

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number : 064150

Trade Name : RIFAMPIN CAPSULES USP 300MG

Generic Name: Rifampin Capsules USP 300mg

Sponsor : Eon Labs Manufacturing, Inc.

Approval Date: May 28, 1997

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APPLICATION 064150

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	Included	Pending Completion	Not Prepared	Not Required
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Pharmacology Review(s)				
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Application Number 064150

APPROVAL LETTER

MAY 28 1997

Eon Labs Manufacturing, Inc.
Attention: Mr Michael Lisjak
227-15 N. Conduit Avenue
Laurelton, NY 11413



Dear Sir:

This is in reference to your abbreviated antibiotic application dated April 12, 1995, submitted pursuant to Section 507 of the Federal Food, Drug, and Cosmetic Act, for Rifampin Capsules USP, 300 mg.

Reference is also made to your amendments dated December 14, 1995, March 25 and May 2, 1997.

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 Rifampin Capsules USP, 300 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Rifadin® Capsules 300 mg of Hoechst Marion Roussel, Inc.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under 21 CFR 314.70, 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. 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-240). 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-240) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

 /S/

5/28/97

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research