



DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 75-718

Food and Drug Administration
Rockville MD 20857

APR 16 2001

Reddy-Cheminor, Inc.
U.S. Agent for: Dr. Reddy's Laboratories Limited
Attention: C. Jeanne Taborsky
6333 Summer Crest Drive
Columbia, MD 21045

Dear Madam:

This is in reference to your abbreviated new drug application dated October 8, 1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Famotidine Tablets USP, 20 mg and 40 mg.

Reference is also made to your amendments dated February 2, March 16, March 20, and March 23, 2001.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Famotidine Tablets USP, 20 mg and 40 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Pepcid® Tablets USP, 20 mg and 40 mg, respectively, of Merck Research Laboratories). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

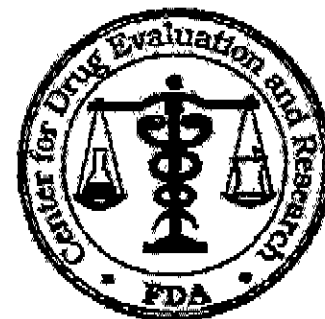
Sincerely yours,



Gary Buehler
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research

ANDA 75-718

845-573-5612

**OFFICE OF GENERIC DRUGS**

Food and Drug Administration
HFD-600, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773
Fax: 301-594-0180

FAX TRANSMISSION COVER SHEET

TO: APPLICANT: Reddy-Cheminor

TEL: 410-309-3145

ATTN: C. Jeanne Taborsky

FAX: ~~202~~ 444-1456FROM: *Paul Campanelli*
Kassandra Sherrod

PROJECT MANAGER: 301-827-5849

Dear Madam:

This facsimile is in reference to your abbreviated new drug application dated October 8, 1999, submitted pursuant to Section 305(j) of the Federal Food, Drug, and Cosmetic Act for Famotidine Tablets USP, 20 mg and 40 mg.

We are pleased to inform you that this application is APPROVED!

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