DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 202503

Watson Laboratories, Inc.
Attention: Krishna K Joshi
Manager, Regulatory Affairs
Morris Corporate Center III
400 Interpace Parkway
Parsippany, NJ 07054

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 24, 2010, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Sildenafil Tablets, 20 mg.

Reference is also made to your amendments dated March 28, July 21, August 22, September 8, and December 2, 2011; and January 9, January 23, February 21, May 29, October 1, October 15, October 16, and October 17, 2012.

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 Sildenafil Tablets, 20 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug product (RLD), Revatio Tablets, 20 mg, of Pfizer Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

As of October 1, 2012, Watson Laboratories, Inc. (Watson) must pay fees in accordance with the Generic Drug User Fee Amendments of 2012 (Public Law 112-144, Title III). Because your ANDA was pending on October 1, 2012, your ANDA is now subject to a backlog fee. However, you will not be penalized until the backlog fee payment is overdue. As indicated in the Federal Register (FR) notice (77 FR 65199), published on October 25, 2012, the backlog fee is due no later than 30 days after

publication of the notice. If you do not pay the fee by the due date, statutory penalties take effect. At that time, FDA cannot receive any further ANDAs or supplements from Watson or its affiliates, and Watson will be placed on a publicly available arrears list until the fee is paid.

In addition, your ANDA is now subject to facility fees. As noted above, 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, the facilities 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/

ROBERT L WEST

11/06/2012

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