DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-044/S-009

Merck & Co., Inc.
Attention: Richard J. Swanson, Ph.D.
Director, Worldwide Regulatory Affairs
P.O. Box 1000, UG2C-50
North Wales, PA 19454-1099

Dear Dr. Swanson:

Please refer to your supplemental new drug application dated October 10, 2008, received October 10, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Janumet (sitaglitpin/metformin fixed dose combination) Tablets.

This "Changes Being Effected" supplemental new drug application provides for the addition of hepatic enzyme elevations under the Postmarketing Experience subsection of the Adverse Reactions setion of the Package Insert. This supplement was submitted in response to our supplement request letter dated August 13, 2008.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (submitted October 10, 2008**), with the following change: In the Full Prescribing Information: Contents, under 17 Patient Counseling Information, remove the statement "FDA-Approved Patient Labeling"**. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 22-044/S-009."

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Julie Marchick, Regulatory Project Manager, at (301) 796-1280.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert, Patient Package Insert

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

/s/

Mary Parks
10/20/2008 10:24:38 AM