DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-410/S-016

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

Dear Dr. Phyall:

Please refer to your supplemental new drug application dated March 31, 2006, received March 31, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avandamet® (rosiglitazone maleate/metformin HCl), 1 mg/500 mg; 2 mg/500 mg; 4 mg/500 mg; 2 mg/1000 mg; 4 mg/1000 mg.

We acknowledge receipt of your submission dated November 15, 2006.

This supplemental application provides clinical information from one clinical study investigating the use of Avandamet® plus insulin in patients with type 2 diabetes mellitus who have not achieved adequate glycemic control with previous anti-diabetic therapies.

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 attached labeling (text for the package insert and patient package insert), submitted January 31, 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 21-410/S-016.**" 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.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division, The Division of Metabolism and Endocrinology Products, and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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 and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure – PI & PPI

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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