

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-958 / S-002

APPROVAL LETTER
w/ APPROVED LABELING



NDA 20958/S-002

Merck Research Laboratories
Attention: Brenda A. McGuire, B.S., R.N.
Regulatory Affairs
P.O. Box 4, BLA-33
West Point, PA 19486

Dear Mrs. McGuire:

Please refer to your supplemental new drug application dated July 5, 2001, received July 6, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pepcid[®] Complete [famotidine 10 mg/antacid (calcium carbonate 800 mg, and aluminum hydroxide 165 mg)] Chewable Tablets.

We acknowledge receipt of your submissions dated July 11, August 03 and October 04, 08, 11, 15, 24 and 29, 2001.

This supplemental new drug application provides for a berry-flavored chewable tablet.

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 agreed upon in your submission dated October 30, 2001, the requirements are as follows:

1. In the *Other information* section of the bottle labeling for all container sizes, the bulleted statements need to be vertically aligned.
2. The graphics associated with the Statement of Identity (i.e., "Acid Reducer + Antacid") on the principal display panel will be modified in order to enhance its prominence in conjunction with the proprietary name.
3. The word "*NEW*" will be deleted from packaging after 180 days of marketing.

The final printed labeling (FPL) must be identical to the attached labeling (immediate container, trade and sample pouch labels, carton labels and package insert) submitted on July 5, 2001, and include the minor editorial revisions indicated above. The final printed labeling 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 20958/S-002." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

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