



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-071/S-014
NDA 21-410/S-009

SM Pharmco Puerto Rico, Inc. (d/b/a GlaxoSmithKline)
Attention: Willa B. Phyll, Ph.D.
Director, U.S. Regulatory Affairs
One Franklin Plaza; P.O. Box 7929
Philadelphia, PA 19101-7929

Dear Dr. Phyll:

Please refer to your supplemental new drug applications dated July 28, 2004, received July 29, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

NDA 21-071 (Avandia) for supplement 014;
NDA 21-410 (Avandamet) for supplement 009.

We acknowledge receipt of your submissions dated November 22, and December 13, 2004.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for revisions to the **CLINICAL PHARMACOLOGY** section, **PRECAUTIONS** section, **Drug Interactions** subsection, and **ADVERSE REACTIONS** section of the package insert labels. Editorial changes were also implemented.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling texts.

The final printed labeling (FPL) must be identical to the labeling submitted (text for the package insert) on December 13, 2004, to NDA 21-071/S-014, and November 22, 2004, to NDA 21-410/S-009.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper.

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Approval of these submissions by FDA is not required before the labeling is used.

If you issue a letter communicating important information about these drug products (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

Enclosure (package insert label for
NDA 21-071 and NDA 21-410)

**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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