DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-700/S-002, S-004

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

Dear Dr. Kreider:

Please refer to your supplemental new drug applications dated December 15, 2005, received December 16, 2005, 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 submissions dated April 7 and 26, 2006.

Your submission of April 26, 2006 constituted a complete response to our April 6, 2006 action letter for NDA 21-700/S-002.

These supplemental new drug applications provide for changes to the package insert to include information regarding macular edema and heart failure with the use of rosiglitazone maleate. Supplement 002 also provides for changes to the patient information leaflet to include information regarding macular edema with the use of rosiglitazone maleate.

We have completed our review of these applications, as amended. These applications are 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 on April 26, 2006). We note that FPL for the patient information leaflet was submitted on December 15, 2005.

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-002, S-004."** Approval of this submission by FDA is not required before the labeling is used.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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, Regulatory Project Manager, at (301) 796-1168.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Acting Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package insert and patient information leaflet

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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