



NDA 21-410/S-001

SB Pharmco Puerto Rico, Inc.
Attention: Willa B. Phyll, Ph.D.
One Franklin Plaza, P.O. Box 7929
Philadelphia, PA 19101-7929

Dear Dr. Phyll:

Please refer to your supplemental new drug application dated April 24, 2003, received April 25, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avandamet (rosiglitazone maleate/metformin HCl); 1 mg/500 mg; 2 mg/500 mg; 4 mg/500 mg Tablets.

We acknowledge receipt of your submission dated August 22, 2003.

This supplemental new drug application proposes to add two new tablet strengths: 2 mg/1000 mg, and 4 mg/1000 mg.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, and immediate container and carton labels) submitted on April 24, 2003.

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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-410/S-001." Approval of this submission by FDA is not required before the labeling is used.

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 the Division of Metabolic and Endocrine Drug Product, 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

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, HFD-410
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 301-827-6422.

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 (PI labeling dated April 10, 2003, submitted April 24, 2003)

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

/s/

Eric Colman
8/25/03 09:26:27 AM
Eric Colman for David Orloff