CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202270Orig1s000

PROPRIETARY NAME REVIEW(S)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202270

PROPRIETARY NAME REQUEST
CONDITIONALLY ACCEPTABLE

Merck Sharp & Dohme Corp.
P.O. Box 1000, UG2C-50
North Wales, PA 19454-1099

Attention: Richard J. Swanson, Ph.D.
Senior Director, Worldwide Regulatory Affairs

Dear Dr. Swanson:

Please refer to your New Drug Application (NDA) dated September 23, 2010, received September 23, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sitagliptin and Metformin Extended-release Tablets, 50 mg/500 mg, 50 mg/1000 mg, and 100 mg/1000 mg.

We also reference your Class 2 resubmission to your New Drug Application (NDA) dated August 3, 2011, and received August 3, 2011.

We also reference your original March 25, 2011, correspondence, received March 25, 2011, requesting review of your proposed proprietary name Janumet XR. Additionally, we also reference your August 16, 2011, correspondence, received August 16, 2011, requesting review of your proposed proprietary name, Janumet XR. We have completed our review of the proposed proprietary name, Janumet XR and have concluded that it is acceptable.

If **any** of the proposed product characteristics as stated in your August 16, 2011, submission are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review.

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Margarita Tossa, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-4053. For any other information regarding this application contact the Office of New Drugs (OND) Regulatory Project Manager, Raymond S. Chiang at (301) 796-1940

Sincerely,
{See appended electronic signature page}

Carol Holquist, RPh
Director
Division of Medication Error Prevention and Analysis
Office of Medication Error Prevention and Risk Management
Office of Surveillance and Epidemiology

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CAROL A HOLQUIST
11/04/2011

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management

Proprietary Name Review--Final

Date:	November 1, 2011
Reviewer(s):	Richard Abate, RPh, MS, Safety Evaluator Division of Medication Error Prevention and Analysis
Team Leader	Carlos Mena-Grillasca, RPh, Team Leader Division of Medication Error Prevention and Analysis
Division Director	Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis
Drug Name(s):	Janumet XR (Sitagliptin and Metformin Extended-release) Tablets, 50 mg/500 mg, 50 mg/1000 mg, and 100 mg/1000 mg
Application Type/Number:	NDA 202270
Applicant:	Merck, Sharpe, and Dohme, Corp
OSE RCM #:	2011-3134

CONTENTS

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.