CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020955

CHEMISTRY REVIEW(S)

DIVISION OF GASTROINTESTINAL AND COAGULATION DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #: 20-955 **CHEM.REVIEW #:** 2 **REVIEW DATE:** February 4, 1999

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
AMENDMENT	**8/19/98**	**8/21/98**	**9/4/98**
ORIGINAL	12/30/97	12/31/97	1/7/98
AMENDMENT	2/9/98	2/10/98	2/19/98
	3/12/98	3/16/98	3/19/98
	4/6/98	4/7/98	4/9/98
	6/16/98	6/17/98	6/23/98

FEB - 4

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

DRUG PRODUCT NAME

Proprietary:	Ferrlecit® Injection
Nonproprietary/USAN:	Sodium ferric gluconate complex in sucrose injection
Code Name/#:	N/A
Chem.Type/Ther.Class:	Hematinic

ANDA Suitability Petition/DESI/Patent Status: N/A

PHARMACOL.CATEGORY/INDICATION: First line treatment for iron deficiency anemia in renal hemodialysis patients on supplemental recombinant human erythropoietin (epoietin)

DOSAGE FORM: Injection

STRENGTHS: 62.5 mg/5 mL

ROUTE OF ADMINISTRATION: Intravenous

DISPENSED: X **Rx** _____ **OTC**

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT:
Sodium ferric gluconate complex in sucrose solution

$[NaFe_2O_3(C_6H_{11}O_7)(C_{12}H_{22}O_{11})_5]_{200}$ (proposed)

Mol. Wt. = 350,000 ± 23,000 daltons (proposed)

Proposed molecular structure provided on pg. 1 of Vol. 1.1 of submission

SUPPORTING DOCUMENTS:

IND [redacted]

DMF [redacted]

RELATED DOCUMENTS (if applicable): N/A

CONSULTS:

Microbiologists Review #1, by Brenda Uratani, Ph.D., Review Microbiologist, HFD-805, April 21, 1998. Conclusion: submission was recommended for approval for issues concerning microbiology.

REMARKS/COMMENTS:

This review primarily covers the amendment dated August 19, 1998, submitted August 21, 1998.

According to the CDER Establishment Evaluation System (EES) as of the date of the first draft of this review (January 29, 1999), all three facilities pertinent to this NDA have been assessed by HFD-324 and received recommendations of ACCEPTABLE. The three facilities are the [redacted] A WITHHOLD recommendation was issued to the [redacted] facility on June 25, 1998, after it was first inspected. A complete response from the firm was received on August 25, 1998, and a recommendation of ACCEPATABLE was issued on December 30, 1998 [redacted]

CONCLUSIONS & RECOMMENDATIONS:

The application may be approved.

APPEARS THIS WAY ON ORI

/S/ [redacted] 2/4/99

Raymond P. Frankewich, Ph.D.
Review Chemist, HFD-180

/S/ [redacted] 2/4/99

Eric P. Duffy, Ph.D.
Chemistry Team Leader, HFD-180

cc:
Orig. NDA 20-955
HFD-180/Division File
DISTRICT OFFICE
HFD-180/RFrankewich
HFD-180/BStrongin
R/D Init by: Eduffy/
RF/rpf/DRAFT 1-29-99/**F/T 2-4-99**
Word: c:\wordfiles\chem\nda\20955812.2rf

APPEARS THIS WAY ON ORIGINAL

DIVISION OF GASTROINTESTINAL AND COAGULATION DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #: 20-955 **CHEM.REVIEW #:** 1 **REVIEW DATE:** May 18, 1998

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
ORIGINAL	12/30/97	12/31/97	1/7/98
AMENDMENT	2/9/98	2/10/98	2/19/98
	3/12/98	3/16/98	3/19/98
	4/6/98	4/7/98	4/9/98

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

MAY 21 1998

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Proposed molecular structure provided on pg. 1 of Vol. 1.1 of submission

SUPPORTING DOCUMENTS:
IND [redacted]
DMF

RELATED DOCUMENTS (if applicable): N/A

CONSULTS:
Microbiologists Review #1, by Brenda Uratani, Ph.D., Review Microbiologist, HFD-805, April 21, 1998. Coclusion: submission was recommended for approval for issues concerning microbiology.

REMARKS/COMMENTS:
See part H., Draft Deficiency Letter

CONCLUSIONS & RECOMMENDATIONS:
According to the CDER Establishment Evaluation System (EES), the only sites scheduled to be inspected are the [redacted] facility [redacted] and [redacted] No reports have been recieved for either inspection. Until these reports are received, with ACCEPTABLE recommendations for the facilities, the status of theis application will be Approvable pending conclusion of the inspection reports. Once the compliance issues are resolved, satisfactory responses to the comments/deficiencies communicated in the Information Request Letter must be received in order for the application to be approved.

/S/ [redacted] 5/21/98
Raymond P. Frankewich, Ph.D.
Review Chemist, HFD-180

/S/ [redacted] 5/21/98
Eric P. Duffy, Ph.D.
Chemistry Team Leader, HFD-180