NDA 21-995

JANUVIA

(sitagliptin)

Tablet

Dipeptidyl peptidase 4 (DPP-4) inhibitor

Merck Sharp & Dohme Corp.

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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL(S)

The goal of this REMS is to inform the patients of the serious risks associated with the use of JANUVIA (sitagliptin).

II. REMS ELEMENTS

A. Medication Guide

Merck Sharp & Dohme Corp. ("Merck") in accordance with 21 CFR 208.24(b) will ensure that the currently approved Medication Guide is available for distribution to patients and dispensed with each JANUVIA prescription.

Merck in accordance with 21 CFR 208.24 will provide the currently approved Medication Guide in sufficient numbers for distribution. Merck will attach a JANUVIA (sitagliptin) Medication Guide to each unit-of-use package of JANUVIA (sitagliptin) to ensure that the Medication Guide is given to each patient with each new prescription and refill. In addition, copies of the Medication Guide may also be provided to US pharmacies for direct distribution to patients.

In accordance with 21 CFR 208.24(d), the JANUVIA (sitagliptin) container labels will include an instruction to the authorized dispenser to provide a copy of the Medication Guide to each patient to whom JANUVIA (sitagliptin) is dispensed.

The Medication Guide will also be available on JANUVIA's website at www.Januvia.com.

B. Timetable for Submission of Assessments

Merck will submit REMS Assessment to FDA 18 months, 3 years, and 7 years from the date of the approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment.

Merck will submit each assessment so that it will be received by the FDA on or before the due date.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21995	SUPPL-12	MERCK CO INC	JANUVIA 100MG (SITAGLIPTIN PHOSPHATE)
NDA-21995	SUPPL-14	MERCK CO INC	JANUVIA 100MG (SITAGLIPTIN PHOSPHATE)
NDA-21995	SUPPL-11	MERCK CO INC	JANUVIA 100MG (SITAGLIPTIN PHOSPHATE)
NDA-21995	SUPPL-10	MERCK CO INC	JANUVIA 100MG (SITAGLIPTIN PHOSPHATE)

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/s/

MARY H PARKS
02/26/2010