

**Acknowledgment and Consent for Disclosure of  
Section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act  
and 18 U.S.C. §208  
Particular Matter Waivers**

Name: Robert Harrington, M.D.

Committee: Drug Safety and Risk Management Advisory Committee

Meeting Date(s): February 1, 2008

I acknowledge that contingent upon public disclosure of the following financial interest submitted on my FDA Form 3410 and related to the agenda item: to discuss the safety and efficacy of new drug application (NDA) 22-054, INJECTAFER (ferric carboxymaltose injection), used for the treatment of iron deficiency anemia in patients with postpartum hemorrhage or heavy uterine bleeding. INJECTAFER is sponsored by Luitpold Pharmaceuticals, Inc., a wholly owned subsidiary of Daiichi Sankyo Co., Ltd. of Japan. If approved, INJECTAFER will be marketed in the U.S. by American Regent, Inc., a subsidiary of Luitpold Pharmaceuticals, Inc. I am eligible to receive particular matter waivers under Section 712(c)(2)(B) and 18 U.S.C. §208.

<b>Type of Interest</b>	<b>Involvement</b>	<b>Magnitude</b>
Unrelated Data Safety Monitoring Committee	Competing Firm	Less than \$10,001 per year

I hereby request that FDA make this information publicly available on my behalf at the start of the advisory committee meeting for which it is issued by reading the statement into the record at the time of the meeting. I understand that without public disclosure of the interest, the waivers are not valid.

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Signature

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Date

1/7/08