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APPLICATION NUMBER:

ANDA 091052

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

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 also made to the tentative approval letter issued by this office on June 10, 2011, and your amendments dated June 20, 2011, September 15, 2011, September 21, 2011, September 28, 2011, September 30, 2011, October 6, 2011, November 17, 2011 and December 12, 2011.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Doxycycline Hyclate Delayed-release Tablets USP, 150 mg (base), to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Doryx Delayed-release Tablets, 150 mg (base), of Mayne Pharma International Faulding Pharm. (Mayne).

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA. The "interim" dissolution specifications are as follows:

Acid stage:
Apparatus: USP Apparatus 1 (baskets), 50 rpm
Medium: 0.06 N hydrochloric acid, 37°C
Volume: 900 mL
Specification: NMT 30% in 20 minutes

Buffer stage:
Apparatus: USP Apparatus 1 (baskets), 50 rpm
Medium: pH 5.5, neutralized phthalate buffer, 37°C
Volume: 1000 mL
Specification: NLT (b) (4) (Q) in 60 minutes

The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data for the first three production size batches. Data should be submitted as a Special Supplement – Changes Being Effected when there are no revisions to the "interim" specifications or when the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

The RLD upon which you have based your ANDA, Mayne's Doryx Delayed-release Tablets, 150 mg (base), 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 have notified the agency that Mylan Pharmaceuticals Inc. (Mylan) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Mylan for infringement of the '161 patent 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]. Although this litigation remains ongoing, the 30-month period identified in section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your ANDA, has expired.

With respect to 180-day generic drug exclusivity, we note that another applicant was the first to submit a substantially complete ANDA for Doxycycline Hyclate Delayed-release Tablets, 150 mg (base), and containing a paragraph IV certification to the '161 patent. The ANDA of the first applicant, however, was not granted tentative approval within the 30-month period described in section 505(j)(5)(D)(i)(IV). The agency has determined that the 180-day exclusivity period described in section 505(j)(5)(B)(iv) of the Act was forfeited by the first applicant. Under section 505(j)(5)(D)(iii), no applicant shall be eligible for a 180-day exclusivity period, and any ANDA containing a paragraph IV certification shall be eligible for final approval.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

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.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on

proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Reference is made to your Letter of Commitment dated September 21, 2011, in which you committed to supplement your ANDA in accordance with MAPP 5223.2 within 60 days of approval. In particular, you committed that "no new single scored 150 mg tablets will be manufactured post approval without a change in the scoring configuration to match the RLD," and that "distribution of the trisected tablets cannot occur until after receipt of approval for the related supplemental application." We regard adherence to this commitment as a condition of approval.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ROBERT L WEST

02/08/2012

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