For Immediate Release
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Luitpold Pharmaceutical's INJECTAFER™ (ferric carboxymaltose injection) receives non-approvable letter from FDA

The attached is the press release issued on March 12, 2008 (US Time) by Luitpold Pharmaceuticals, Inc., an US affiliate of DAIICHI SANKYO COMPANY LIMITED.

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PRESS RELEASE

FOR IMMEDIATE RELEASE
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Luitpold Pharmaceutical's INJECTAFER™ (ferric carboxymaltose injection) receives non-approvable letter from FDA

Shirley, NY – Luitpold Pharmaceuticals, Inc. reported today that the U.S. Food and Drug Administration (FDA) has issued a non-approvable letter for its new drug application (NDA) for **Injectafer™** (ferric carboxymaltose injection) (Internal name VIT-45), an intravenous iron injection, for the treatment of iron deficiency anemia in women due to postpartum (PP) or heavy uterine bleeding (HUB).

In the non-approvable letter, the FDA requested safety data from additional clinical studies to address concerns over the safety of **Injectafer™** in this population, specifically the mortality signal discussed at the February 1, 2008 meeting of the Drug Safety and Risk Management Advisory Committee.

"While we are disappointed about this latest decision, we are committed to the further development of **Injectafer™** and are working on new studies in support of our application and to address the FDA's concerns," said Mary Jane Helenek, President & CEO.

In February 2008, the Drug Safety and Risk Management Advisory Committee of the FDA voted that that the available safety and efficacy data supported a favorable risk / benefit profile of **Injectafer™** (ferric carboxymaltose injection) for the treatment of iron

deficiency anemia patients in women with heavy uterine or post-partum bleeding, but recommended that the usage be restricted to patients who have had an unsatisfactory response to oral iron or are intolerant to oral iron.

The development program for **Injectafaer™** represents the largest prospectively enrolled program of any intravenous iron product ever submitted to the Agency for approval. Data were derived from 12 multicenter trials involving more than 3,000 subjects with iron deficiency anemia secondary to a variety of conditions besides HUB and PP, including non-dialysis and hemodialysis dependent chronic kidney disease patients and patients with inflammatory bowel disease.

Iron deficiency anemia represents a significant health issue in women. More than half of the 4 million women who give birth each year develop iron deficiency and approximately 1 million of these women progress to iron deficiency anemia. In addition, as many as one in five women will suffer from heavy uterine bleeding, defined as excessive or prolonged blood loss.

Once approved, **Injectafer™** will be marketed in the U.S. by American Regent, Inc., a subsidiary of Luitpold Pharmaceuticals.

Injectafer™ was approved in 18 countries in Europe in June 2007 and in Switzerland in November 2007.

About Luitpold Pharmaceuticals, Inc.

Luitpold Pharmaceuticals, Inc., headquartered in Shirley, NY, manufactures and distributes over 65 pharmaceutical products including Venofer® (iron sucrose injection, USP), the leading IV iron therapy in the U.S., through its human health subsidiary, American Regent, Inc. Luitpold Pharmaceuticals, Inc., a Daiichi Sankyo group company, also markets dental bone regeneration products and veterinary pharmaceuticals through its Osteohealth and Animal Health divisions. Daiichi Sankyo Co., Ltd. is a major Japanese pharmaceutical company. Injectafer™ will be marketed under license from Vifor (International) Inc., a company of the Galenica Group. See www.luitpold.com

Source: Luitpold Pharmaceuticals, Inc.

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