DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-549/S-009
Merck & Co., Inc.
Attention: Vijay Tammara, Ph.D.
Director, Regulatory Affairs
Sumneytown Pike
P.O. Box 4, BLA-2
West Point, PA 19486-0004

Dear Dr. Tammara:

Please refer to your supplemental new drug application dated December 9, 2004, received December 9, 2004 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Emend™ (aprepitant) 80 mg and 125 mg Capsules.

We also refer to your May 23, 2005 submission containing updated labeling and your June 7, 2005 submission received via email containing a clean version of your proposed package insert identified as (~~9565002~~) to be followed by a submission containing the same electronic label to the Central Document Room.

This supplemental new drug application provides for an update to the PRECAUTIONS section of the package insert to reflect study #094 results for use of Emend™ and dolasetron concomitantly. We note that study #094 was done in order to satisfy your post marketing commitment (PMC) #3 as follows:

> "Merck will conduct a drug interaction study in healthy subjects, including some who are CYP2D poor metabolizers, to evaluate the effect of aprepitant on dolasetron."

Please also note that you have satisfactorily fulfilled PMC #3 and the fulfillment will be communicated as a comprehensive document reflecting your other post marketing commitments as well in a separate letter at a later date.

We completed our review of this application. 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 package insert submitted June 7, 2005.

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-009." 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 Betsy Scroggs, Pharm.D., Regulatory Health Project Manager at (301) 827-1250.

Sincerely,

{See appended electronic signature page}

Brian E. Harvey, M.D., Ph.D.
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/

Kathy Robie-Suh
6/9/05 05:28:23 PM
signing for Dr. Brian E. Harvey