DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-925/S-001

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

Dear Ms. Pritza:

Please refer to your supplemental new drug application dated December 5, 2006, received December 6, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for DUETACT™ (pioglitazone HCl + glimepiride) fixed-dose combination tablets, 30 mg/2 mg and 30 mg/4 mg.

This supplemental application, submitted as "Supplement - Changes Being Effected" proposes to:

Update the **PRECAUTIONS** and **ADVERSE REACTIONS** sections of the package insert to include the macular edema language previously submitted to NDA 21-073/S-027 (Actos), and NDA 21-842/S-001 (Actoplus Met), approved on August 30, 2006;

Update the **CLINICAL PHARMACOLOGY** section, **Drug-Drug Interaction** subsection to describe the interaction between pioglitazone and gemfibrozil or rifampin, and the **PRECAUTIONS** section **Drug Interactions** subsection of the package insert, to incorporate additional language regarding inhibitors and inducers of CYP2C8 that was previously submitted to NDA 21-073/S-028 (Actos), and NDA 21-842/S-002 (Actoplus Met), approved on November 4, 2006;

Update the patient information sheet to include revised phonetic spelling of the tradename and to incorporate the macular edema information for patients in the "What should I tell my doctor before taking DUETACT?" section, and "How should I store DUETACT?" section.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on December 5, 2006.

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 the requirements for an approved NDA set forth under 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 (FPL + PPI)

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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Mary Parks

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