Aparna Dagar, PhD, RAC
Sr. Director, Regulatory Affairs
Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

April, 2, 2021

Re: Docket No. FDA-2020-P-2048

Dear Dr. Dagar:

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 4, 2020. Your petition requests that the Agency determine whether the new drug application (NDA) holder (Abraxis Pharmaceutical Products) for Manganese Sulfate, Equivalent 0.1 milligram manganese/milliliter, (NDA 019228) has withdrawn the product for reasons of safety or efficacy.

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,

Nam E. Kim -S

Digitally signed by Nam E. Kim -S
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Date: 2021.04.02 13:59:46 -04'00'

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