

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75-547

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 4
2. ANDA # 75-547
3. NAME AND ADDRESS OF APPLICANT
Bedford Laboratories
270 Northfield Road
Bedford, Ohio 44146
4. LEGAL BASIS FOR SUBMISSION
Accepted by OGD
5. SUPPLEMENT(s)
N/A
6. PROPRIETARY NAME
N/A
7. NONPROPRIETARY NAME
Thiotepa
8. SUPPLEMENT(s) PROVIDE(s) FOR:
NA
9. AMENDMENTS AND OTHER DATES:
FIRM:
12/29/98 Original ANDA Submission
2/4/99 Amendment (Production Batch size changed)
3/12/99 New Correspondence
7/20/99 ANDA MAJOR Amendment
3/22/00 ANDA MINOR Amendment
2/2/01 ANDA MINOR Amendment
2/26/01 Telephone Amendment
3/1/01 (2) Telephone Amendments
FDA:
2/9/99 Filing Acceptability letter
2/23/99 Bio Waiver Review (Granted)
3/18/99 Labeling Review
6/17/99 Chemistry Review #1; N/A MAJOR
2/17/00 Chemistry Review #2; N/A MINOR
4/21/00 Chemistry Review #3; N/A MINOR
10. PHARMACOLOGICAL CATEGORY
Antitumor
11. Rx or OTC
Rx
12. RELATED IND/NDA/DMF(s)
13. DOSAGE FORM
Injection (lyophilized)
14. POTENCY
15 mg/vial

als)
)

15. CHEMICAL NAME AND STRUCTURE

See USP 24, page 1650.

16. RECORDS AND REPORTS: N/A

17. COMMENTS: USP 24 was referenced for specifications for the drug substance and release specifications for the drug product.

A. Telephone Amendment Issues:

1. Firm has revised their Specification sheets.
2. Bedford has indicated that they are proposing a 12 month expiration dating period for the referenced drug product. Bedford has also certified that the expiration dating period will only be extended via prior-approval supplement.
3. Microbial limits of the drug substance have been revised to be consistent with the manner that the Division recently requested for their ANDA 75290.

B. Other Issues:

1. The microbiologist's review of the submission for sterility assurance has been completed and is a recommendation for approval based on sterility assurance.
2. A satisfactory CGMP compliance evaluation for the firms referenced in the ANDA was received. EER is O.K. as of 5/5/00.

18. CONCLUSIONS AND RECOMMENDATIONS

This ANDA is Approvable.

19. REVIEWER:

Kenneth J. Furnkranz 2/28/01

DATE COMPLETED: 2/12/01

DATE REVISED: 2/28/01

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Commercial/Confidential
Information and are not
releasable.

Item Rev 4

2/28/01

1. CHEMISTRY REVIEW NO. 3

2. ANDA #: 75-547

3. NAME AND ADDRESS OF APPLICANT

Bedford Laboratories
270 Northfield Road
Bedford, Ohio 44146

4. LEGAL BASIS FOR SUBMISSION

Accepted by OGD

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

N/A

7. NONPROPRIETARY NAME

Thiotepa

8. SUPPLEMENT(s) PROVIDE(s) FOR:

NA

9. AMENDMENTS AND OTHER DATES:

FIRM:

12/29/98 Original ANDA Submission
2/4/99 Amendment (Production Batch size changed)
3/12/99 New Correspondence
7/20/99 ANDA MAJOR Amendment
3/22/00 ANDA MINOR Amendment

FDA:

2/9/99 Filing Acceptability letter
2/23/99 Bio Waiver Review (Granted)
3/18/99 Labeling Review
6/17/99 Chemistry Review #1; N/A MAJOR
2/17/00 Chemistry Review #2; N/A MINOR

10. PHARMACOLOGICAL CATEGORY

Antitumor

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

:
,
,

bing Vials)
rubber)

13. DOSAGE FORM

Injection (lyophilized)

14. POTENCY

15 mg/vial

15. CHEMICAL NAME AND STRUCTURE

See USP 23, page 1544.

16. RECORDS AND REPORTS

N/A

17. COMMENTS

Approved NDA 20-058 and the USP 23 were referenced for specifications for the drug substance and release specifications for the drug product.

A. Deficiencies:

1. The ... is ... a) is deficient.

B. Other Issues:

1. The microbiologist's review of the submission for sterility assurance is pending.
2. A satisfactory CGMP compliance evaluation for the firms referenced in the ANDA is required for approval.

18. CONCLUSIONS AND RECOMMENDATIONS

This ANDA is not approvable.

19. REVIEWER:

Kenneth J. Furnkranz

DATE COMPLETED: 4/5/00

DATE REVISED: 4/12/00

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chem Rev 3
4/5/00