DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

July 24, 2013

FILE COPY

Steve Caffé, M.D.
Chief Development & Regulatory Officer
AMAG Pharmaceuticals, Inc.
100 Hayden Avenue
Lexington, MA 02421

Dear Dr. Caffé:

Your petition to the Food and Drug Administration requesting to refrain from approving any Abbreviated New Drug Application (ANDA) referencing Feraheme until the Nulecit Post Market Contract Studies take actions stated in the petition with respect to Feraheme, was received by this office on 07/24/2013. It was assigned docket number FDA-2013-P-0885/CP1, and it was filed on 07/24/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Kennard

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)

FDA-2013-P-0885

ACK