



ANDA 091052

Mylan Pharmaceuticals Inc.  
Attention: S. Wayne Talton  
Vice President, Regulatory Affairs  
781 Chestnut Ridge Road  
P.O. Box 4310  
Morgantown, WV 26504-4310

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 22, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Doxycycline Hyclate Delayed-release Tablets USP, 150 mg (base).

Reference is made to your amendments dated March 26, May 11, and September 2, 2009; January 11, February 11, April 21, November 9, and December 22, (2) 2010; and May 18, 2011.

We have completed the review of this ANDA, and based upon the information you have presented to date we have concluded that the drug is safe and effective for use as recommended in the submitted labeling. However, we are unable to grant final approval to your ANDA at this time because of the patent issue noted below. Therefore, the ANDA is **tentatively approved**. This determination is based upon information available to the agency at this time (i.e., information in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention. This letter does not address issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The reference listed drug (RLD) upon which you have based your ANDA, Doryx Delayed-release Tablets, 150 mg (base), of Mayne Pharma International Faulding Pharm., is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 6,958,161 (the '161 patent) is scheduled to expire on December 15, 2022. Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '161 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Doxycycline Hyclate Delayed-release Tablets USP, 150 mg (base), under this ANDA. You notified the agency that Mylan Pharmaceuticals Inc. (Mylan) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '161 patent was brought against Mylan within the statutory 45-day period in the United States District Court for the District of New Jersey

[Warner Chilcott Laboratories Ireland Limited, Warner Chilcott Company, Inc., Warner Chilcott (US), LLC and Mayne Pharma International Pty. Ltd. v. Mylan Pharmaceuticals Inc. and Mylan Inc., Civil Action No. 2:09-cv-02073].

Therefore, final approval cannot be granted until:

1.
  - a. the expiration of the 30-month period provided for in section 505(j)(5)(B)(iii),
  - b. the date the court decides<sup>1</sup> that the '161 patent is invalid or not infringed (see sections 505(j)(5)(B)(iii)(I), (II), and (III) of the Act), or
  - c. the '161 patent has expired, and
2. The agency is assured there is no new information that would affect whether final approval should be granted.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

To reactivate your ANDA prior to final approval, please submit a “MINOR AMENDMENT – FINAL APPROVAL REQUESTED” 90 days prior to the date you believe that your ANDA will be eligible for final approval. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of a court decision, or a settlement or licensing agreement, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a MINOR AMENDMENT – FINAL APPROVAL REQUESTED.

In addition to the amendment requested above, the agency may request at any time prior to the date of final approval that you submit an additional amendment containing the requested information. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your ANDA, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this ANDA as well as changes in the status of the manufacturing and testing facilities' cGMPs are subject to agency review before final approval of the ANDA will be made. Such changes should be categorized as representing either “major” or “minor” changes, and they will be reviewed according to OGD policy in effect at the time of receipt. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

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<sup>1</sup>This decision may be either a decision of the district court or the court of appeals, whichever court is the first to decide that the patent is invalid or not infringed.

This drug product may not be marketed without final agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the Act. Also, until the agency issues the final approval letter, this drug product will not be deemed to be approved for marketing under section 505 of the Act, and will not be listed in the “Orange Book.”

For further information on the status of this ANDA, or prior to submitting additional amendments, please contact Mark Gonitzke, Project Manager, at (240) 276-8422.

Sincerely yours,

*{See appended electronic signature page}*

Keith Webber, Ph.D.  
Deputy Director  
Office of Pharmaceutical Science  
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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ROBERT L WEST

06/10/2011

Deputy Director, Office of Generic Drugs  
for Keith Webber, Ph.D.