DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-925/S-003

Takeda Global Research & Development Center, Inc.
Attention: Mary Jo Pritza, MPH, PharmD
Associate Director, Regulatory Affairs
One Takeda Parkway
Deerfield, IL 60015

Dear Ms. Pritza:

Please refer to your supplemental new drug application dated May 31, 2007, received June 1, 2007, 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 September 20, and 21, and October 1, 2007.

This supplemental new drug application provides for a modified formulation of DUETACT to include updated stability data supporting a 24-month expiration dating period, the addition of a physician sample package designed as aluminum blisters with aluminum push-thru lidding containing 7 tablets per blister package, revised carton and container labeling, and revisions to the **DESCRIPTION** and **CLINICAL PHARMACOLOGY** sections of the package insert.

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.

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 and patient package insert submitted electronically on October 1, 2007). 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."

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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
+ Patient 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

10/1/2007 03:10:29 PM