DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-410/S-019

SB Pharmco Puerto Rico, Inc (d/b/a/GlaxoSmithKline)
Attention: Willa Phyall, Ph.D.
Director, U.S. Regulatory Affairs
One Franklin Plaza; P.O. Box 7929
Philadelphia, PA 19102-7929

Dear Dr. Phyall:

Please refer to your supplemental new drug application dated October 23, 2006, received October 23, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avandamet® (rosiglitazone maleate and metformin HCl), 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 April 5, and 23 (email), 2007.

This supplemental application, submitted as "Supplement - Changes Being Effected", proposes labeling revisions to the **PRECAUTIONS**, **ADVERSE REACTIONS** and **HOW SUPPLIED** sections of the package insert.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed upon final printed labeling (FPL) submitted on April 23, 2007.

Within 21 days of the date of this letter, submit 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 in content to the enclosed labeling (text for the package insert submitted April 23, 2007). Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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 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
patient information leaflet

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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