



NDA 20-752

Merck Research Laboratories
Attention: Michelle W. Kloss, Ph.D.
P.O. Box 4, BLA-20
West Point, PA 19486-0004

Dear Dr. Kloss:

Please refer to your new drug application (NDA) dated August 1, 1996, received August 2, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pepcid RPD™ (famotidine) Orally Disintegrating Tablets, 20 mg and 40 mg.

We acknowledge receipt of your submissions dated October 8 and 31; November 26; December 4, 1997; and May 11, 13 (2 submissions), 20, 21, and 27, 1998. Your submission of November 26, 1997 constituted a full response to our July 31, 1997 action letter. The user fee goal date for this application is May 28, 1998.

This new drug application provides for a new oral dosage form for Pepcid (famotidine).

We have completed the review of this 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 submitted labeling (package insert submitted December 4, 1997, immediate container and carton labels submitted May 21, 1998) with the agreed upon revisions listed below. Accordingly, the application is approved effective on the date of this letter.

1. Revise the dosage form name on all labeling for this drug product to "Orally Disintegrating Tablets."
2. In the CLINICAL PHARMACOLOGY, Pharmacokinetics section of the package insert, revise the statement "The three oral formulations of PEPCID are rapidly absorbed and achieve essentially identical maximum plasma concentrations (C_{max}) and areas under the curve (AUC) for famotidine. Dose-related peak plasma concentrations occur at 1-3 hours." to "After oral doses, peak plasma levels occur in 1-3 hours."

In addition, sufficient stability data for this drug product has been submitted to support an expiration period of 24 month with the storage statement "Store below 30°C (86°F)."

The final printed labeling (FPL) must be identical to the submitted draft labeling with the revisions committed to in the May 27, 1998 submission. Marketing the product with FPL that is not identical to the approved agreed upon labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case 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 NDA 20-752." Approval of this submission by FDA is not required before the labeling is used.

In addition, we remind you of your commitment made in the submission dated November 26, 1997 committing to submit, within six months of approval, the results of a feasibility study investigating possible marking methodologies for the tablets.

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.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 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, contact Michael Folkendt, Project Manager, at 301-443-0487.

Sincerely,

Lilia Talarico, M.D.
Director
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

cc: