DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-044/S-007

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 November 2, 2007, received Novemebr 2, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Janumet (sitagliptin/metformin hydrochloride fixed dose combination) Tablets.

We acknowledge receipt of your submission dated April 9, 2008.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of the Manati, Puerto Rico manufacturing site.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling to be used at the Manati, Puerto Rico manufacturing site.

The final printed labeling (FPL) to be used at the Manati, Puerto Rico manufacturing site must be identical to the enclosed labeling (immediate container and carton labels submitted on April 9, 2008).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 22-044/S-007**." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your commitment communicated by email on April 29, 2008, to Teshara Bouie, to provide stability data from the first commercial batch which, when available, will be provided in the next annual report.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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

Enclosures: Carton and Container Labels to be used at the Manati, Puerto Rico manufacturing site

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/s/

Mary Parks
5/1/2008 04:00:43 PM