DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-135/S-013

Luitpold Pharmaceuticals, Inc.
Attention: Marsha E. Simon, CQA
Manager, Regulatory Affairs and Quality Assurance
1000 Madison Avenue
Norristown, PA 19403

Dear Ms. Simons:

Please refer to your supplemental new drug application dated December 16, 2005, received December 17, 2005, 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 January 24, March 16, March 18, April 14, July 8, July 12, July 22, August 8, September 9, and October 6, 2005.

This supplemental new drug application provides for the use of Venofer (iron sucrose injection, USP) for treatment of iron deficiency anemia in peritoneal dialysis dependent-chronic kidney disease (PDD-CKD) patients receiving an erythropoietin.

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 enclosed labeling text for the package insert, submitted October 6, 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-013**." 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 this application.

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) 796-1381.

Sincerely,

{See appended electronic signature page}

George Mills, M.D.
Director
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

George Mills
10/17/2005 01:25:38 PM