DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-071/S-004

SmithKline Beecham Pharmco Puerto Rico, Inc. d/b/a
GlaxoSmithKline
Attention: Sharon W. Shapowal, R.Ph.
Director, Avandia USRA
One Franklin Plaza; P.O. Box 7929
Philadelphia, PA 19101

Dear Ms. Shapowal:

Please refer to your supplemental new drug application dated February 7, 2000, received February 8, 2000, submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act for Avandia® (rosiglitazone maleate) Tablets, 2 mg, 4 mg and 8 mg.

We acknowledge receipt of your submissions dated May 5, 11, and 26, 2000, June 29, October 6, November 1 and 8, 2000, February 15, May 11, and August 26, 2002, and February 19, 20, and 27, 2003.

Your August 26, 2002, submission constituted a complete response to our February 8, 2001, action letter.

This supplemental new drug application proposes a new indication for the use of Avandia in combination with insulin for the treatment of patients with Type 2 diabetes mellitus.

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.

The final printed labeling (FPL) must be identical to the draft labeling (text for the package insert) submitted on February 27, 2003, and be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-081/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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 301-208-9354.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: package insert (final draft submitted on February 27, 2003).

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

David Orloff

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