CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-036

ADMINISTRATIVE DOCUMENTS

APPROVAL SUMMARY PACKAGE

ANDA NUMBER: 75-036

FIRM: Bedford Laboratories

DOSAGE FORM: Injection

STRENGTH: 1 mg/mL (50 mg/vial and 100 mg/vial)

DRUG: Cisplatin Injection

CGMP STATEMENT/EIR UPDATED STATUS:
EER for all facilities listed in section # 33 of this ANDA (CR # 4) is in **withhold** status. A FUR is pending.

BIO STUDY:
Bio status: Acceptable per bio letter to the firm issued on 5-20-97.

METHODS VALIDATION - (DESCRIPTION OF DOSAGE FORM SAME AS FIRM'S):
MV: Acceptable as of 9-21-00.

STABILITY - ARE CONTAINERS USED IN STUDY IDENTICAL TO THOSE IN CONTAINER SECTION?
Containers used in the stability studies are identical to those listed in container section.

LABELING:
Acceptable per T. Watkins's review completed on 3-8-00.

STERILIZATION VALIDATION (IF APPLICABLE):
Micro review: Acceptable as of 11-5-98.

SIZE OF BIO BATCH - (FIRM'S SOURCE OF NDS O.K.?):
Bio waiver is requested.

Source of NDS:
DMF Adequate per review completed on 10-16-00 by this reviewer.

SIZE OF STABILITY BATCHES - (IF DIFFERENT FROM BIO BATCH WERE THEY MANUFACTURED VIA SAME PROCESS?)
Exhibit batches:

Lot # 832-57-0002 (50 mg/vial): Batch size is liters.

Lot # 832-60-0002 (100 mg/vial): Batch size is liters.

There is no bio batch.

PROPOSED PRODUCTION BATCH - MANUFACTURING PROCESS THE SAME AS BIO/STABILITY?

Intended production batch size liters for 50 mg/mL vials and liters for 100 mL vial.

Manufacturing process for the intended production size is identical to that used for the exhibit/bio/stability batch.

Mujahid L. Shaikh
Review Chemist
Division of Chemistry I
OGD/CDER

10/30/00 10/30/00

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

ANDA Number: 75-036 Date of Submission: December 23, 1996

Applicant's Name: **Bedford Laboratories**

Established Name: **CISplatin Injection 1 mg/mL, 50 mL and 100 mL vials**

Labeling Deficiencies:

1. GENERAL COMMENTS:

   Revise the established name on all labels and labeling to read:

   CISplatin Injection

   [Note: We are requesting all firms that market this product to make this revision in order to differentiate from t he similar established name "CARBOPLATIN". Ensure the "CIS" has greater prominence as shown above. In addition, you may print "CIS" with a contrasting color].

2. CONTAINER (50 mL and 100 mL)

   a. See GENERAL COMMENT.

   b. If space permits, relocate the "Exercise caution to prevent..." to the main panel or increase the prominence of the statement.

   c. Revise the temperature storage recommendations to read as follows:

      Store at 15° to 25°...

      [Note: Delete "controlled room temperature".]

   d. Increase the prominence of "Protect from light."

3. CARTON (1 x 50 mL and 1 x 100 mL)

   See comments under CONTAINER.

4. ALUMINUM SEALS AND PLASTIC FLIP OFF CAPS

Satisfactory in draft.

5. INSERT

a. TITLE

See GENERAL COMMENT.

b. DOSAGE AND ADMINISTRATION

i. Metastatic Ovarian Tumors - Revise paragraph three to read:

...refer to the cyclophosphamide package insert.

ii. Advanced Bladder Cancer

A) Paragraph two:

(1) Revise the second sentence to read:

Dextrose 5% in 0.33% or 0.45% Sodium Chloride Injection containing...

(2) Revise the penultimate sentence to read:

...just Dextrose 5%.

B) Paragraph four, last sentence - ...cisplatin solution contacts... [Note: delete "powder or".]

iii. STABILITY

A) Decrease the prominence of the subsection heading.

B) Delete "room temperature" from the storage temperature recommendations.

Please revise your container labels, carton and insert labeling, as instructed above, and submit final printed container labels, aluminum seals, plastic flip off caps, carton and insert labeling.

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.

Adolph Vezza for /

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