



NDA 21-410/S-022

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 March 22, 2007, received March 22, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avandamet (rosiglitazone maleate + metformin HCl) Tablets, 2 mg/500 mg, 4 mg/500 mg, 2 mg/1000 mg, and 4 mg/1000 mg.

We acknowledge receipt of your submission dated September 20, 2007, (via electronic mail).

This supplemental new drug application provides for revisions to the **PRECAUTIONS** section of the package insert and patient package insert to include information from fracture cases in patients taking rosiglitazone containing products.

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

As soon as possible, but no later than 14 days from the date of this letter, please submit 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> that is identical to the enclosed labeling (text for the package insert) submitted September 20, 2007. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-410."

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

Enclosure (package insert +  
patient package insert)

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Mary Parks  
9/20/2007 09:55:58 PM