



NDA 21-135/S-017

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

Dear Ms. Goulding:

Please refer to your supplemental new drug application dated June 15, 2007, received June 18, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Venofer[®] (Iron Sucrose Injection, USP).

We acknowledge receipt of your submission dated November 30, 2007.

This "Changes Being Effected" supplemental new drug application provides for revisions to the **Hypersensitivity Reactions** subsection under the **PRECAUTIONS** section.

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 and with editorial revisions listed below and indicated in the enclosed labeling.

In the **ADVERSE REACTIONS** section, **Hypersensitivity Reactions** subsection, in the first sentence, "In clinical studies, several patients experienced hypersensitivity reactions presenting with wheezing, dyspnea, hypotension, rashes, or pruritis." the "pruritis" should read "pruritus."

The final printed labeling (FPL) must be identical, and include the editorial revision indicated, to the enclosed labeling (text for the package insert) and/or submitted labeling (package insert submitted November 30, 2007).

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-017.**" Approval of this submission by FDA is not required before the labeling is used.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Hyon-Zu Lee, Pharm.D., Regulatory Project Manager, at 301-796-2050.

Sincerely,

{See appended electronic signature page}

Rafel Dwaine Rieves, M.D.
Acting 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/

Rafel Rieves

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