DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

February 09, 2022

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

Sent via email to: clandmon@axinn.com

Dear Petitioner:

Your submission requesting that the Commissioner of the Food and Drug Administration to:

1. Deny any Injectafer NDAs 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 advers reaction;
2. Strengthen Injectafer warnings and precautions and its dosage and administration in relation to severe and symptomatic hypophosphatemia and its consequences;
3. and require any potential future expanded or additional indication for Injectafer to be based on well-controlled clinical studies that specifically assess the risks of sever and symptomatic hypophosphatemia and its consequences for such intended use.

It was was received and processed under CFR 10.30 by this office on 02/08/2022 and assigned docket number FDA-2022-P-0144. Please refer to this docket number in future correspondence on this subject with the Agency.

Also, note that the acceptance of the petition for filing is a procedural matter and in no way reflects the agency's decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2022.02.09 16:17:10 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)