DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-801/S-007

Merck & Co., Inc.
Brenda McGuire, M.S., R.N.
Regulatory Affairs
Sumneytown Pike, P.O. Box 4, BLX-29
West Point, PA 19486

Dear Ms. McGuire:

Please refer to your supplemental new drug application dated January 17, 2002, received January 18, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pepcid ®AC AC Chewable Tablets. We acknowledge receipt of your submission dated January 28, 2002.

This supplemental new drug application provides for outer carton labeling consisting of a 30-count pack of Pepcid ®AC with a 5-count bonus pack of Pepcid®Complete.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text and with the minor editorial revisions listed below. Accordingly, the supplemental application is approved effective on the date of this letter.

1. Position the trade name "Pepcid AC" and the SOI so that the letter "P" in "Pepcid" does not appear to be part of the SOI.

2. Revise the phrase "Prevents & Relieves Heartburn due to Acid Indigestion" so that the words "Prevents" and "Heartburn" will be unbolded.

3. Revise the graphic of the human upper torso with an arrow pointing to the heart and the phrase "PREVENTS HEARTBURN" to "PREVENTS & RELIEVES HEARTBURN".

4. Under **Directions**, the directions for "adults and children 12 years and over" will be revised to reflect the most recent approved labeling. The directions will be revised by bolding the words in the entire second bullet ("do not swallow tablet whole, chew completely"), and by bolding the word "chew" in the third and fourth bullets.

5. The expiration date applied to the outer package will reflect the shortest expiration date of either product contained inside.

The final printed labeling (FPL) must be identical to the draft labeling submitted on January 17, 2001, (carton label), with the inclusion of the changes proposed in your letter of commitment dated January 28, 2002, and must be formatted in accordance with the requirements of 21 CFR 201.66. These revisions are terms of the approval of this application.

NDA 20-801 S-007

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-801/S-007." Approval of this submission by FDA is not required before the labeling is used.

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

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 Daniel P. Keravich, M.S., M.B.A., Regulatory Health Project Manager, at 301-827-2248.

Sincerely,

{See appended electronic signature page}

Linda M. Katz, M.D., M.P.H.
Deputy 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/

Linda Katz

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