DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-549/S-007

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 June 25, 2004, received June 25, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Emend® (aprepitant) Capsules, 80 mg and 125 mg.

We also refer to your supplemental new drug application dated June 15, 2004 and approved December 15, 2004.

We also refer to receipt of your agreed-upon package insert, via facsimile, on December 22, 2004.

This supplemental new drug application provides for changes in the PRECAUTIONS section of the Package Insert (PI) to include information about the use of hormonal contraceptives with Emend® as well as to update the Patient Prescription Information (PPI) sheet.

We completed our review of this application. This application is approved, as amended, 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 attached label.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-549/S-007. Approval of this submission by FDA is not required before the labeling is used.

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
FDA
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 Dr. Betsy Scroggs, Regulatory Project Manager, at (301) 827-1250.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Acting Director
Division of Gastrointestinal and Coagulation Drug 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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