

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

64-217

CHEMISTRY REVIEW(S)

OFFICE OF GENERIC DRUGS
CHEMISTRY, MANUFACTURING AND CONTROLS REVIEW

1. CHEMIST'S REVIEW NO. 3
2. ANDA# 64-217
3. NAME AND ADDRESS OF APPLICANT
Bedford Laboratories
300 Northfield Road
Bedford, OH 44146
4. LEGAL BASIS FOR ANDA SUBMISSION
The reference listed drug is Rifadin® I.V. manufactured by Hoechst Marion Roussel (NDA 50-627).
5. SUPPLEMENT(s)
N/A
6. PROPRIETARY NAME
N/A
7. NONPROPRIETARY NAME
Rifampin for Injection USP
8. SUPPLEMENT(s) PROVIDE(s) FOR
N/A
9. AMENDMENTS AND OTHER DATES
Firm:
Original Submission: 10/17/97
Major Amendment: 9/16/98
Minor Amendment: 6/15/99
Amendment: 6/28/99
Telephone Amendment: 9/16/99

FDA:
Acknowledgement: 11/24/97
Major Deficiencies: 7/1/98
Facsimile Deficiencies: 4/27/99
Telephone Conversation: 9/14/99
10. PHARMACOLOGICAL CATEGORY
Antibacterial (tuberculostatic)
11. HOW DISPENSED
Rx

12. RELATED IND/NDA/DMFs

NDA 50-627 - Hoechst Marion Roussel (RLD)

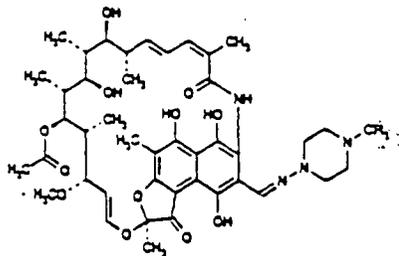
13. DOSAGE FORM/ROUTE OF ADMINISTRATION

Sterile lyophilized powder for intravenous injection

14. STRENGTH

600 mg/vial

15. CHEMICAL NAME AND STRUCTURE



(1) Rifamycin, 3-[[[(4-methyl-1-piperazinyl)imino]methyl]-;
(2) 5,6,9,17,19,21-Hexahydroxy-23-methoxy-2,4,12,16,18,
20,22-heptamethyl-8-[N-(4-methyl-1-piperazinyl)formimidoyl]-
2,7-(epoxypentadeca[1,11,13]trienimino)naphtho[2,1-b]furan-
1,-11(2H)-dione 21-acetate.

C₄₃H₅₃N₄O₁₂.

Molecular Weight: 822.95

16. RECORDS AND REPORTS

N/A

17. COMMENTS

All pending CMC deficiencies have been resolved. The EER is acceptable, as well as the labeling. The microbiologist recommends approval on the basis of sterility assurance, and the Division of Bioequivalence has granted the bio-waiver. This is the first generic for this drug product.

18. CONCLUSIONS/RECOMMENDATIONS

Approval is recommended

19. REVIEWER

Susan Rosencrance

S. Rosencrance
4/24/99

DATE COMPLETED

9/17/99

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Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable.

Chem Rev 3

9/17/99