DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-071/S-031

Supplement Approval

SB Pharmco Puerto Rico, Inc (d/b/a/GlaxoSmithKline)
Attention: David Cocchetto, Ph.D.
U.S. Regulatory Affairs
One Franklin Plaza; 200 North 16th Street FP-1005
Philadelphia, PA 19102-7929

Dear Dr. Cocchetto:

Please refer to your supplemental new drug application (sNDA) dated November 13, 2007, received November 13, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avandia (rosiglitazone maleate) Tablets, 2 mg, 4 mg, and 8 mg.

We acknowledge receipt of your submissions dated November 13 (2) and 14, 2007 (received via email).

This application provides for the conversion of the package insert to the format prescribed by the Physician Labeling Rule (PLR). In addition to the PLR format and content changes, information is added to the Boxed Warning and the **WARNINGS AND PRECAUTIONS** section of the package insert to include information on myocardial ischemic adverse events. Language for the Patient Information Leaflet (PIL) is also revised.

We have 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.

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(1)] in structured product labeling (SPL) format as described at *http://www.fda.gov/oc/datacouncil/spl/html*. The content of the labeling must be identical to the enclosed labeling (text for the package insert and patient information leaflet) submitted November 14, 2007. Upon receipt, we will transmit that labeling to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as "**SPL for approved NDA 21-071/S-031.**"

Marketing the product with FPL that is not identical to the approved labeling may render the product misbranded and an unapproved new drug.

We remind you of your postmarketing study commitment in your submission dated November 13, 2007. This commitment is listed below.

1. To design and conduct a randomized, prospective, controlled clinical study to assess the effect of rosiglitazone on macrovascular events in patients with type 2 diabetes compared to another anti-diabetic agent.

Protocol Submission:	by July 31, 2008
Study Start:	by November 30, 2008
Final Report Submission:	by March 31, 2014

Submit the clinical protocol to your IND for this product. Submit the study final report to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of the commitment in your annual report to this NDA. The status summary should include the number of patients entered into the study, the expected summary completion and final report submission dates, and any changes in plans since the last annual report.

All submissions, including supplements, relating to this postmarketing study commitment should be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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

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 (PI), Patient Information Leaflet (PIL)

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

11/14/2007 11:41:26 AM