DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 091347

Teva Pharmaceuticals USA
Attention: Jean W. Zwicker
Senior Director, Regulatory Affairs
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated March 5, 2009, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Vardenafil Hydrochloride Tablets, 2.5 mg, 5 mg, 10 mg, and 20 mg.

Reference is also made to your amendments dated July 10, September 4, October 23, and November 4, 2009; June 7, 2010; January 3, August 26, December 2, and December 9, 2011; and January 19, and April 16, 2012. We also acknowledge receipt of your patent amendments dated January 19, and June 17, 2010; February 18, 2011; and March 2, and April 16, 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 Vardenafil Hydrochloride Tablets, 2.5 mg, 5 mg, 10 mg, and 20 mg to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Levitra Tablets, 2.5 mg, 5 mg, 10 mg and 20 mg, respectively, of Bayer Healthcare Pharmaceuticals, Inc. (Bayer). 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, Bayer's Levitra Tablets, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 6,362,178 (the '178 patent) and 7,696,206 (the '206 patent) are both scheduled to expire on October 31, 2018.

Your ANDA contains paragraph IV certifications to each of these patents under section 505(j)(2)(A)(vii)(IV) of the Act stating that these patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Vardenafil Hydrochloride Tablets, 2.5 mg, 5 mg, 10 mg, and 20 mg, under this ANDA. You have notified the agency that Teva Pharmaceuticals USA (Teva) complied with the requirements of section 505(j)(2)(B) of the Act,

and litigation for infringement of the '178 patent was brought against Teva within the statutory 45-day period in the United States District Court for the District of Delaware [Bayer Schering Pharma AG, Bayer Healthcare Pharmaceuticals, Inc., and Schering Corporation v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals, Ltd., Civil Action Nos. 09-480 (20 mg strength) and 09-536 (5 mg and 10 mg strengths) and 09-682 (2.5 mg strength)]. You also notified the agency that litigation for infringement of the '206 patent was brought against Teva in the United States District Court for the District of Delaware [Bayer Schering Pharma AG, Bayer Healthcare Pharmaceuticals, Inc., and Schering Corporation v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals, Ltd., Civil Action No. 10-0299]. We note that the '206 patent was not listed in the Orange Book at the time that your ANDA was filed. All Civil Actions were subsequently consolidated under CA 09-480. A consent judgment and order was entered on November 9, 2011, resolving the litigation.

Teva was the first applicant to submit a substantially complete ANDA with paragraph IV certifications to the '178 and '206 patents. As a first applicant, therefore, Teva may be eligible for 180 days of generic drug exclusivity for Vardenafil Hydrochloride Tablets, 2.5 mg, 5 mg, 10 mg, and 20 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, would begin to run from the date of the commercial marketing. The agency notes that Teva failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) (forfeiture of exclusivity for failure to obtain tentative approval). The agency is not, however, making a formal determination at this time of Teva's eligibility for 180-day generic drug exclusivity. Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins.

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}

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
05/03/2012
Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.