DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-410/S-023

SB Pharmco Puerto Rico, Inc (d/b/a GlaxoSmithKline)
Attention: Margaret Kreider, Ph.D.
Director, U.S. 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 August 15, 2007, received August 15, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avandamet® (rosiglitazone maleate and metformin) Tablets.

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. This application is **approved**, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

We acknowledge that you have submitted 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. We will transmit that version to the National Library of Medicine for public dissemination.

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/

Hylton Joffe
8/21/2007 11:43:37 AM
Hylton Joffe for Mary Parks