

Errata Sheet
To the CDER Background Package
for the
September 29, 2005 Blood Products Advisory Committee Meeting
NDA 21-882

The Agency would like to respectively submit this errata sheet for the CDER Background package for the September 29, 2005 Blood Products Advisory Committee for NDA 21-882.

1. Behind Tab 1 “Summary”, on page 5, in paragraph 3, a phrase should be added to the first sentence as follows:

Non-inferiority of Exjade compared to DFO was to be claimed if the lower bound of the 2-sided 95% confidence interval (CI) of the difference in the proportion of success was greater than -0.15.

2. Behind Tab 3 “Draft Clinical Review”, on page 86, in paragraph 3, the third sentence should read as follows:

In one prospective study of 16 children with β -thalassemia (9), LIC fell from a baseline value of approximately 33 to 26 mg Fe/g dw after one year of therapy with DFO.