CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-024

REMS

NDA 22-024___ ACTOPLUS MET XR (pioglitazone hydrochloride and metformin hydrochloride extended-release) tablets

Takeda Global Research and Development Center, Inc.
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PROPOSED RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL:

The goal of this REMS is to communicate the risks of ACTOPLUS MET XR.

II. REMS ELEMENTS:

A. Medication Guide

A Medication Guide will be dispensed with each ACTOPLUS MET XR 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 ACTOPLUS MET XR, Takeda has met the requirements of 21 CFR 208.24 for distribution and dispensing of the Medication Guide.

B. Communication Plan

The REMS for ACTOPLUS MET XR does not include a Communication Plan.

C. Elements To Assure Safe Use

This REMS for ACTOPLUS MET XR does not include elements to assure safe use.

D. Implementation System

Because this REMS for ACTOPLUS MET XR 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: 18 months from approval
2nd FDAAA assessment: 3 years from approval
3rd FDAAA assessment: 7 years from approval

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