

August 6, 2004

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20852

0700 00 03-0 2117



7361 Calhoun Place,
Suite 500
Rockville, Maryland 20855-2765
301.838.3120
fax: 301.838.3182

CITIZEN PETITION

The undersigned, on behalf of a client, submits this petition in triplicate pursuant to 21 U.S.C. 355(j)(2)(C) and 21 CFR 10.30 and 314.93. Petitioner requests that the Food and Drug Administration (FDA) determine that 10 ml/125 mg elemental iron as sodium ferric gluconate complex in sucrose injection is suitable for an Abbreviated New Drug Application (ANDA) based on the listed drug Ferrlecit® Injection 5 ml/62.5 mg of elemental iron.

A. ACTION REQUESTED

Petitioner seeks a determination that a 10 ml/125 mg of elemental iron injection drug product is suitable for an ANDA based on the listed drug Ferrlecit® Injection 5 ml/62.5 mg elemental iron.

B. STATEMENT OF GROUNDS

The reference listed drug (RLD) for the proposed generic drug product is Ferrlecit® Injection 5 ml/62.5 mg elemental iron. The recommended dose for Ferrlecit® is 10 ml of Ferrlecit (125 mg of elemental iron).

The 10 ml vial injection containing 125 mg of elemental iron will facilitate administration of this drug product to patients. The normal dose administration of Ferrlecit® for the repletion treatment of iron deficiency in hemodialysis patients is 10 ml of Ferrlecit® (125 mg of elemental iron).

2004P-0360

CPI

The composition of the proposed formulation is identical to the innovator's formulation as described in **Table 1**. In addition, the dosage form, the route of administration, and the conditions of use for the proposed formulation is also identical to the innovator's product, as described in **Table 2**.

TABLE 1
UNIT DOSE FORMULATION

Ingredient	RLD Ferrlecit® (sodium ferric gluconate complex in sucrose injection)	Proposed Sodium Ferric Gluconate Complex in Sucrose Injection
Sodium Ferric Gluconate Complex (Elemental Iron)	12.5 mg	12.5 mg
Sucrose, NF	195 mg	195 mg
Benzyl Alcohol, NF/EP/BP	9 mg	9 mg
Water for Injection, USP	q.s. to 1.0 mL	q.s. to 1.0 mL

TABLE 2
Comparison of Active Ingredient, Strength, Dosage Form, Route(s) of Administration and Conditions of Use

	RLD Ferrlecit® (sodium ferric gluconate complex in sucrose injection) 12.5 mg/mL of Elemental Iron	Proposed Sodium Ferric Gluconate Complex in Sucrose Injection 12.5 mg/mL of Elemental Iron
Active Ingredient(s)	Sodium Ferric Gluconate Complex	Sodium Ferric Gluconate Complex
Strength	12.5 mg/mL	12.5 mg/mL
Dosage Form	Injection	Injection
Route(s) of Administration	Intravenous	Intravenous
Conditions of Use	Indicated for treatment of iron deficiency anemia in patients undergoing chronic hemodialysis who are receiving supplemental epoetin therapy.	Indicated for treatment of iron deficiency anemia in patients undergoing chronic hemodialysis who are receiving supplemental epoetin therapy.

Because the proposed drug product is dose proportional containing the same active and inactive ingredients, it should be bioequivalent to Ferrlecit®. The proposed drug product is expected to have the same therapeutic effect as Ferrlecit® when administered to patients under the same conditions of use. In accordance with FDA regulations and policy, the client will conduct the necessary testing and stability studies to support the approval of the ANDA.

Pursuant to 21 CFR 314.93 (d), a copy of the approved labeling for Ferrlecit® is included (Attachment A). A copy of the proposed labeling for a generic 125 mg/iron) injection of that drug product is also included (Attachment B). No changes to the labeling are necessary other than those necessitated by the different strength and manufacturer. The brand name Ferrlecit® will be deleted, and descriptions of the strength and references to the manufacturer of Ferrlecit® will be modified.

C. ENVIRONMENTAL IMPACT

Pursuant to 21 CFR 25.31(a), this petition qualifies for a categorical exclusion from the requirement for submission of an environmental assessment.

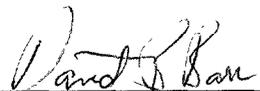
D. ECONOMIC IMPACT

According to 21 CFR 10.30(b), information on economic impact is to be submitted only when requested by the Commissioner following review of this petition.

E. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which is unfavorable to the petition.

Respectfully submitted,

for 

Anthony C. Celeste
President

Attachments