DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 076801

Mylan Pharmaceuticals Inc.
Attention: S. Wayne Talton
Vice President, Regulatory Affairs
781 Chestnut Ridge Road
P.O Box 4310
Morgantown, WV 26505

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) received on July 15, 2003, and submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Pioglitazone Tablets USP, 15 mg, 30 mg, and 45 mg.

Reference is also made to the tentative approval letter issued by this office on November 3, 2004, and to your amendments dated September 10, 2008; November 20, 2009; April 12, 2010; March 3, and November 30, 2011; and May 22, June 7, June 25, and August 14, 2012. We also acknowledge receipt of your correspondences dated March 22, and August 30, 2010; January 6, and February 2, 2011; and May 22, 2012, addressing the patent issues noted below.

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 Tablets USP, 15 mg, 30 mg, and 45 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Actos Tablets, 15 mg, 30 mg and 45 mg, respectively, of Takeda Pharmaceuticals North America, 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 Actos Tablets, is subject to periods of patent protection. The

following 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
6,150,383 (the '383 patent)	June 19, 2016
6,150,384 (the '384 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
6,211,205 (the '205 patent)	June 19, 2016
6,271,243 (the '243 patent)	June 19, 2016
6,303,640 (the '640 patent)	August 9, 2016
6,329,404 (the '404 patent)	June 19, 2016

Your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these patents is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Pioglitazone Tablets USP, 15 mg, 30 mg, and 45 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 no action for infringement of any of these patents was brought against Mylan within the statutory 45-day period.

With respect to 180-day generic drug exclusivity, we note that Mylan was a first ANDA applicant to submit a substantially complete ANDA with a valid paragraph IV certification to each of the listed patents.[1] Therefore, with this approval, Mylan is eligible for 180 days of generic drug exclusivity for Pioglitazone Tablets USP, 15 mg, 30 mg, and 45 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the earlier of the commercial marketing or court decision dates identified in section 505(j)(5)(B)(iv).[2] Please submit correspondence to

[1] Your paragraph IV certifications to the '584 and '404 patents were contained in your original ANDA, received on July 15, 2003. Your paragraph IV certifications to the eight other patents listed above were contained in an amendment dated March 22, 2010.

[2] Because your ANDA was filed before the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) on December 8, 2003, this reference to the 180-day exclusivity provision is to the section of the Act as in effect prior to December 8, 2003. See MMA § 1102(b)(1).

this ANDA informing the agency of the date the exclusivity begins to run.

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 directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
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 Office of Prescription Drug Promotion 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/UCM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Gregory P. Geba, M.D., M.P.H.
Director
Office of Generic Drugs
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

08/17/2012

Deputy Director, Office of Generic Drugs
for Gregory P. Geba, M.D., M.P.H.