DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-044/S-003 and S-004

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 April 27, 2007, received April 27, 2007 (S-003); and dated May 11, 2007, received May 11, 2008 (S-004), 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 submissions dated August 24, 2007, January 22, and February 25, 2008, to S-003 and dated August 27, 2007, January 22, and February 25, 2008 to S-004.

These supplemental new drug applications provide for:

S-003: Additions to the Package Insert (PI) describing the results of a study of sitagliptin and metformin co-administration in patients with inadequate glycemic control on diet and exercise alone.

S-004: Additions to the PI describing the results of (1) a study of sitagliptin add-on therapy in patients with inadequate glycemic control on metformin and glimepiride, and (2) a non-inferiority study comparing sitagliptin add-on therapy to glipizide add-on therapy in patients with inadequate glycemic control on metformin.

Also, in response to our supplement request letter dated November 21, 2007, changes were made to the Indications and Usage section, and a statement regarding macrovascular outcome data was added to the Warning and Precautions section of the PI. Revisions were made to the Patient Package Insert (PPI).

We 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) changing the dates in the Highlights section of the PI from "XX/200X" to "2/2008" and (2) revising the date at the end of the PPI from "Month 200X" to "February 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 in content to the enclosed labeling (text for package insert and text for patient package insert submitted on February 25, 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 22-044/S-003, S-004."

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

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

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