DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-549/S-012

Merck & Co., Inc.
Attention: Nicholas Andrew
Associate Director, MRL Regulatory Affairs
P.O. Box 1000, UG2CD-48
North Wales, PA 19454

Dear Mr. Andrew:

Please refer to your supplemental new drug application dated September 29, 2006, received October 2, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for EMEND (aprepitant) Capsules 80 and 125 mg.

We acknowledge receipt of your submissions dated April 20, 2007, May 16, 2007, and November 9, 2007.

Your submission of May 16, 2007 constituted a complete response to our April 2, 2007 action letter.

This supplemental new drug application provides for a label change addressing Post Marketing Commitments (PMC) listed as Commitment #2 in the March 26, 2003 approval letter:

- Commitment #2
  Merck will conduct a drug interaction study to evaluate the effect of aprepitant on either vinorelbine or irinotecan.

  The timeline is as follows:
  - Protocol Submission — 1st Quarter 2004
  - Completion of patient portion of study — 4th Quarter 2005
  - Submission of Clinical Study Report — 3rd Quarter 2006

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and submitted labeling (package insert submitted November 9, 2007).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this

submission "**FPL for approved supplement NDA 21-549/S-012.**" Approval of this submission by FDA is not required before the labeling is used.

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

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., MPH
Deputy Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: 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/

Joyce Korvick

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