



NDA 21-135/SCP-010

Luitpold Pharmaceuticals, Inc.  
Attention: Barbara Goulding  
PO Box 9001  
Shirley, New York 11967

Dear Ms. Goulding:

Please refer to your supplemental new drug application dated November 29, 2004, received November 30, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Venofer<sup>®</sup> (Iron Sucrose Injection, USP).

We acknowledge receipt of your submission dated March 28, 2005.

This supplemental new drug application provides for the addition of three new single dose vial sizes for Venofer<sup>®</sup> (Iron Sucrose Injection, USP):

1. 2.5 mL fill in a 4 mL vial .(b) (4) -- -----
2. 3.75 mL fill in a 4 mL vial-- - -----
3. 3.75 mL fill in a 5 mL vial-- - -----

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 (text for the package insert, immediate container and carton labels), submitted November 29, 2004.

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/SCP-010.**" Approval of this submission by FDA is not required before the labeling is used.

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}*

Liang Zhou, Ph.D.

Chemistry Team Leader for the

Division of Gastrointestinal and Coagulation Drug Products,  
(HFD-180)

DNDC II, Office of New Drug Chemistry

Center for Drug Evaluation and Research

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

/s/

-----  
Marie Kowblansky

3/29/05 01:08:16 PM

Marie Kowblansky, Acting Team Leader for Liang Zhou