DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-801/S-004

Merck Research Laboratories
Attention: Edwin L. Hemwall, Ph.D.
Vice President, Global Regulatory Affairs
Johnson & Johnson Merck
BLA-33, PO Box 4
West Point, PA 19486-004

Dear Dr. Hemwall:

Please refer to your supplemental new drug application dated November 27, 2000, received November 30, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pepcid®AC Chewable Tablets.

We acknowledge receipt of your submissions dated December 7, 2000, March 6, 22, and 28, 2001.

This supplemental new drug application provides for an additional container-closure system packaged in 45 cc and 60 cc HDPE bottles with polypropylene caps.

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.

As stated in your fax letter of commitment dated March 28, 2001, the following revisions in the labeling will be made in accordance with 21 CFR 201.21 (b).

- The carton labeling (45 cc and 60 cc cartons) and bottle labeling (45 cc and 60 cc bottles) will be revised so that the phenylalanine content statement in "**Other Information**" begins each word in the phrase (except mg) with a capital letter.

The above changes must be made on the final printed labeling.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (patient package insert submitted March 22, 2000, immediate container and carton labels submitted March 22, 2000) and must be formatted in accordance with the requirements of 21 CFR 201.66. These revisions are terms of the approval of this application.

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-004." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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