

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
40347

MICROBIOLOGY REVIEW

OFFICE OF GENERIC DRUGS, HFD-620
Microbiology Review #1
January 31, 2000

- A. 1. ANDA 40-347
- APPLICANT Bedford Laboratories
270 Northfield Road
Bedford, OH 44146
2. PRODUCT NAME: Leucovorin Calcium Injection, USP,
10mg/mL; 30mL/vial and 50mL/vial
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: I/V and I/M
Injection.
4. METHOD(S) OF STERILIZATION:
5. PHARMACOLOGICAL CATEGORY: Antidote to Folic acid
antagonists.
- B. 1. DATE OF INITIAL SUBMISSION: November 19, 1998
Subject of this Review (Received, November 20, 1998)
2. DATE OF AMENDMENT: Major Amendment, July 27, 1999.
Subject of this Review (Received, July 29, 1999)
3. RELATED DOCUMENTS: None
4. ASSIGNED FOR REVIEW: January 24, 2000
- C. REMARKS: The subject drug product is manufactured in the
of the Ben
Venue Laboratories manufacturing facility in
Bedford, OH.
- D. CONCLUSIONS: The submission is not recommended for
approval on the basis of sterility assurance.
Specific comments are provided in "E. Review
Notes" and "Microbiology Comments to be Provided
to the Applicant" found at the end of this review.
The above deficiencies represent a minor
amendment.

/S/
Nrapendra Nath, Ph. D.

cc: Original ANDA
Duplicate ANDA
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Field Copy
Drafted by N. Nath, HFD 600; V:\microrev\40-347.doc
Initialed by A. High

CSA 5/15/00

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micro #1

OFFICE OF GENERIC DRUGS, HFD-620
Microbiology Review #2
April 6, 2000

A. 1. ANDA 40-347

APPLICANT Bedford Laboratories
270 Northfield Road
Bedford, OH 44146

2. PRODUCT NAME: Leucovorin Calcium Injection, USP,
10mg/mL; 30mL/vial and 50mL/vial

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: I/V and I/M
Injection.

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Antidote to Folic acid
antagonists.

B. 1. DATE OF INITIAL SUBMISSION: November 19, 1998

2. DATE OF AMENDMENT: March 30, 2000.
Subject of this Review (Received, March 31, 2000)

3. RELATED DOCUMENTS: None

4. ASSIGNED FOR REVIEW: April 6, 2000

C. REMARKS: The subject amendment provides for the response to
microbiology deficiencies in the fax dated March
24, 2000.

D. CONCLUSIONS: The submission is recommended for approval on
the basis of sterility assurance. Specific
comments are provided in "E. Review Notes".

IS/
Nrapehdra Nath, Ph. D.

CC: Original **ANDA**
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Drafted by N. Nath, HFD 600; V:\microrev\40-347a2.doc
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