DEPARTMENT OF HEALTH & HUMAN SERVICES

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

MAR 28 2014

Peter S. Reichertz
Sheppard Mullin Richter & Hampton LLP
1300 I St. NW, 11th Floor East
Washington, DC 20005-3314

Re: Docket No. FDA-2013-P-1294

Dear Mr. Reichertz:

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 October 1, 2013. Your petition requests that the FDA only approve a New Drug Application (NDA) or NDA supplement for injectable iron products for treatment of iron deficiency anemia outside of chronic kidney disease if the approval is based on pivotal clinical studies that include a necessary run-in period where patients take oral iron to confirm intolerance to, or unsatisfactory response to, oral iron or similar confirmatory data. You also request that FDA require that any injectable iron product be contraindicated for use in patients with previous history of allergic reaction to iron products or allergies to two or more classes of drugs if the studies submitted for approval of the drug excluded such patients.

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 possible given the numerous demands on the Agency's resources.

Sincerely,

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