

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**21-700**

**APPROVABLE 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: Linda Rebar  
Associate Director, US Regulatory Affairs  
200 N. 16<sup>th</sup> Street  
Philadelphia, PA 19102

Dear Ms. Rebar:

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 January 20 and 29, March 8, 15, and 31, May 13, 20, and 21, June 8 and 24, July 16, August 6, 12 (2 submissions), and 24, 2004.

We completed our review of this application, as amended, and it is approvable. During a recent inspection of the manufacturing facility for this application, our field investigator conveyed deficiencies to the facility representative. Satisfactory resolution to these deficiencies is required before this application may be approved. Please notify us in writing, when your facility has been inspected and found acceptable.

Labeling will be discussed at a later date.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

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:

Division of Drug Marketing, Advertising, and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed.

We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

The drug product may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, call Lina AlJuburi, Regulatory Project Manager, at (301) 827-6414.

Sincerely,

*{See appended electronic signature page}*

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

-----  
**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

8/30/04 03:45:21 PM