

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020955

MICROBIOLOGY REVIEW(S)

**REVIEW FOR HFD-180
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805**

Microbiologist's Review #1 of NDA 20-955
April 17, 1998



A. 1. APPLICATION NUMBER: 20-955

APPLICANT: R & D Laboratories
4640 Admiralty Way
Suite 710
Marina del Rey, CA 90292

APR 21 1998

2. PRODUCT NAMES: Ferrlecit Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Sterile single-dose ampoule containing an aqueous solution of sodium ferric gluconate complex in sucrose injection (62.5 mg/5 ml) for intravenous administration.

4. METHOD(S) OF STERILIZATION: [REDACTED]

5. PHARMACOLOGICAL CATEGORY: 1P; Ferrlecit Injection is indicated for treatment of iron deficiency anemia in renal hemodialysis patients on supplemental recombinant human erythropoietin.

B. 1. DATE OF INITIAL SUBMISSION: December 30, 1997

2. AMENDMENT: none

3. RELATED DOCUMENTS: DMF [REDACTED]
IND [REDACTED]
Response to Information Request 4/6/98.

4. ASSIGNED FOR REVIEW: January 24, 1998

5. DATE OF CONSULT REQUEST: January 21, 1998

C. REMARKS:

Ferrlecit Injection is a macromolucule complex of sodium ferric gluconate in sucrose. It is an alkaline aqueous solution with 19.5% of sucrose at a pH of 7.7 to 9.7. The complex is negatively charged at alkaline pH and is present in solution with

sodium cations. The product has a deep red color indicative of the ferric oxide linkages.

D. CONCLUSIONS:

The validation data are satisfactory to ensure sterility assurance for the drug product. The submission is recommended for approval for issues concerning microbiology.

APPEARS THIS WAY ON ORIGINAL
[Redacted]

[Redacted] /SI/

4/17/98

Brenda Uratani, Ph.D.
Review Microbiologist

[Redacted] /SI/

4/21/98

cc:

APPEARS THIS WAY
ON ORIGINAL

NDA 20-955
HFD-180/ Div. File
HFD-805/ Uratani
HFD-180/CSO/ B. Strongin
drafted by: Brenda Uratani, 4/17/98
R/D initialed by P. Cooney, 4/17/98