CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 21-135

MICROBIOLOGY REVIEW(S)
A. 1. NDA 21-135
   APPLICANT: Luitpold Pharmaceuticals, Inc.
   One Luitpold Drive
   Shirley, New York 11967

2. PRODUCT NAME: Venofer® (iron sucrose) Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
   The product is a solution for intravenous injection. The product is supplied in
   5 mL single dose vials (5 mL fill) containing 20 mg elemental iron per mL.

4. METHODS OF STERILIZATION:
   The product is

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
   The product is indicated in the treatment of dialysis-associated anemia

B. 1. DATE OF INITIAL SUBMISSION: 6 August 1999

2. DATE OF AMENDMENT: (none)

3. RELATED DOCUMENTS: (none)

4. ASSIGNED FOR REVIEW: 20 September 1999

C. REMARKS: The submission provides for manufacture of the drug product at
   the applicant's Shirley, New York facility. Following filling the
   drug product vials
D. CONCLUSIONS: The application is approvable upon resolution of microbiology concerns.

\[\text{\underline{\text{\textbackslash S}}}\]  
3 February 2000

Paul Stinavage, Ph.D.

cc: Original NDA 21-135
    HFD-180/B. Strongin/Division File
    HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 3 February 2000
R/D initialed by P. Cooney
\[\text{\underline{\text{\textbackslash S}}}\]  
2/24/2000

\centerline{\textbf{APPEARS THIS WAY ON ORIGINAL}}

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A. 1. NDA 21-135 BC
   APPLICANT: Luitpold Pharmaceuticals, Inc.
   One Luitpold Drive
   Shirley, New York 11967

2. PRODUCT NAME: Venofer® (iron sucrose) Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
   The product is a solution for intravenous injection. The product is supplied in
   5 mL single dose vials (5 mL fill) containing 20 mg elemental iron per mL.

4. METHODS OF STERILIZATION:
   The product is

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
   The product is indicated in the treatment of dialysis-associated anemia.

B. 1. DATE OF INITIAL SUBMISSION: 6 August 1999

2. DATE OF AMENDMENT: 20 June 2000 (Subject of this Review)

3. RELATED DOCUMENTS: (none)

4. ASSIGNED FOR REVIEW: 20 July 2000

C. REMARKS: The submission provides for manufacture of the drug product at
   the applicant's Shirley, New York facility. Following filling the
   drug product vials
D. CONCLUSIONS: The application is recommended for approval on the basis of sterility assurance.

[Signature]
Paul Stinavage, Ph.D.  
29 August 2000

cc: Original NDA 21-135  
HFD-180/B. Strongin/Division File  
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 29 August 2000  
R/D initialed by P. Cooney

APPEARS THIS WAY  
ON ORIGINAL