DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

JAN 13 2014

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

Re: Docket No. FDA-2013-P-0885

Dear Dr. Caffé:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on July 24, 2013. Your petition requests that the Agency refuse to approve any Abbreviated New Drug Application (ANDA) referencing Feraheme (ferumoxytol) until after the Nulecit Post Market Contract Studies have been completed. It also requests that the Agency require ANDA applicants to show that their proposed generic ferumoxytol products are equivalent to Feraheme using (1) a comparative clinical trial with safety and efficacy endpoints, and (2) three of the assays from the Nulecit Post Market Contract Studies.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research