

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75-036

MICROBIOLOGY REVIEW

OFFICE OF GENERIC DRUGS

Microbiologist's Review #2

November 2, 1998

A. 1. ANDA: 75-036

APPLICANT: Bedford Laboratories
A Division of Ben Venue Laboratories, Inc.
Attention: Robert V. Kasubick, Ph.D.
270 Northfield Road
Bedford, Ohio 44146

2. PRODUCT NAMES: **Cisplatin Injection**

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: **1 mg/mL**

Sterile nonpyrogenic solution for intravenous injection,
which is packaged in multiple dose vials as follows:

50 mL fill in a 100 cc vial [50 mg]
100 mL fill in a 100 cc vial [100 mg]

4. METHOD OF STERILIZATION

5. PRINCIPLE INDICATIONS: For use in combination therapy for
metastatic testicular and ovarian tumors and as a single
agent for metastatic ovarian and transitional cell bladder
cancer

6. PHARMACOLOGICAL CATEGORY: Anticancer chemotherapeutic agent

B. 1. DATE OF INITIAL SUBMISSION:

December 23, 1996 (Received by OGD on 12/24/96)

2. DATE OF AMENDMENT:

~~April 13, 1998~~ - Subject of this Review.

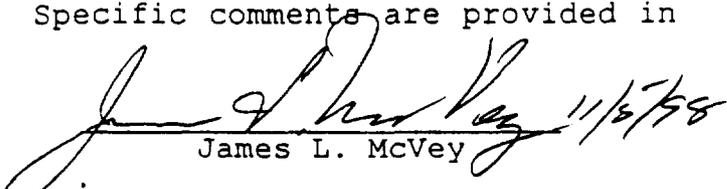
October 22, 1998 - Subject of this review.

3. RELATED DOCUMENTS:

4. ASSIGNED FOR REVIEW: November 2, 1998.

C. REMARKS: First review was completed by K. Muhvich in 1996.

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


James L. McVey 11/5/98

Initialed by M. Fanning  11/5/98

cc:

2.m

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Information and are not
releasable.

MICRO REV. 2

11/2/98

DIVISION OF CHEMISTRY I
OFFICE OF GENERIC DRUGS

Microbiologist's Review #1

March 7, 1997

A. 1. ANDA: **75-036**

APPLICANT: Bedford Laboratories
A Division of Ben Venue Laboratories, Inc.
Attention: Robert V. Kasubick, Ph.D.
270 Northfield Road
Bedford, Ohio 44146

2. PRODUCT NAMES: **Cisplatin Injection**

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: **1 mg/mL**

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which is packaged in multiple dose vials as follows:

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4. METHOD OF STERILIZATION:

5. PRINCIPLE INDICATIONS: For use in combination therapy for
metastatic testicular and ovarian tumors and as a single
agent for metastatic ovarian and transitional cell bladder
cancer

6. PHARMACOLOGICAL CATEGORY: Anticancer chemotherapeutic agent

B. 1. DATE OF INITIAL SUBMISSION:

December 23, 1996 (Received by OGD on 12/24/96)

- Subject of this Review

2. DATE OF AMENDMENT: N/A; no amendments were submitted that
contained sterility assurance information by the time of
this review

3. RELATED DOCUMENTS:

4. ASSIGNED FOR REVIEW: March 4, 1997

:J]

C. REMARKS: Microbiological validation for the used to manufacture the subject drug product was found on pages 141 - 386 (Section XI). The information provided in the application was insufficient to determine if the applicant is taking the necessary steps to ensure the sterility of the subject drug product (Cisplatin Injection). For example, recent revalidation data for of glass vials using s needs to be submitted.

D. CONCLUSIONS: The submissions are therefore 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."

Kenneth H. Muhvich 3/7/97
Kenneth H. Muhvich, Ph.D.

HFD-620/initialed by RPatel
drafted by: KHMuhvich, 3/7/97

cc:

R Patel
3/7/97

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micro Rev. 1

3/7/97