



ANDA 077337

**ANDA APPROVAL**

Teva Pharmaceuticals USA, Inc.  
425 Privet Road  
Horsham, PA 19044  
Attention: Rich Leone

Dear Sir:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on October 22, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Rosiglitazone Maleate and Metformin Hydrochloride Tablets, 1 mg (base)/500 mg.<sup>1</sup>

Reference is also made to the tentative approval letter issued by this office on May 7, 2014, and to your amendments dated May 9, December 12, 2016 and May 5, 2017.

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 Rosiglitazone Maleate and Metformin Hydrochloride Tablets, 1 mg (base)/500 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Avandamet (rosiglitazone maleate and metformin hydrochloride) Tablets, 1 mg/500 mg, of SB Pharmco Puerto Rico Inc. (SB Pharmco). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The RLD upon which you have based your ANDA, SB Pharmco's Avandamet Tablets, 1 mg/500 mg, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the Agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
6,288,095 (the '095 patent)	August 11, 2017*
7,358,366 (the '366 patent)	October 19, 2020*

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<sup>1</sup> We note that the RLD, Avandamet (rosiglitazone maleate and metformin hydrochloride) Tablets, 1 mg/500 mg, of SB Pharmco, is no longer being marketed in the U.S. and has been moved to the discontinued section of the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book). In the Federal Register of January 9, 2015 (Volume 80, No. 6), the Agency announced its determination that Avandamet (rosiglitazone maleate and metformin hydrochloride) Tablets, 1 mg/500 mg, was not withdrawn from the market for reasons of safety or effectiveness. This determination allows the Agency to continue to approve ANDAs for the discontinued drug product.

8,236,345 (the '345 patent)

October 7, 2022

\* with pediatric exclusivity added

Your ANDA contains paragraph IV certifications to each of the patents<sup>2</sup> under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Rosiglitazone Maleate and Metformin Hydrochloride Tablets, 1 mg (base)/500 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.

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 Rosiglitazone Maleate and Metformin Hydrochloride Tablets, 1 mg (base)/500 mg. This exclusivity, which is provided for under 505(j)(5)(B)(iv) of the FD&C Act, will begin to run from the date of the commercial marketing by any first applicant, as identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date you begin commercial marketing.

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 and 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.

### **REPORTING REQUIREMENTS**

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**

You may request advisory comments on proposed introductory advertising and promotional labeling materials prior to publication or dissemination. Please note that these submissions are voluntary. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert (PI), Medication Guide, and patient PI (as applicable) to:

OPDP Regulatory Project Manager  
Food and Drug Administration

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<sup>2</sup> The agency notes that the '366 and '345 patents were submitted to the agency after submission of your ANDA. Litigation, if any, with respect to these patents would not create a statutory stay of approval.

Center for Drug Evaluation and Research  
Office of Prescription Drug Promotion  
5901-B Ammendale Road  
Beltsville, MD 20705

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf> ).

You must also submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>.

Information and Instructions for completing the form can be found at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For

more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

### **ANNUAL FACILITY FEES**

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 by June 1<sup>st</sup> 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.

### **CONTENT OF LABELING**

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.

The Electronic Common Technical Document (eCTD) is CDER's standard format for electronic regulatory submissions. Beginning May 5, 2017, ANDAs must be submitted in eCTD format and beginning May 5, 2018, drug master files must be submitted in eCTD format. Submissions that do not adhere to the requirements stated in the eCTD Guidance will be subject to rejection. For more information please visit: [www.fda.gov/ectd](http://www.fda.gov/ectd).

Sincerely yours,

*{See appended electronic signature page}*

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



Carol  
Holquist

Digitally signed by Carol Holquist  
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