DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-549/S-008

Merck & Co., Inc.
Attention: Vijay Tammara, Ph.D.
Director, Regulatory Affairs
Sumneytown Pike, P.O. Box 4, BLA-20
West Point, PA 19486

Dear Dr. Tammara:

Please refer to your supplemental new drug application dated September 29, 2004, received September 29, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Emend™ (aprepitant) Capsules, 80 mg and 125 mg.

We acknowledge receipt of your submissions dated September 29 and December 17, 2004, as well as your submissions dated January 5, January 28, May 20, June 14, June 15, June 16, June 20, and July 22, 2005.

We also acknowledge receipt of your submission dated October 27, 2005 sent via email containing your currently approved packaging components.

This supplemental new drug application provides for the use of Emend™ (aprepitant) in the prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.

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 the text for the patient package insert, (package insert submitted via email October 25, 2005 and patient package insert submitted via email October 18, 2005). In addition, the FPL must be identical to the packaging components submitted via email October 27, 2005, as follows: Trade-Tri-Fold 80-125 mg, Sample Tri-Fold 80-125 mg, HUD carton 125 mg, HUD Blister 80 mg, HUD carton 80 mg, HUD Blister 125 mg, Sample carton 80 mg, Sample Foil 80 mg, Sample Carton 125 mg, and Sample Foil 125 mg.

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-008.**" Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for ages 0 to less than 6 months of age and deferring pediatric studies for ages 6 months to less than 17 years of age for this application.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA for the use of Emend ™ (aprepitant) in the prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy in pediatric patients 6 months to less than 17 years of age.

   Final Report Submission: December 31, 2007

We also remind you of your postmarketing study commitment submitted October 25, 2005 via email and agreed-upon in an October 25, 2005 teleconference between you and this Division. This commitment is listed below.

2. Conduct an appropriately powered randomized controlled clinical trial, in patients receiving moderately emetogenic chemotherapy (MEC), designed to document generalizability among various chemotherapies and an evaluation of efficacy in male patients.

Protocol Submission:	by March 31, 2006
Study Start:	by December 31, 2006
Final Report Submssion:	by December 31, 2008

Submit final study reports to this NDA. For administrative purposes, all submissions related to the pediatric postmarketing study commitment must be clearly designated "**Required Pediatric Study Commitment**."

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705

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, HFD-410
Food and Drug Administration
Center for Drug Evaluation and Research
5901-B Ammendale Road
Beltsville, MD 20705-1266

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 Betsy Scroggs, Regulatory Project Manager, at (301) 796-0991.

Sincerely,

{See appended electronic signature page}

Brian E. Harvey, M.D., Ph.D.
Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure:

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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