DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-925

Takeda Global Research & Development Center, Inc.
Attention: Mary Jo Pritza, MPH, PharmD
Manager, Regulatory Affairs
475 Half Day Road
Lincolnshire, IL 60069

Dear Dr. Pritza:

Please refer to your new drug application (NDA) dated June 28, 2005, received June 29, 2005, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Duetact (pioglitazone HCl + glimepiride) fixed-dose combination tablets, 30 mg/2 mg, 30 mg/4 mg (b)(4)

(b)(4)

We acknowledge receipt of your submissions dated October 26, and December 15, 2005, February 7 (2), and March 24 (2), April 20, May 25, and June 14, and 23, 2006.

Your amendment dated April 20, 2006, extended the user fee goal date for this application to July 29, 2006.

(b)(4)

NDA 21-925: for Duetact (pioglitazone HCl + glimepiride) fixed-dose combination tablets, 30 mg/2 mg; 30 mg/4 mg.

(b)(4)

NDA 21-925 provides for the use of Duetact (pioglitazone HCl + glimepiride) fixed-dose combination tablets, 30 mg/2 mg, and 30 mg/4 mg, 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 pioglitazone and a sulfonylurea or whose diabetes is not adequately controlled with a sulfonylurea 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 submitted labeling (package insert submitted July 28, 2006, patient package insert submitted July 28, 2006, and immediate container and carton label submitted July 28, 2006).

Marketing the 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 21-925**." 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 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 Division of Metabolism and Endocrinology Products 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, please call Ms. Jena Weber, Project Manager, at 301-796-1306.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology 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/

Mary Parks

7/28/2006 05:00:57 PM