DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-023/S-001

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

Dear Mr. Andrew:

Please refer to your supplemental new drug application dated April 25, 2008, received April 25, 2008 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for EMEND (fosaprepitant dimeglumine) for Injection, 115 mg/mL.

We acknowledge receipt of your submissions dated June 4, 2008 and January 14, 2009.

This "Changes Being Effected" supplemental new drug application provides for the addition of the postmarketing adverse reactions pruritus, rash, urticaria, and hypersensitivity reactions including anaphylactic reactions to the package insert label and patient package insert label.

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.

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 to the enclosed labeling (text for the package insert, text for the patient package insert) and submitted labeling (package insert submitted January 14, 2009, patient package insert submitted January 14, 2009). 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 supplemental NDA 22-023/S-001."

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and 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}

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

Enclosure: Package insert label
Patient 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/

Joyce Korvick

2/2/2009 05:17:43 PM