DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-925/S-005

Takeda Global Research & Development Center, Inc.
Attention: Mary Jo Pritza, Pharm.D.
Associate Director, Regulatory Affairs
675 N. Field Drive
Lake Forest, IL 60045

Dear Ms. Pritza:

Please refer to your supplemental new drug application dated February 1, 2008, received February 4, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Duetact (pioglitazone HCl plus glimepiride fixed-dose combination tablets), 30 mg/2 mg and 30 mg/4 mg.

We acknowledge receipt of your submissions dated August 25, and December 17, 2008.

This supplemental new drug application provides for labeling revisions to the **INDICATIONS AND USAGE** and **PRECAUTIONS** sections of the package insert labeling.

We completed our review of this application, as amended. This application 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 enclosed labeling (text for the package insert submitted December 17, 2008).

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert) submitted December 17, 2008. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, **"SPL for approved NDA 21-925/S-005."**

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 301-796-1306.

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

Enclosure (package insert)

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

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