DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-024

JUN 22 1998

Hoechst Marion Roussel, Inc.
Attention: Ms. Libby Hayes, B.S.
10236 Marion Park Drive
P.O. Box 9627
Kansas City, MO 64134-0627

Dear Ms. Hayes:

Please refer to your new drug application dated December 22, 1997, received December 22, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PRIFTIN® (rifapentine) 150 mg tablets.

We acknowledge receipt of your submissions dated as follows.

January 23, 1998	March 19, 1998	June 3, 1998
January 28, 1998	March 27, 1998	June 4, 1998
January 29, 1998	April 6, 1998	June 5, 1998
February 3, 1998	April 13, 1998	June 9, 1998
February 5, 1998	April 28, 1998	June 10, 1998
February 9, 1998	April 30, 1998	June 11, 1998
February 16, 1998	May 12, 1998	June 16, 1998
March 3, 1998	May 19, 1998	June 22, 1998
March 16, 1998	May 22, 1998(3)	
March 18, 1998	May 29, 1998	

The User Fee goal date for this application is June 22, 1998.

This new drug application provides for the use of PRIFTIN® (rifapentine) 150 mg tablets in the treatment of pulmonary tuberculosis.

We have completed the review of this application, including the submitted draft labeling, according to the regulations for accelerated approval and have concluded that adequate information has been presented to approve PRIFTIN® (rifapentine) 150 mg tablets for use as recommended in the draft labeling in the submission dated June 15, 1998, as revised on June 22, 1998. Accordingly, the application is approved under 21 CFR 314.510. Approval is effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on June 22, 1998. Marketing the product with FPL that is not identical to this draft labeling 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 "FINAL PRINTED LABELING" for approved NDA 21-024. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of labeling may be required.

Products approved under the Accelerated Approval Regulations (21 CFR 314.510) require further adequate and well-controlled studies to verify and describe clinical benefit. The accelerated approval commitments are not specifically designated in your June 15, 1998, letter; therefore, they are listed as follows:

We remind you of your Phase 4 commitments specified in your submission dated June 15, 1998, and to our June 11, 1998, facsimile, and to our letter dated June 5, 1998. These commitments, along with any completion dates agreed upon, are listed below.

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We also remind you that 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.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. Should an IND not be required to meet your Phase 4 commitments, please submit protocol, data, and final reports to this NDA as correspondences. In addition, we request under 21 CFR 314.81(b)(2)(vii) that you include in your annual report to this application, a status summary of each commitment. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

We also remind you that, under 21 CFR 314.550, after the initial 120 day period following this approval, you must submit all promotional materials, including promotional labeling as well as advertisements, at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement.

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, please contact Brenda Atkins, Project Manager, at (301) 827-2127.

Sincerely yours,

/S/

M. Dianne Murphy, M.D.
Director
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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