15 January 2021

Dr Farrell, Director, Division of Hematology Products
Office of Drug Evaluation and Research
Food and Drug Administration
Central Document Room
5901-B Ammendale Rd
Beltsville, MD. 20705-1266

RESPONSE TO PREA NON-COMPLIANCE LETTER
NDA PMR 3667-4
Accrufer (Ferric Maltol) 30 mg Capsules - NDA 212320; SN071

Dear Dr. Farrell:

The following is a response to the Notification of Non-Compliance with PREA, dated 24 November 2020, but only received via US mail on 5th December 2020.

The Non-Compliance Letter refers to the non-receipt of the pediatric assessment under PMR 3667-4, related to Study ST10-01-104, which was due on 31 October 2020.

A Deferral Extension Request was submitted on 25th November 2020 requesting an extension for the deferred pediatric assessment from October 31st 2020 to 31 March 2021. This Extension was granted by FDA on January 6th 2021.

As explained in the Deferral Extension Request, the study has been delayed as a result of:

- Technical issues with development of an age-appropriate pediatric formulation; these difficulties have now been overcome.
- Delay in manufacture and release of the clinical batch due to COVID-related resource issues at the manufacturing site.
- Delays in the start-up of ST10-01-104 due to COVID-related study-site issues and protocol changes to safe-guard study participants.
- Prolonged study recruitment period attributed to need for volunteers to take a COVID test prior to study enrollment.

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Please do not hesitate to contact either myself or the US Countersigner/Agent for Shield TX (UK) Ltd. NDA 212320 at (720) 644-0688 or via email at fschmidberger@clinipace.com if you require additional information or have any questions or concerns regarding the enclosed application.

Yours sincerely,

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cc:
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