**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-995/S-002, S-003, S-004, S-006

Merck & Co., Inc.
Attention: Steven A. Aurecchia, M.D.
Director, Regulatory Affairs
UG2CD-48, P.O. Box 1000
North Wales, PA 19454-1099

Dear Dr. Aurecchia:

Please refer to your supplemental new drug applications dated December 11, 2006, received December 12, 2007 (S-002); dated December 14, 2006, received December 15, 2007 (S-003); dated April 18, 2007, received April 19, 2007 (S-004); and dated September 19, 2007, received September 19, 2007 (S-006), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Januvia (sitagliptin) Tablets.

We acknowledge receipt of your submissions dated March 8, April 11, July 31, September 25, and October 12, 2007 to S-002, April 13, July 31, and October 12, 2007 to S-003, May 4 and 11, and October 12, 2007 to S-004, and October 12, 2007 to S-006.

These supplemental new drug applications provide for:

S-002: Additions to the Package Insert (PI) describing the results of (1) a study of combination therapy with a sulfonylurea when the single agent alone does not provide adequate glycemic control and in combination therapy with a sulfonylurea plus metformin when dual therapy does not provide adequate glycemic control, and (2) a non-inferiority study comparing Januvia to glipizide in patients without adequate glycemic control on metformin.

S-003: Additions to the PI describing the results of a study of initial therapy in combination with metformin when diet and exercise do not provide adequate glycemic control.

S-004: Additions to the PI and Patient Package Insert (PPI) to include hypersensitivity post-marketing adverse reaction data.

S-006: Additions to the PI and PPI to include hypersensitivity as a contraindication.

We have completed our review of these applications, as amended. These applications are 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) removal of the blank line within the Highlights of Prescribing Information, and (2) removal of the comma after Warnings and Precautions in the Recent Major Changes section of the Highlights of Prescribing Information.

We waive the requirements of 21 CRF 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

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 in content to the enclosed labeling (text for package insert and text for patient package insert submitted on October 12, 2007. 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-002, S-003, S-004, S-006."

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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
Center for Drug Evaluation and Research

Enclosures: Package Insert, Patient Package Insert

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

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/s/

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Mary Parks

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