



ANDA 077342

**ANDA APPROVAL**

Teva Pharmaceuticals USA, Inc.  
425 Privet Road  
Horsham, Pennsylvania 19044  
Attention: Rich Leone  
Senior Director, Regulatory Affairs

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA), submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Sildenafil Citrate Tablets, 25 mg, 50 mg and 100 mg.

Reference is also made to the tentative approval letter issued by this office on April 24, 2007, and to your amendments dated March 5 and April 9, 2008; April 19, 2013; and August 28, October 14, and November 10, 2015.

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 Office of Bioequivalence has determined your Sildenafil Citrate Tablets, 25 mg, 50 mg and 100 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Viagra Tablets of Pfizer Ireland (Pfizer). 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, Pfizer's Viagra Tablets, is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 6,469,012 (the '012 patent), is scheduled to expire on April 22, 2020.

Your ANDA contains a paragraph IV certification to the '012 patent under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Sildenafil Citrate Tablets, 25 mg, 50 mg and 100 mg, under this ANDA. You have notified the agency that Teva Pharmaceuticals USA, Inc. (Teva) complied with the requirements of section 505(j)(2)(B) of the FD&C Act, and that no action for infringement was brought against Teva within the statutory 45-day period.<sup>1</sup>

<sup>1</sup> We note that Pfizer initiated litigation for infringement of the '012 patent against Teva outside of the statutory 45-day period in the United States District Court for the Eastern District of Virginia, [Pfizer Inc., Pfizer Limited and Pfizer Ireland Pharmaceuticals v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd., Civil Action No. 10CV 0128]. On August 15, 2011, the district court ruled in Pfizer's favor, finding that Teva's product would infringe the '012 patent and that the '012 patent is valid and enforceable. Teva appealed this ruling to the

With respect to 180-day generic drug exclusivity, we note that Teva was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Teva is eligible for 180 days of generic drug exclusivity for Sildenafil Citrate Tablets, 25 mg, 50 mg, and 100 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

Under section 506A of the FD&C 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 FD&C 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(s) 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.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur

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U.S. Court of Appeals for the Federal Circuit, and on December 17, 2013, the appellate court issued a mandate granting the parties' joint motion to voluntarily dismiss the appeal. Prior to this dismissal, the district court had issued an amended judgment, holding, in part, that Teva is enjoined from activities related to the manufacture and/or sale of Teva's drug product until the expiration of the '012 patent, except as expressly permitted under a settlement agreement dated July 18, 2013.

by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

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,

For Carol A. Holquist, RPh  
Acting Deputy Director  
Office of Regulatory Operations  
Office of Generic Drugs  
Center for Drug Evaluation and Research