DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 078709

ANDA APPROVAL

Teva Pharmaceuticals USA
425 Privet Road
Horsham, PA 19044
Attention: Rich Leone
Senior Director, Regulatory Affairs, US Generics

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 Rosiglitazone Maleate and Glimepiride Tablets, 4 mg (base)/1 mg, 4 mg (base)/2 mg, 4 mg (base)/4 mg, 8 mg (base)/2 mg, and 8 mg (base)/4 mg.

Reference is made to the tentative approval letter issued by this office on November 2, 2009. Reference is also made to the complete response letter issued by this office on May 25, 2012, and to your amendments dated July 27, August 9, September 14, December 19, 2012; April 17, April 22, May 5, 2014; June 16, July 1, August 11, August 27, September 15, September 18, September 22, 2015; and March 8, 2016.

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.[1] The Office of Bioequivalence has determined your Rosiglitazone Maleate and Glimepiride Tablets, 4 mg (base)/1 mg, 4 mg (base)/2 mg, 4 mg (base)/4 mg, 8 mg (base)/2 mg, and 8 mg (base)/4 mg to be bioequivalent and, therefore, therapeutically equivalent to the RLD, Avandaryl Tablets, 4 mg (base)/1 mg, 4 mg (base)/2 mg, 4 mg (base)/4 mg, 8 mg (base)/2 mg, and 8 mg (base)/4 mg, of SKB. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

[1] We note that the reference listed drug (RLD) upon which you have based your ANDA, Avandaryl Tablets, 4 mg (base)1 mg, 4 mg (base)/2 mg, 4 mg (base)/4 mg, 8 mg (base)/2 mg, and 8 mg (base)/4 mg, of SmithKlineBeecham (Cork) Ltd. (SKB), is no longer being marketed in the United States, and is currently listed in the discontinued section of the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). The agency has announced its determination that SKB's Avandaryl Tablets, 4 mg (base)/1 mg, 4 mg (base)/2 mg, 4 mg (base)/4 mg, 8 mg (base)/2 mg, and 8 mg (base)/4 mg, were not withdrawn from sale for

The RLD upon which you have based your ANDA, SKB's Avandaryl, Tablets, 4 mg (base)/1 mg, 4 mg (base)/2 mg, 4 mg (base)/4 mg, 8 mg (base)/2 mg, and 8 mg (base)/4 mg, is subject to a period of patent protection. As noted in the Orange Book, U.S. Patent No. 7,358,366 (the '366 patent), is scheduled to expire on October 19, 2020 (with pediatric exclusivity added).

Your ANDA contains a paragraph IV certification to the '366 patent[2] 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 Rosiglitazone Maleate and Glimepiride Tablets, 4 mg (base)/1 mg, 4 mg (base)/2 mg, 4 mg (base)/4 mg, 8 mg (base)/2 mg, and 8 mg (base)/4 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 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 for Rosiglitazone Maleate and Glimepiride Tablets, 4 mg (base)/1 mg, 4 mg (base)/2 mg, 4 mg (base)/4 mg, 8 mg (base)/2 mg, and 8 mg (base)/4 mg, to submit a substantially complete ANDA with a paragraph IV certification. The agency has determined that Teva has forfeited eligibility for 180-day exclusivity for Rosiglitazone Maleate and Glimepiride Tablets, 4 mg (base)/1 mg, 4 mg (base)/2 mg, and 4 mg (base)/4 mg. Specifically, eligibility for exclusivity on those strengths was based on a previously listed patent, U.S. Patent No. 5,745,803 (the '803 patent), and that patent has expired. See section 505(j)(5)(D)(i)(VI) of the FD&C Act (forfeiture of exclusivity for expiration of patents). With respect to the 8 mg (base)/2 mg and 8 mg (base)/4 mg strengths, 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 Glimepiride Tablets, 8 mg (base)/2 mg and 8 mg (base)/4 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) of the FD&C Act. 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.

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reasons of safety or effectiveness (80 FR 66911; October 30, 2015). This determination allows the agency to approve ANDAs for the discontinued drug products.

[2] The agency notes that the '366 patent was submitted to the agency for the 4 mg (base)/1 mg, 4 mg (base)/2 mg and 4 mg (base)/4 mg strengths after submission of your ANDA. Litigation, if any, with respect to this patent for the 4

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 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

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mg (base)/1 mg, 4 mg (base)/2 mg and 4 mg (base)/4 mg strengths would not create a statutory stay of approval for these strengths.

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,

William P. Rickman -S

Digitally signed by William P. Rickman -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300043242, cn=William P. Rickman -S
Date: 2016.04.01 12:16:30 -04'00'

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