DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-549/S-014 **APPROVAL LETTER**

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 February 5, 2008, received February 5, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for EMEND (aprepitant) capsules 125 mg, 80 mg, and 40 mg.

We acknowledge receipt of your submissions dated February 12, 2008; December 18, 2008; February 16, 2009; and July 13, 2009.

Your submission of December 18, 2008 constituted a complete response to our October 17, 2008 action letter.

This "Changes Being Effected" supplemental new drug application provides for:

- a revised package insert label and patient package insert label to reflect the availability of an I.V. dosage form on Day 1 of the three day regimen, and to be consistent with NDA 22-023 Emend (fosaprepitant dimeglumine) for Injection
- a new bifold blister package

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 enclosed agreed-upon labeling text.

Within 14 days of the date of this letter, submit 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 the package insert and text for the patient package insert). 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 supplement NDA 021549/S-014**."

Submit final printed carton and container labels that are identical to the carton and immediate container labels as agreed in your submission dated July 13, 2009, as soon as they are available,

but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved supplemental NDA 21-549/S-014**." Approval of this submission by FDA is not required before the labeling is used.

In addition, within 14 days of the date of this letter, amend any pending applications for this NDA with content of labeling in structured product labeling (SPL) format to include the changes approved in this 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
Patient Package Insert Label

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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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Donna Griebel

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