DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-044/S-002, S-005, 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 April 18, 2007, received April 19, 2007 (S-002); dated August 23, 2007, received August 23, 2007 (S-005); 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 Janumet (sitagliptin/metformin hydrochloride fixed-dose combination) Tablets.

We acknowledge receipt of your submissions dated May 11, 2007, May 16, 2007, October 29, 2007, and November 30, 2007, to S-002; September 28, 2007, October 29, 2007, and November 30, 2007 to S-005; and October 29, 2007, and November 30, 2007, to S-006.

Your submission of October 29, 2007, constituted a complete response to our October 19, 2007, action letter for S-002.

These supplemental new drug applications provide for:

S-002: Additions to the Package Insert (PI) and Patient Package Insert (PPI) to include hypersensitivity post-marketing adverse reaction data.

S-005: Additions to the PI and PPI to include upper respiratory tract infection post-marketing adverse reaction information.

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

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) revising the dates in the Highlights section of the PI to "1/2008" and (2) revising the date at the end of the PPI to "January 2008".

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 November 30, 2007, with minor revisions). 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-002, S-005, 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 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
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