



NDA 021549/S-017

**SUPPLEMENT APPROVAL**

Merck Sharp & Dohme Corp.  
Attention: Nicholas Andrew  
Associate Director, Regulatory Affairs  
128 E. Lincoln Avenue  
PO Box 2000, RY33-200  
Rahway, NJ 07065-0900

Dear Mr. Andrew:

Please refer to your supplemental new drug application dated May 19, 2009, received May 19, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for EMEND (aprepitant) capsules 125 mg, 80 mg and 40 mg.

We acknowledge receipt of your submissions dated May 19, 2009; June 26, 2009; July 9, 2009; August 14, 2009; August 21, 2009; September 15, 2009; October 16, 2009; November 18, 2009; January 21, 2010; and March 18, 2010.

This "Prior Approval" supplemental new drug application provides for:

- updates to the package insert label based upon data from postmarketing study report Protocol 130 ("A Randomized, Double-Blind, Parallel-Group Study Conducted Under In-House Blinding Conditions to Determine the Efficacy and Tolerability of Aprepitant for the Prevention of Chemotherapy-Induced Nausea and Vomiting Associated With Moderately Emetogenic Chemotherapy"),
- conversion of the package insert label into PLR format, and
- revisions to the patient package insert label.

**CONTENT OF LABELING**

We have completed our review of this application, as amended. It 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)(1)(i)] 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). For administrative purposes, please designate this submission, "**SPL for approved NDA 021549/S-017**."

## **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

## **LETTERS TO HEALTH CARE PROFESSIONALS**

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  
5600 Fishers Lane, Room 12B05  
Rockville, MD 20857

## **REPORTING REQUIREMENTS**

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21549	SUPPL-17	MERCK AND CO INC	EMEND (APREPITANT) 80MG/125MG

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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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JOYCE A KORVICK  
03/19/2010