CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 090406

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 090406

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 March 5, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Pioglitazone Hydrochloride and Metformin Hydrochloride Tablets, 15 mg/500 mg and 15 mg/850 mg.

Reference is also made to your amendments dated October 1, and November 24, 2008; March 3, and June 17, 2009; April 6, August 16, and October 29, 2010; and January 17, and February 22, 2011. We also acknowledge receipt of your correspondence dated June 23, and September 8, 2008; March 31, 2010; and January 16, and February 2, 2011, pertaining to the patent issues associated with this ANDA.

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 Pioglitazone Hydrochloride and Metformin Hydrochloride Tablets, 15 mg/500 mg and 15 mg/850 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Actoplus Met Tablets 15 mg/500 mg and 15 mg/850 mg, respectively, of Takeda Global Research Development Center, Inc. (Takeda). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, Takeda's Actoplus Met, 15/500 mg and 15/850 mg, is subject to periods of patent protection. The following unexpired patents and their expiration dates are currently listed in the agency's

publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

U.S. Patent Number	Expiration Date
5,965,584 (the '584 patent)	June 19, 2016
6,166,042 (the '042 patent)	June 19, 2016
6,166,043 (the '043 patent)	June 19, 2016
6,172,090 (the '090 patent)	June 19, 2016

With respect to each of these patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Pioglitazone Hydrochloride and Metformin Hydrochloride Tablets, 15/500 mg and 15/850 mg, 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 for infringement of the '584, '043 and '090 patents was initiated against Mylan within the statutory 45-day period in the United States District Court for the Southern District of New York [Takeda Pharmaceutical Co., Ltd., Takeda Pharmaceuticals North America, Inc., and Takeda Global Research and Development Center, Inc., vs. Mylan, Inc., Mylan Pharmaceuticals, Inc., and UDL Laboratories, Inc., Civil Action No. 08-6999]. You have also notified the agency that the case was dismissed and you have entered into a license agreement with Takeda; therefore, under section 505(j)(5)(B)(iii) your ANDA is eligible for approval.

Mylan was the first ANDA applicant to submit a substantially complete ANDA with paragraph IV certifications to the '116, '584, '042, '043, and '090 patents. As a first applicant, therefore, Mylan was eligible for 180 days of generic drug exclusivity for Pioglitazone Hydrochloride and Metformin Hydrochloride Tablets, 15/500 mg and 15/850 mg. The Agency has determined, however, that Mylan has forfeited its 180-day exclusivity period because it failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed.[1] See section 505(j)(5)(D)(I)(IV) of the Act.

[1] Mylan's ANDA 090406 was received (filed) on March 16, 2008. 30 months from that date was September 16, 2010. ANDA 090406 was never tentatively approved. The agency finds that this failure to obtain tentative approval by September 16, 2010, was not caused by either a change in or a review of the requirements for approval, or a related citizen petition that was subject to section 505(q) of the Act (Docket No. FDA-2009-P-0411). That petition did not pertain to an ANDA, such as Mylan's, that submitted a paragraph IV certification to the '584 patent.

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.

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 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.

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/U_CM072392.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

02/25/2011

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