

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

<u>SUBMISSION TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
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 - 2

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: 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

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

<u>SUBMISSION TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
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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MAY 21 1998

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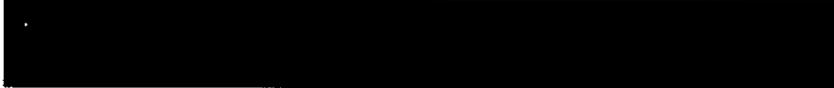
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Mol. Wt. = 350,000 ± 23,000 daltons (proposed)

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

SUPPORTING DOCUMENTS:

IND
DMF



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:

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 received for either inspection. Until these reports are received, with ACCEPTABLE recommendations for the facilities, the status of their 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