DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-071/S-028

SB Pharmco Puerto Rico, Inc (d/b/a GlaxoSmithKline)
Attention: Margaret Kreider, Ph.D.
Director, Regulatory Affairs
One Franklin Plaza; P.O. Box 7929
Philadelphia, PA 19101-7929

Dear Dr. Kreider:

Please refer to your supplemental new drug application dated May 31, 2007, received May 31, 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 submission dated August 13, 2007.

This supplemental new drug application proposes labeling revisions to add a **BOXED WARNING** to more prominently discuss the risks for congestive heart failure, a statement to the **CONTRAINDICATIONS** section to state that initiation of rosiglitazone is contraindicated in patients with New York Heart Association (NYHA) Class III and IV heart failure, and changes to the **WARNINGS, PRECAUTIONS**, **ADVERSE REACTIONS** and **DOSAGE AND ADMINISTRATION** sections.

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.

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 (package insert submitted August 13, 2007). 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."

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) submitted August 13, 2007.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-071/S-028**." Approval of this submission by FDA is not required before the labeling is used.

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 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

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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