DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-410/S-010

SB Pharmco Puerto Rico, Inc. (d/b/a/ GlaxoSmithKline)
Attention: Willa Phyall, Ph.D.
One Franklin Plaza; 200 North 16th Street, FP-1005
Philadelphia, PA 19102

Dear Dr. Phyall:

Please refer to your supplemental new drug application dated June 30, 2005, received July 1, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avandamet® (rosiglitazone maleate and metformin HCl) tablets, 1 mg/500 mg; 2 mg/500 mg; 4 mg/500 mg; 2 mg/1000 mg; and 4 mg/1000 mg.

We acknowledge receipt of your submissions dated October 14, and 31, 2005, and April 19, 2006.

This supplemental new drug application provides clinical data in support of Avandamet® (rosiglitazone maleate and metformin HCl) as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus when treatment with dual rosiglitazone and metformin therapy is appropriate.

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 enclosed labeling (text for the package insert) submitted via electronic mail May 19, 2006.

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-010**." Approval of this submission by FDA is not required before the labeling is used.

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 are waiving the pediatric study requirement for this application as specified in our letter dated October 10, 2002.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Parks, M.D.
Acting Director
Division of Metabolism and 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

5/19/2006 04:26:16 PM