DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-071/S-026

SB Pharmco Puerto Rico, Inc (d/b/a/GlaxoSmithKline)
Attention: Margaret M. Kreider, Ph.D.
Director, Therapeutic Area, Regulatory Affairs
One Franklin Plaza; 200 North 16th Street FP-1005
Philadelphia, PA 19102-7929

Dear Dr. Kreider:

Please refer to your supplemental new drug application dated February 28, 2007, received February 28, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avandia (rosiglitazone maleate) 2 mg, 4 mg and 8 mg Tablets.

We acknowledge receipt of your submissions dated June 15 and 18, November 28, December 6 and 10, 2007, and April 16, and 30, May 9, and 13, 2008.

This supplemental new drug application for Avandia (rosiglitazone maleate) provides the results from the study entitled "A Diabetes Outcome Progression Trial," (ADOPT). This study report was submitted to satisfy a postmarketing commitment from the initial May 25, 1999 NDA approval.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the attached labeling (text for the package insert and Medication Guide) submitted May 13, 2008.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert and Medication Guide) submitted May 13, 2008). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-071/S-026."

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

We will issue a separate letter notifying you that the post marketing commitment has been fulfilled.

If you have any questions, please call Ms. Jena Weber, Regulatory Project Manager, at 301-796-1306.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism & Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure (package insert & Medication Guide)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Mary Parks

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