DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-549/S-015

Merck & Co., Inc.
Attention: Nicholas Andrew
Associate Director, Worldwide Regulatory Affairs
P.O. Box 2000, RY 33-200
Rahway, NJ 07065-0900

Dear Mr. Andrew:

Please refer to your supplemental new drug application dated April 18, 2008, received April 18, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for EMEND (aprepitant) 40 mg, 80 mg, and 125 mg oral capsules.

We acknowledge receipt of your submissions dated August 20, 2008 and November 12, 2008. We also refer to your submission dated December 17, 2007 to NDA 21-549/S-010 containing a postmarketing study commitment final report.

This supplemental new drug application provides for revised PRECAUTIONS, Drug Interactions sections of the label to include information regarding the use of a 40 mg dose of EMEND with tolbutamide and oral contraceptives. In addition, this application addresses the following postmarketing commitment from NDA 21-549/S-010, approved on June 30, 2006:

- Study Commitment #2: An open label study to evaluate the effect of a single 40-mg dose of aprepitant on the activity of Cytochrome P-450 2C9 in healthy young adult subjects.

  Protocol Submission: October 31, 2006
  Study Start: February 28, 2007
  Final report Submission: December 31, 2007

We 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. We also conclude that the above postmarketing commitment is fulfilled.

Within 14 days of the date of this letter, submit an amendment to all pending Changes Being Effected supplemental applications with content of labeling in SPL format that has been revised to include the changes approved in this prior approval supplemental application.

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 Jagjit Grewal, Regulatory Project Manager, at (301) 796-0846.

Sincerely,

{See appended electronic signature page}

Donna Griebel, M.D.
Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Package Insert Label

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

/s/

Donna Griebel

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