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

May 25, 2021

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

Dear Dr. Dagar:

This letter responds to your citizen petition received on October 4, 2020, requesting that the Food and Drug Administration (FDA) determine whether the new drug application (NDA) holder (Abraxis Pharmaceutical Products) for Manganese Sulfate, Equivalent (Eq) 0.1 milligram (mg) manganese/milliliter (mL), (NDA 019228) has withdrawn the product for reasons of safety or efficacy.

FDA has reviewed its records and determined that Manganese Sulfate, injectable, Eq 0.1 mg manganese/mL, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Manganese Sulfate, injectable, Eq 0.1 mg manganese/mL, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (240) 402-9674.

Sincerely,

Sungjoon Chi -S

Digitally signed by Sungjoon Chi -S
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Date: 2021.05.25 09:05:22 -04'00'

Sungjoon Chi
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure