DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-700/S-003

SB Pharmco Puerto Rico Inc. d/b/a GlaxoSmithKline
Attention: Barbara E. Arning, M.D.
Sr. Director, US Regulatory Affairs
One Franklin Plaza
200 N. 16th Street, FP1005
Philadelphia, PA 19102

Dear Dr. Arning:

Please refer to your supplemental new drug application dated December 19, 2005, received December 20, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avandaryl (rosiglitazone maleate and glimepiride) Tablets, 4 mg/1 mg, 4 mg/2 mg, 4 mg/4 mg.

We acknowledge receipt of your submissions dated March 13 and October 17 and 23(email), 2006.

This supplemental new drug application provides for additional clinical information for Avandaryl (rosiglitazone maleate and glimepiride) Tablets in adult patients with type 2 diabetes mellitus who are naive to pharmacologic therapy.

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 enclosed labeling text for the package insert (submitted by email October 23, 2006) and enclosed text for the patient package insert (submitted by email October 23, 2006).

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 (submitted by email October 23, 2006). Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

Please submit an electronic version of the FPL or you may submit 20 paper copies of the FPL as soon as it is available (no more than 30 days after it is printed). If you submit paper FPL, 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-003**." 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 Lina AlJuburi, Pharm.D., M.S., Regulatory Project Manager, at 301-796-1168.

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

Enclosures:
Package Insert
Patient Package Insert

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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