DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-135/S-008

Luitpold Pharmaceuticals, Inc.
Attention: Marsha E. Simon, CQA
1000 Madison Avenue
Norristown, PA 19403

Dear Ms. Simon:

Please refer to your supplemental new drug application dated August 15, 2003, received August 18, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Venofer® (Iron Sucrose Injection, USP).

We acknowledge receipt of your submissions dated December 16, 2004, January 24, March 24, April 11, May 23, June 14, June 16, and June 17, 2005

Your submission of December 16, 2004 constituted a complete response to our June 18, 2004 action letter.

This supplemental new drug application provides for the use of Venofer® (Iron Sucrose Injection, USP) for the treatment of iron deficiency anemia in the following patients:

- non-dialysis dependent chronic kidney disease (NDD-CKD) patients receiving an erythropoietin
- non-dialysis dependent chronic kidney disease (NDD-CKD) patients not receiving an erythropoietin.

Recommended dosing in these patients is a total cumulative dose of 1000 mg over a 14 day period as a slow IV injection undiluted over 2 to 5 minutes on 5 different occasions within a 14 day period.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted June 17, 2005).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-135/S-008.**" Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for ages birth to < 2 years and deferring pediatric studies for ages ≥ 2 years to < 16 years for this application.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The statuses of these postmarketing studies shall be reported annually according to 21 CFR 314.81. These commitments are listed below.

1. Deferred pediatric study under PREA for a pharmacokinetic study of Venofer administration to adolescent non-dialysis dependent chronic kidney disease (NDD-CKD) patients, ≥ 12 years to < 16 years of age, receiving or not receiving erythropoietin.

Final Report Submission: December 31, 2010

2. Deferred pediatric study under PREA for the treatment of iron deficiency anemia in non-dialysis dependent chronic kidney disease (NDD-CKD) pediatric patients ages ≥ 2 years to < 12 years receiving or not receiving erythropoietin.

Final Report Submission: December 31, 2010

Submit final study reports to this NDA. For administrative purposes, all submissions related to these pediatric postmarketing study commitments must be clearly designated "**Required Pediatric Study Commitments**".

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Alice Kacuba, Regulatory Health Project Manager, at (301) 827-9334.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Kathy Robie-Suh
6/17/05 06:54:56 PM
signing for Dr. Joyce Korvick