**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-410/S-013

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 October 20, 2005, received October 21, 2005, 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.

This "Changes Being Effected in 30 days" supplemental new drug application provides for revisions to the package insert label as requested in FDA's letter dated June 24, 2005. Minor editorial changes were also implemented.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on October 20, 2005.

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

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/s/

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Mary Parks

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