

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
75405

MICROBIOLOGY REVIEW

OFFICE OF GENERIC DRUGS
HFD-620
Microbiology Review #1
June 11, 1999

A. 1. ANDA: 75-405

APPLICANT: Bedford Laboratories
300 Northfield Road
Bedford, OH 44146

2. PRODUCT NAME: Cladribine Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 10mL (at 1 mg/mL) in 20 cc vials, intravenous injection, single dose vial

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: synthetic antineoplastic agent for treatment of Hairy Cell Leukemia

B. 1. DATE OF INITIAL SUBMISSION: June 29, 1998
Subject of this Review (Received June 30, 1998)

2. DATE OF AMENDMENTS: 7/14/98 - labeling deficiencies
3/23/99 - Chemistry deficiencies
5/10/99 - Chemistry deficiencies

3. RELATED DOCUMENTS:
DMF glass vials
DMF stoppers

4. ASSIGNED FOR REVIEW: June 3, 1999

C. REMARKS: The chemistry review is complete (5/21/99).

D. CONCLUSIONS: The submission is **not recommended** for approval on the basis of sterility assurance. Specific comments regarding the processing are provided in "E. Review Notes" and a Microbiologist's draft of deficiencies to be provided to the Applicant found at the end of the review.

LSI 6/11/99
Lynne A. Ensor, Ph. D.

AC 7/6/99
MJ 7/7/99

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Micro Review #1

Microbiology Comments to be Provided to the Applicant

ANDA: 75-405

APPLICANT: Bedford Laboratories

DRUG PRODUCT: Cladribine Injection, 10mL (at 1 mg/mL) in 20cc vials

A. Microbiology Deficiencies:

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microbiology Deficiencies

MICROBIOLOGY DEFICIENCIES" should also be noted in your cover page/letter.

Sincerely yours,

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Mary Fanning, M.D., Ph.D.
Associate Director of Medical Affairs
Office of Generic Drugs
Center for Drug Evaluation and Research

OFFICE OF GENERIC DRUGS

HFD-620

Microbiology Review #2

August 5, 1999

A. 1. **ANDA:** 75-405

APPLICANT: Bedford Laboratories
300 Northfield Road
Bedford, OH 44146

2. PRODUCT NAME: Cladribine Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 10mL (at 1 mg/mL) in 20 cc vials, intravenous injection, single dose vial

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: synthetic antineoplastic agent for treatment of Hairy Cell Leukemia

B. 1. DATE OF INITIAL SUBMISSION: June 29, 1998
(Received June 30, 1998)

2. DATE OF AMENDMENTS: August 2, 1999
Subject of this Review (Received August 3, 1999)

3. RELATED DOCUMENTS:
DMF glass vials
DMF stoppers

4. ASSIGNED FOR REVIEW: August 5, 1999

C. REMARKS: The chemistry review is complete (5/21/99).

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

/S/ 8/5/99
Lynne A. Ensor, Ph. D.

cc: Original **ANDA** 75-405a

Duplicate ANDA

Division Copy

Field Copy

Drafted by L. Ensor, HFD 620 v:wp\microrev\75405a

Initialed by M. Fanning, P. Cooney

PhC 8/10/99

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micro review # 2

Microbiology Comments to be Provided to the Applicant

ANDA: 75-405

APPLICANT: Bedford Laboratories

DRUG PRODUCT: Cladribine Injection, 10mL (at 1 mg/mL) in 20cc vials

A. Microbiology Deficiencies:

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microbiology deficiencies

MICROBIOLOGY DEFICIENCIES" should also be noted in your cover page/letter.

Sincerely yours,

MS

Mary Fanning, M.D., Ph.D.
Associate Director of Medical Affairs
Office of Generic Drugs
Center for Drug Evaluation and Research