05 May 2017

RESPONSE TO PREA NON-COMPLIANCE LETTER
DEFERRAL EXTENSION REQUESTED

Ann Farrell, M.D.
Director, Division of Hematology Products
U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Division of Hematology Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

RE: NDA 022180 — FERAHEME® (ferumoxytol) Injection
Response to PREA Non-Compliance Letter and Deferral Extension Requested
Seq 0174

Dear Dr. Farrell:

Reference is made to NDA 022180 for Feraheme® (ferumoxytol) Injection, approved on 30 June 2009, and the Agency's Notification of Non-Compliance with PREA letter dated 07 April 2017 regarding PREA Postmaketing Requirements (PMRs) 24-1 and 24-2.

Reference is also made to the recent Type C Meeting teleconference of 13 Dec 2016 in which you and your team graciously took your time to discuss at length the current status, challenges and potential solutions to move our PREA commitment forward to completion in a timely manner. Thus reference is also made to the Meeting Minutes from this teleconference issued by the Agency on 20 Dec 2016, and AMAG's subsequent submission on 07 Feb 2017 (Seq 0173) which provided the information requested by the Agency following the discussions on 13 Dec 2016 and documented in the Meeting Minutes of 20 Dec 2016.

AMAG is accountable for these outstanding PREA PMRs and we are committed to completing these requirements for Feraheme NDA 022180 and to working with the Agency to achieve this goal. We look forward to receiving any comments on this response and any further guidance you are able to share on the clinical plan submitted on 07 Feb 2017 (Seq 0173, 1.6.9, Appendix 1) to enable us to expeditiously and successfully move forward.

This submission provides the following information:

Information	eCTD Location
Request for extension of deferral of PREA PMRs and revised timelines	1.9.2 – Request for deferral of pediatric studies

The structure of this amendment conforms to current eCTD specifications. The entire submission is approximately 5 MB and is being submitted through the FDA Electronic Submission Gateway (ESG). All files in this electronic submission have been verified to be virus free using Symantec Endpoint Protection, version 12.1.5337.5000, virus definition file 05/04/2017, rev. 1.

Please contact me directly by phone at (781) 434-8475 or by e-mail at dknauss@amagpharma.com should you have any questions or require additional information.

Sincerely,

David A. Knauss
Sr. Manager, Regulatory Affairs

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