DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22-023/S-002
NDA 22-023/S-003
NDA 22-203/S-005

SUPPLEMENT APPROVAL

Merck & Co., Inc.
Attention: Nicholas Andrew
Associate Director, Worldwide Regulatory Affairs
126 E. Lincoln Ave.
P.O. Box 2000
Rahway, NJ 07065-0900

Dear Mr. Andrew:

Please refer to the following supplemental new drug applications you submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for EMEND (fosaprepitant dimeglumine) for Injection:

Supplement	Submitted and Received	Supplement Type
S-002	June 29, 2009	Prior Approval
S-003	August 14, 2009	Changes Being Effected
S-005	October 23, 2009	Changes Being Effected

The "Prior Approval" supplemental new drug application provides for the conversion of the package insert (PI) to Physician's Labeling Rule (PLR) format. The "Changes Being Effected" supplemental new drug applications affect the (PI) and patient package insert (PPI). The changes include revisions to Warnings and Precautions, including the addition of hypersensitivity reactions based on postmarketing data, as well as various revisions for consistency with the approved labeling for Emend Capsules (21-549/S-014).

We have completed our review of these applications, as amended. They are 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 (PI and PPI). For administrative purposes, please designate this submission, "SPL for approved NDA 22-023/S-002, S-003, S-005".

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 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, 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 Heather Buck, Regulatory Project Manager, at (301) 796-1413.

Sincerely,

{See appended electronic signature page}

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

Enclosures – Package Insert and Patient Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22023	SUPPL-5	MERCK AND CO INC	EMEND FOR INJECTION
NDA-22023	SUPPL-3	MERCK AND CO INC	EMEND FOR INJECTION
NDA-22023	SUPPL-2	MERCK AND CO INC	EMEND FOR INJECTION

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

/s/

JOYCE A KORVICK
03/22/2010