manufacturing facilities for this application, our field investigator observed objectionable conditions at the facilities and conveyed that information to the representative of each of the facilities at the close of the inspections. Satisfactory resolution of these observations is required before this application may be approved.

**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 [PLR Requirements for Prescribing Information](#) and [Pregnancy and Lactation Labeling Final Rule](#) 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.

If you revise labeling, use the SRPI checklist to ensure that the prescribing information conforms with format items in regulations and guidances. Your response must include updated content of

labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

### **ADDITIONAL COMMENTS**

We have the following comments/recommendations that are not approvability issues:

#### **Product Quality**

You have proposed to

(b) (4)

(b) (4)

#### **Regulatory**

In your application, we note that you specified that you are relying on FDA's findings of safety and effectiveness for the listed drugs approved under ANDA 062663 and ANDA 060180. Based upon Agency records, it appears that ANDA 060180 is actually an NDA although it is listed as a discontinued ANDA in the Orange Book. We acknowledge that you have chosen to rely on FDA's finding of safety and effectiveness for a discontinued listed drug with the understanding that you are using the ANDA product listed in the Orange Book (i.e., ANDA 062663 that you have identified in your application) to establish a bridge between your proposed drug product and the specified listed drug.

However, your application cannot rely upon ANDA 062663 which does not contain full reports of safety and effectiveness. When you resubmit your application, identify ANDA 060180 as the application containing full reports of investigations of safety and effectiveness upon which your application relies. When completing the 356h form, please remove ANDA 062663 from the space designated for "Application Number or Relied Upon Products."

You should also use the labeling for ANDA 060180 as the reference labeling, rather than the labeling for ANDA 062663. We note that labeling for ANDA 061080 is available at [Drugs@FDA](mailto:Drugs@FDA).

**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 FDA Guidance for Industry, "Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products," March 2015 at <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm437431.pdf>.

The drug product may not be legally marketed until you have been notified in writing that this application is approved.

If you have any questions, call Deepak Aggarwal MS, MSPH, Regulatory Project Manager, at (301) 796-0746.

Sincerely,

*{See appended electronic signature page}*

Sumathi Nambiar, MD, MPH  
Director  
Division of Anti-Infective Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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SUMATHI NAMBIAR  
05/19/2017