NDA 202270/S-025

SUPPLEMENT APPROVAL

Merck Sharp & Dohme Corp.,
a subsidiary of Merck & Co., Inc.
Attention: Lou Ann Eader, PhD
Director, Global Regulatory Affairs
351 N. Sumneytown Pike, P. O. Box 1000
UG2D-44
North Wales, PA 19454

Dear Dr. Eader:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 1, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Janumet XR (sitagliptin and metformin hydrochloride extended-release) tablets.

This "Changes Being Effected" supplemental new drug application provides for correction of the salt equivalency statement for metformin HCl in Section 11 of the package insert in response to FDA's Supplement Request letter dated May 04, 2021.

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling and with minor editorial revisions listed below and reflected in the enclosed labeling.

The revision date listed at the end of the Highlights of Prescribing Information has been updated to "11/2021."

CONTENT OF LABELING

Within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Christopher LaFleur, Regulatory Business Process Manager, at (240) 402 - 4724.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Chief, Branch 1
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:
Content of Labeling