DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-527/S-027

PRIOR APPROVAL SUPPLEMENT

Merck & Co., Inc.
Attention: Mary Beth Wigley
770 Sumneytown Pike
P.O. Box 4, BLA-20
West Point, PA 19486-0004

Dear Ms. Wigley:

We refer to your supplemental new drug application dated May 26, 2004, received May 27, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pepcid® (famotidine) Oral Suspension.

This supplemental new drug application proposes changes to the labeling for Pepcid® (famotidine) Oral Suspension to reflect the addition of a new manufacturing site, change in manufacturing process, and change to tablet images for the Pepcid® tablet dosage form.

We have completed the review of this supplemental application and it is approved.

Please submit final printed labeling (FPL) identical to the enclosed labeling text for the package insert, submitted May 26, 2004.

You may 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 19-527/S-027". Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Paul E. Levine, Jr., R.Ph., J.D., Regulatory Health Project Manager, at (301) 827 7310.

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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