DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-410

GlaxoSmithKline
Attention: Sharon Shapowal, R.Ph.
Director, U.S. Regulatory Affairs
One Franklin Plaza; P.O. Box 7929
Philadelphia, PA 19101-7929

Dear Ms. Shapowal:

Please refer to your new drug application NDA 21-410, dated November 29, 2001, received December 10, 2001, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Avandamet™ (rosiglitazone maleate/metformin HCl) Tablets, 1 mg/500 mg, 2 mg/500 mg, and 4 mg/500 mg.

We acknowledge receipt of your submissions dated December 19, 2001, February 15, April 17 and 24, June 20, July 31, August 5 and 23, and October 1 and 2, 2002.

This new drug application provides for the use of Avandamet™ (rosiglitazone maleate/metformin HCl) Tablets, 1 mg/500 mg, 2 mg/500 mg, and 4 mg/500 mg, as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus who are already treated with combination rosiglitazone and metformin, or who are not adequately controlled on metformin alone.

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 draft labeling text for the package insert submitted October 9, 2002. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.
FPL for the immediate container and carton labels were submitted on September 26, 2002.

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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-410**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens must contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (21 CFR 314.55).

We note that in your November 29, 2001, submission, you requested a waiver. Based on the information submitted, we are waiving the pediatric study requirement for this new drug 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, the Division of Metabolic and Endocrine Drug Products, 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

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 Drugs Evaluation and Research

Enclosure