

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-700**

**APPROVAL LETTER**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 21-700

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

Dear Dr. Kreider:

Please refer to your new drug application (NDA) dated October 31, 2003, received October 31, 2003, 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 September 9 and 15, 2004, and June 8, September 23, November 7 and 22, 2005.

The September 23, 2005, submission constituted a complete response to our August 30, 2004, action letter.

This new drug application provides for the use of Avandaryl (rosiglitazone maleate and glimepiride) Tablets as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes who are already treated with a combination of rosiglitazone and sulfonyleurea or who are not adequately controlled on a sulfonyleurea alone or for those patients who have initially responded to rosiglitazone alone and require additional glycemic control.

We completed our review of this application, as amended. It 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 [package insert, patient package insert, and container labels (4 mg/1 mg bottles of 30, 4 mg/2 mg bottles of 30, 4 mg/4 mg bottles of 30, and *sample* 4 mg/2 mg bottles of 30.)] Marketing this product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-700.**" Approval of this submission by FDA is not required before the labeling is used.

The requested 24-month shelf-life for Avandaryl Tablets packaged into HDPE bottles is acceptable.

All applications for new active ingredients, new dosage form, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

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

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}*

David Orloff, 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, Container Labels (4 mg/1 mg bottles of 30, 4 mg/2 mg bottles of 30, the 4 mg/4 mg bottles of 30, and *sample* 4 mg/2 mg bottles of 30)

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/s/

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Mary Parks  
11/23/2005 12:58:03 PM  
for Dr. Orloff