**NDA 21-925 DUETACT** (pioglitazone HCl plus glimepiride fixed-dose combination) tablets

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**PROPOSED RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

## I. GOAL:

The goal of this REMS is to communicate the risks of DUETACT.

## II. REMS ELEMENTS:

### A. Medication Guide

A Medication Guide will be dispensed with each DUETACT prescription. The Medication Guide will be included at the end of the prescribing information as a perforated attachment. Each packaging configuration including bottles, sample cards and trays will contain a Medication Guide.

Because the Medication Guide is included as part of the packaging and provided by additional means for DUETACT, Takeda has met the requirements of 21 CFR 208.24 for distribution and dispensing of the Medication Guide.

### B. Communication Plan

The REMS for DUETACT does not include a Communication Plan.

### C. Elements To Assure Safe Use

This REMS for DUETACT does not include elements to assure safe use.

### D. Implementation System

Because this REMS for DUETACT does not include elements to assure safe use, an implementation system is not required.

### E. Timetable for Submission of Assessments

The Timetable for Assessments is as follows:
1st FDAAA assessment: March 2011 18 months from approval of REMS
2nd FDAAA assessment: September 2012 3 years from approval of REMS
3rd FDAAA assessment: September 2016 7 years from approval of REMS

Takeda will submit the assessments within 60 days of the close of the intervals as noted above.