

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

64-217

ADMINISTRATIVE DOCUMENTS

**REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH**

ANDA Number: 64-217

Date of Submission: September 16, 1998

Applicant's Name: Bedford Laboratories, Inc.

Established Name: Rifampin for Injection USP, 600 mg/vial

Labeling Deficiencies:

1. CONTAINER

Relocate "Rx only" to appear prominently on the principal display panel.

2. CARTON

See comment under CONTAINER.

3. INSERT

a. DESCRIPTION

Correct the structural formula. We refer you to USP 23.

b. CLINICAL PHARMACOLOGY

i. Intravenous Administration

Revise "(n 5)" to read "(n=5)".

ii. Pediatrics (Intravenous Administration)

In the first sentence revise "patients" to read "pediatric patients" and "(n 12)" to read "(n=12)".

iii. Susceptibility Tests

A) Start a new paragraph with the sentence, "The radiometric broth ...".

B) Diffusion Techniques

In the first sentence revise "... procedure that has ..." to read "... procedure^{3,4} that has ...".

c. INDICATIONS AND USAGE

Delete trade names "Rifater" and "Rifamate".

d. OVERDOSAGE (Acute Toxicity)

Start a new paragraph with the second sentence.

e. DOSAGE AND ADMINISTRATION

i. Revise the first sentence to read, "Rifampin for Injection is ...".

ii. Tuberculosis
Delete the trade name "(eg, RIFATER*)." [Two locations]

iii. Add the following as the last paragraph of this section:

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. We refer you to 21 CFR 201.57(j).

f. HOW SUPPLIED

We encourage you to relocate "Rx only" to appear immediately beneath the title.

Please revise your labels and labeling, as instructed above, and submit 12 final printed copies.

Please note that we reserve the right to request further changes in your labels and/or labeling based upon changes in the approved labeling of the listed drug or upon further review of the application prior to approval.

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

A handwritten signature in cursive script, appearing to read "Jerry Phillips for", is written over a horizontal line.

Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

RECORD OF TELEPHONE CONVERSATION

<p>Susan Rosencrance and I called Pratemala Patel regarding ANDA 64-217 and the 6/23/99 minor amendment.</p> <p>Ms. Rosencrance said that we had previously asked the firm to include a test for solution completeness and clarity in their stability testing protocol and that the firm had agreed to do so. However, the updated stability data provided in the 6/23/99 amendment did not include these items. She requested the data be provided.</p> <p>Ms. Rosencrance also noted that the submitted stability data contained entries for "MR" (meets requirements). She requested actual results be reported.</p> <p>Ms. Patel said she would send an amendment as a Minor Telephone Amendment (fax with hard copy to follow).</p>	<p>DATE 9/14/99</p>
	<p>APPLICATION NUMBER 64-217</p>
	<p>TELECON</p>
	<p>INITIATED BY FDA</p>
	<p>PRODUCT NAME Rifampin for Injection USP</p>
	<p>FIRM NAME Bedford</p>
	<p>NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD Pratemala Patel DRA</p>
	<p>TELEPHONE NUMBER 440-232-3320 469</p>
	<p>SIGNATURE <i>Mark Anderson</i> <i>S. M. Rosencrance</i> 9/17/99</p>
	<p>v:\firmsam\bedford\telecons\64217.001</p>

Rifampin

Injection solution, 600 mg/vial (lyophilized powder)

Reviewer: Gur J.P. Singh

AADA# 64-217

File # 64217W-097

Bedford Laboratories

300 Northfield Road

Bedford, OH 44146

Submission Date:

October 17, 1997.

REVIEW OF A WAIVER REQUEST

BACKGROUND: The firm is seeking waiver of *in vivo* bioequivalence study requirements for its Rifampin injection solution, 600 mg/vial, to be marketed as lyophilized powder. The reference product Rifadin® 600 mg/vial (Hoechst Marion Roussel, NDA #50627) is marketed as injection solution (lyophilized powder). It is indicated for treatment of tuberculosis and the meningococcal carrier state.

COMPARATIVE COMPOSITION (Not to be released under FOI):

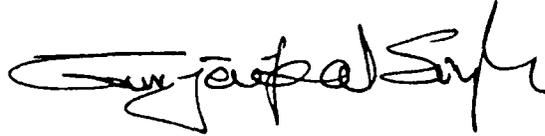
<i>Ingredient</i>	<i>mg/vial</i>	
	<i>Test</i>	<i>Reference</i>
Rifampin	600	600
Sodium Formaldehyde Sulfoxylate	10	10
Sodium Hydroxide	Adjust pH	Adjust pH

COMMENTS:

1. The test product is eligible for a waiver of *in vivo* bioequivalence study requirements pursuant to 21 CFR 320.22 (1) because:
 - a. It is a parenteral solution intended solely for injection.
 - b. It contains the same active ingredient and inactive ingredients in the same concentration as a drug product that is subject of an approved full new drug application.

RECOMMENDATION : The Division of Bioequivalence agrees that the information submitted by Bedford Laboratories demonstrates that the Rifampin 600 mg/vial injection falls under 21 CFR Section 320.22(b)(1) of Bioavailability/Bioequivalence Regulations. The waiver of *in vivo* bioequivalence study requirements for of Rifampin 600 mg/vial injection of the test product is granted. From the Bioequivalence point of view, the Division of Bioequivalence deems the test formulation to be bioequivalent to Rifadin® 600 mg/vial injection manufactured by Hoechst Marion Roussel:

Gur J.P. Singh, Ph.D.
Division of Bioequivalence
Review Branch II.



RD INITIALED SNERURKAR
FT INITIALED SNERURKAR



2/17/1998

CONCUR:

Dale P. Conner
Dale P. Conner, Pharm.D
Director
Division of Bioequivalence.

Date: 2/17/98