DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-995/S-007

Merck & Co., Inc.
Attention: Richard J. Swanson, Ph.D.
Director, 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 January 22, 2008, received January 22, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Januvia (sitagliptin) Tablets.

We acknowledge receipt of your submission dated July 21, 2008.

This supplemental new drug application provides for the following changes:

1. The following statement was added under Warnings and Precautions in the Package Insert (PI): "There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with JANUVIA or any other anti-diabetic drug."

2. The following sentence was removed under Clinical Studies in the PI: "JANUVIA has been studied as monotherapy and in combination with metformin, pioglitazone, glimepiride, and glimepiride+metformin."

3. The following sentence was removed under What is Januvia? in the Patient Package Insert (PPI): "JANUVIA may be taken alone or along with certain other medicines to control blood sugar."

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 text and with the following minor editorial revisions: (1) changing the dates in the Highlights section of the PI from "XX/20XX" to "7/2008" and (2) revising the date at the end of the PPI from "Month Year" to "July 2008".

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 (text for the package insert, submitted July 21, 2008**)**. 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 21-995/S-007."

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: 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
7/22/2008 09:22:03 AM