DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-325/S-017, 20-801/S-010, 20-902/S-007, 20-958/S-010

Merck Research Laboratories
Attn: Brenda McGuire, M.S., R.N.
Associate Director, Worldwide OTC Regulatory Affairs
Sumneytown Pike, P.O. Box 4, BLX-29
West Point, PA 19486

Dear Ms. McGuire:

Please refer to your supplemental new drug applications dated April 26, 2004, received April 27, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pepcid AC Film Coated (10mg and 20mg famotidine) Tablets (20-325/S-017), Pepcid AC Chewable (10mg famotidine) Tablets (20-801/S-010), Pepcid AC Gelcaps (10mg famotidine) Capsules (20-902/S-007), and Pepcid Complete (10mg famotidine, 800mg calcium carbonate, 165mg magnesium hydroxide) Tablets (20-958/S-010).

We acknowledge receipt of your submissions dated October 19, 2004.

These supplemental new drug applications provide for revised labeling incorporating additional warning statements.

We have completed our review of these applications, as amended. These applications are 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 following labeling submitted on October 19, 2004:

Pepcid AC Film Coated Tablets, 10 mg:
- package insert
- 6-ct blister carton
- 60-ct bottle label

Pepcid AC Film Coated Tablets, 20 mg (Maximum Strength):
- package insert
- 5-ct blister carton
- 1-ct sample pouch
- 50-ct bottle label,

Pepcid AC Chewable Tablets:
- package insert
- 60-ct bottle carton
- 60-ct bottle label

Pepcid AC Gelcaps:
- package insert
- 6-ct blister carton
- 60-ct bottle label

Pepcid Complete:
- package insert
- 5-ct pouch carton
- 25-ct bottle label
- 1-ct sample pouch

We note that the following pieces of labeling are also under review as a part of these supplemental applications:
(b)(4)

We also refer to your October 19, 2004, submission, which did not include a revised copy for these pieces but stated that you would be revising these pieces accordingly. For these pieces of labeling that were not provided in the October 19 submission, the revisions that you have committed to are considered a condition of approval.

You should submit FPL for **all** pieces of approved labeling acknowledged above. The FPL must be formatted in accordance with the requirements of 21 CFR 201.66.

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, these submissions should be designated "FPL for approved supplement NDA 20-325/S-017, NDA 20-801/S-010, NDA 20-902/S-007, NDA 20-958/S-010." Approval of these submissions by FDA is not required before the labeling is used.

We also recommend the following labeling change for Pepcid AC Maximum Strength (NDA 20-325/S-017). This change is not a condition of approval. You may incorporate this change in the labeling at the next time of printing and report the revised labeling in the following annual report.

> Vertically align the additional bulleted statements ("frequent wheezing, particularly with heartburn" and "nausea or vomiting") with bulleted statements appearing on the previous horizontal line for the 5-ct blister carton label as required under 21 CFR 201.66(d)(4).

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 LCDR Keith Olin, Regulatory Project Manager, at (301) 827-2293.

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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

/s/

Charles Ganley

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