DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-700/S-005

SB Pharmco Puerto Rico, Inc. d/b/a GlaxoSmithKline
Attention: Margaret M. Kreider, Ph.D.
Director, US Regulatory Affairs
One Franklin Plaza
200 N. 16th Street, FP1005
Philadelphia, Pennsylvania 19102

Dear Dr. Kreider:

Please refer to your supplemental new drug application dated December 1, 2006, received December 1, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avandaryl (rosiglitazone maleate and glimepiride) Tablets.

We acknowledge receipt of your submission dated March 30, 2007.

This supplemental new drug application provides for two new tablet strengths of Avandaryl containing 8 mg rosiglitazone with either 2 mg or 4 mg glimepiride.

We have 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.

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. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

The final printed labeling (FPL) must be identical to the enclosed labeling [text for package insert, submitted December 1, 2006; text for patient package insert, submitted December 1, 2006; and container labels (8 mg/2 mg bottles of 30, submitted March 30, 2007, and 8 mg/4 mg bottles of 30, submitted December 1, 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 21-700/S-005**." Approval of this submission by FDA is not required before the labeling is used.

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 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, call Julie Marchick, Regulatory Project Manager, at (301) 796-1280.

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: Package Insert, Patient Package Insert, Container Labels (8 mg/2 mg bottles of 30 and 8 mg/4 mg bottles of 30)

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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