DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-071/S-032 **SUPPLEMENT APPROVAL**

SB Pharmco Puerto Rico, Inc (d/b/a GlaxoSmithKline)
Attention: Margaret Kreider, Ph.D.
Senior 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 December 17, 2007, received December 18, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avandia (rosiglitazone maleate) Tablets.

We acknowledge receipt of your submissions dated January 29 and February 4, 2008.

This supplemental new drug application provides for the conversion of the approved Patient Information to a Medication Guide.

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(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the attached labeling (text for the Medication Guide submitted February 4, 2008, for supplement 032). 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-032."

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

2/22/2008 06:35:36 AM