DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-958/S-015

Merck & Co., Inc.
Attention: Paulette Midgette
Manager, Regulatory Affairs
Worldwide OTC Regulatory Affairs
Sumneytown Pike, P.O. Box 4, UN-D129
West Point, PA 19486

Dear Ms. Midgette:

Please refer to your supplemental new drug application for NDA 20-958 dated July 18, 2008, received July 18, 2008, submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for Pepcid Complete (10 mg famotidine, 800 mg calcium carbonate and 165 mg magnesium hydroxide) chewable Tablets.

We also acknowledge receipt of your submissions dated July 31, August 8, September 12 and 19, October 28 and 29 and November 5, 2008.

This supplemental new drug application provides for the replacement of the current Pepcid™ Complete chewable tablet product with a new chewable tablet (EZ Chews) formulation and the introduction of a new "Tropical Fruit" flavor with associated packaging and labeling changes.

We have 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. Only the referenced labels and count sizes for the new chewable tablet formulation are approved for use under this application.

The final printed labeling (FPL) must be identical to the enclosed labeling (5-, and 8-count carton label and 25x1-count dispensit carton label and 1-ct trade pouch label for the tropical fruit flavor; 25- and 50-count bottle label and 1-count sample pouch label for the tropical fruit, berry and mint flavors; and 100-count bottle label for the berry flavor), and must be formatted in accordance with the requirements of 21 CFR 201.66.

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 these submissions "**FPL for approved supplement NDA 20-958/S-015**." Approval of these submissions by FDA is not required before the labeling is used.

Per your November 12, 2008 commitment, we remind you that the prominence of the tamper resistance statement will be increased and the statement "The makers of Pepcid Complete do not

manufacture store brands" will be removed from the back carton label on all tropical fruit carton labels by July 2009. We also remind you that the "NEW TASTE" and "NEW FLAVOR" flags must be removed from the label and labeling, wherever it appears, after the first six months of marketing.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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 Mary Vienna, Regulatory Project Manager, at (301) 796-4150.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
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/

Joel Schiffenbauer

11/18/2008 06:12:22 AM