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APPLICATION NUMBER:

202270Orig1s000

RISK ASSESSMENT and RISK MITIGATION REVIEW(S)

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Risk Evaluation and Mitigation Strategy (REMS) Memorandum
REMS Retraction

U.S. FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE of Drug Evaluation II
DIVISION of Metabolism and Endocrinology Products

NDA/BLA #s:	202270
Products:	JANUMET XR (sitagliptin/extended release metformin fixed-dose combination) Tablets
APPLICANT:	Merck Sharp & Dohme Corporation
FROM:	Mary H. Parks, M.D.
DATE:	July 1, 2011

On December 3, 2010, we issued a REMS notification letter for the pending NDA for JANUMET XR (sitagliptin/extended release metformin fixed-dose combination) to ensure the benefits of the drug outweigh the risk of acute pancreatitis, including necrotizing pancreatitis. The REMS was to consist of a Medication Guide, and a timetable for submission of assessments of the REMS.

On December 16, 2010, the applicant submitted a proposed REMS which included a Medication Guide and a timetable for submission of assessments of the REMS.

On April 14, 2011 we issued Release REMS Requirement letters for NDA 021995/S-017 JANUVIA (sitagliptin) and NDA 022044/S-016 JANUMET (sitagliptin/metformin hydrochloride) after a determination was made that a REMS for these products was no longer necessary to ensure the benefits of the drug outweigh the risk described above.

After consultations between the Division of Metabolism and Endocrinology Products (DMEP) in the Office of New Drugs (OND) and the Division of Risk Management (DRISK) in the Office of Surveillance and Epidemiology (OSE), we have determined that a REMS for JANUMET XR (sitagliptin/extended release metformin fixed-dose combination) will not be necessary to ensure the benefits of the drug outweigh the risks described above. The Medication Guide will be approved as part of the labeling and will be adequate to address the serious and significant public health concern and will meet the standard in 21 CFR 208.1. The Medication Guide will be part of the approved labeling in accordance with 21 CFR 208. Like other labeling, Medication Guides are subject to the safety labeling change provisions of section 505(o)(4) of the FDCA.

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/s/

AMY G EGAN
07/20/2011
Amy Egan for Mary Parks

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