

## DRAFT QUESTIONS

1. (Discussion) Injectafer is proposed for use in the treatment of iron deficiency anemia among postpartum patients (PP) and patients with heavy uterine bleeding (HUB). This population includes patients who might otherwise be treated with oral iron. The Injectafer clinical database included mortality data, as follows:

<b>Mortality</b>		
<b>Group</b>	<b>Injectafer</b>	<b>Control</b>
All randomized, multicenter studies	5/1206 (0.4%)	1/994* (0.1%)
Randomized, multicenter, oral-iron controlled studies	4/1057 (0.4%)	0/834 (0%)

\*oral iron, Venofer or placebo

Correlates to the mortality data include a slightly higher rate of serious cardiac events among patients receiving Injectafer than oral iron (0.9% vs. 0.4% in oral-iron controlled studies) and the relatively common occurrence of grade 3 hypophosphatemia (8 to 70% vs. 0 in oral-iron controlled, PP and HUB studies).

Do these data suggest Injectafer is associated with a mortality disadvantage compared to oral iron?

2. (Vote) FDA concurs with the manufacturer's assessment that Injectafer corrects iron deficiency anemia. Does this benefit, in light of the potential risks, result in a positive benefit/risk assessment?

3. (Discussion) If you regard the data as showing a positive benefit/risk assessment, for which patients with iron deficiency anemia should the product be indicated?

a. the proposed population of postpartum patients and patients with heavy uterine bleeding?

b. postpartum patients and patients with heavy uterine bleeding in whom oral iron treatment is unsatisfactory or impossible?

4. (Discussion) If you recommend marketing:

a. Discuss the important features for a Risk Management Plan.

b. Identify the important features of any important post-marketing study commitments.

5. (Discussion) If you do not recommend marketing, discuss the important features of additional studies to help support the safety and net clinical benefit for Injectafer.