



NDA 21-700/S-007

SB Pharmco Puerto Rico, Inc (d/b/a GlaxoSmithKline)  
Attention: Margaret Kreider, Ph.D.  
Director, U.S. Regulatory Affairs  
One Franklin Plaza; P.O. Box 7929  
Philadelphia, PA 19101-7929

Dear Dr. Kreider:

Please refer to your supplemental new drug application dated August 15, 2007, received August 15, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avandaryl® (rosiglitazone maleate and glimepiride) Tablets.

This supplemental new drug application proposes labeling revisions to add a **BOXED WARNING** to more prominently discuss the risks for congestive heart failure, a statement to the **CONTRAINDICATIONS** section to state that initiation of rosiglitazone is contraindicated in patients with New York Heart Association (NYHA) Class III and IV heart failure, and changes to the **WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, and DOSAGE AND ADMINISTRATION** sections.

We completed our review of this application. This application is **approved**, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

We acknowledge that you have submitted the 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>. We will transmit that version to the National Library of Medicine for public dissemination.

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

Enclosure

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/s/

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Hylton Joffe  
8/21/2007 11:38:40 AM  
Hylton Joffe for Mary Parks