DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 076798

Watson Laboratories, Inc.
Attention: Janie M. Gwinn
Director, Regulatory Affairs
311 Bonnie Circle
Corona, CA 92880

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated July 15, 2003, 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 made to the tentative approval letters issued by this office on December 13, 2005, and August 23, 2012, and to your amendments dated October 22, 2012 (two submissions).

Reference is also made to the order of the United States District Court for the District of Columbia [Watson Laboratories, Inc. v. Sebelius, Civil Action No. 12-1344(ABJ)] dated October 22, 2012, in which the agency was ordered to –

> approve Watson Laboratories' ANDA for generic pioglitazone effective immediately so that Watson Laboratories may participate in what remains of the shared exclusivity period previously awarded to other generic manufacturers of the drug.

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. 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

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 the patent 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 Watson Laboratories, Inc. (Watson) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Watson for infringement of the '584 and '404 patents within the statutory 45-day period in the United States District Court for the Southern District of New York [Takeda Chemical Industries, Ltd., and Takeda Pharmaceuticals North America, Inc. v. Watson Laboratories, Inc., Civil Action No. 03-CV-8254]. You subsequently notified the agency that Watson been granted a license with respect all the above listed patents.

In addition, your ANDA is now subject to facility fee(s). You must pay fees in accordance with the Generic Drug User Fee Amendments of 2012 (Public Law 112-144, Title III). You will not be penalized for nonpayment of the facility fee until the fee payment is overdue. The fee must be paid by the date listed in the Federal Register (FR) notice announcing the facility fee amount. If the facility fee is not paid by the due date, statutory penalties take effect. At that time, FDA will deem misbranded this ANDA product and all products from facilities

that have not paid the appropriate fee. In addition, facilities that have not paid the fee will be placed on a publicly available arrears list, until the fee is paid or the facilities are removed from the ANDA.

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/

GREGORY P GEBA
10/26/2012