



NDA 21-925/S-002

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 March 6, 2007, received March 7, 2007, 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 replace the current 30-count Physicians Sample bottle with a 7-count Physicians Sample bottle.

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 labeling submitted on March 6, 2007.

In addition, The Division of Medication Errors and Technical Support (DMETS) has completed their review of the professional sample blister labels and carton labeling and request the following:

Please revise the blister labels and carton labeling so that only one color appears on the label and labeling. For example, the color used on the blister label matches the corresponding color used on the carton labeling (i.e., light green for the 30 mg/ 2 mg and purple for the 30 mg/4 mg product strengths). Do not use any combination of these colors. If you prefer to use a different color than that which is currently presented on the labels and labeling, none of the colors should overlap.

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

**This is a representation of an electronic record that was signed electronically and
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/s/

Mary Parks

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