

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

64-217

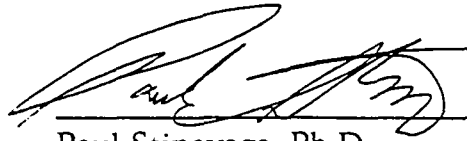
MICROBIOLOGY REVIEW

MAY 10 1999

REVIEW FOR OFFICE OF GENERIC DRUGS
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #2 OF ANDA 64-217
10 May 1999

- A. 1. ANDA 64-217 N/AC
APPLICANT: Bedford Laboratories
300 Northfield Road
Bedford, OH 44146
2. PRODUCT NAMES: Rifampin for Injection, USP
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is provided in single-dose 30 mL vials containing 600 mg/vial of lyophilized drug product for reconstitution and intravenous administration only.
4. METHODS OF STERILIZATION:
The product is
5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The product is indicated for treatment of tuberculosis in combination with at least one other antituberculosis drug.
- B. 1. DATE OF INITIAL SUBMISSION: 17 October 1997
2. DATE OF AMENDMENT: 16 September 1998 (Subject of this review.)
3. INNOVATOR PRODUCT/MANUFACTURER: Rifadin I.V. (NDA 50-627)/Hoechst Marion Roussel
4. ASSIGNED FOR REVIEW: 30 April 1999
- C. REMARKS: The drug product is compounded, filtered, filled, sealed, labeled and packaged at Ben Venue Laboratories, Inc., 300 Northfield Road, Bedford, OH.

D. CONCLUSIONS: The application is recommended for approval on the basis of sterility assurance.


Paul Stinavage, Ph.D.

10 May 1999

JAC 5/10/99
MJ 5/14/99

CC:

Page(s) 2

Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable.

Micro Review 2
5/10/99

225 117

REVIEW FOR OFFICE OF GENERIC DRUGS
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 OF ANDA 64-217
9 June 1998

A. 1. ANDA 64-217

APPLICANT: Bedford Laboratories
300 Northfield Road
Bedford, OH 44146

2. PRODUCT NAMES: Rifampin for Injection, USP

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:

The product is provided in single-dose 30 mL vials containing 600 mg/vial of lyophilized drug product for reconstitution and intravenous administration only.

4. METHODS OF STERILIZATION:

The product is aseptically filled.

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:

The product is indicated for treatment of tuberculosis in combination with at least one other antituberculosis drug.

B. 1. DATE OF INITIAL SUBMISSION: 17 October 1997

2. DATE OF AMENDMENT: (none)

3. INNOVATOR PRODUCT/MANUFACTURER: Rifadin I.V. (NDA 50-627)/Hoechst Marion
Roussel

4. ASSIGNED FOR REVIEW: 10 April 1998

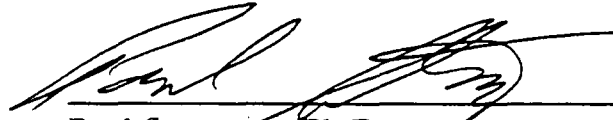
C. REMARKS:

The drug product is compounded, filtered, filled, sealed, labeled and packaged at Ben Venue Laboratories, Inc., 300 Northfield Road, Bedford, OH.

ANDA 64-217, Rifampin for Inj., USP, Bedford Labs, Micro. Rev. #1

D. CONCLUSIONS:

The application is approvable pending resolution of microbiology issues. Specific comments are provided in "E. Review Notes" and "Microbiologist's Draft of Letter to Applicant".


Paul Stinavage, Ph.D. 9 June 1998
PAC 6/9/98

cc:

Page(s) 10

Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable.

micro Rev. #/

6/9/98