U.S. FOOD & DRUG ADMINISTRATION

Chad A. Landmon
Axinn, Veltrop & Harkrider LLP
90 State House Square
Hartford, CT 06103

August 3, 2022

Re: Docket No. FDA-2022-P-0144

Dear Mr. Landmon:

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 February 8, 2022. Your petition requests that the Agency:

1. Deny any Injectafer sNDAs for any labeling changes based on the FAIR-HF and CONFIRM-HF trials, including any supportive data from AFFIRM-AHF, unless intended to add or strengthen a contraindication, warning, precaution, or adverse reaction.
2. Strengthen Injectafer warnings and precautions and its dosage and administration in relation to severe and symptomatic hypophosphatemia and its consequences.
3. Require any potential future expanded or additional indication for Injectafer to be based on well-controlled clinical studies that specifically assess the risks of severe and symptomatic hypophosphatemia and its consequences for such intended use.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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,

Carol Bennett -S

Digitally signed by Carol Bennett -S
Date: 2022.08.03 09:03:59 -04'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

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