Manish Singireddy
Regulatory Specialist
Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

Re: Docket No. FDA-2020-P-0678

June 24, 2020

Dear Mr. Singireddy:

This letter responds to your citizen petition received on February 6, 2020, requesting that the Food and Drug Administration (FDA) determine whether the new drug application (NDA) holder for Dextrose 70% in Plastic Container (dextrose) injectable, 70 grams (g)/100 milliliters (mL) (NDA 017521), has withdrawn the product for reasons of safety or effectiveness (Petition at 1).[1]

FDA has reviewed its records and determined that Dextrose 70% in Plastic Container (dextrose) injectable, 70 g/100 mL, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Dextrose 70% in Plastic Container (dextrose), injectable, 70 g/100 mL, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).[2]

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 (301) 796-8767.

Sincerely,

David Faranda -S

Digitally signed by David Faranda -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=David Faranda -S, 0.9.2342.19200300.100.1.1=2000523569
Date: 2020.06.24 06:41:07 -04'00'

David Faranda
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

[1] Additionally, FDA considered whether Dextrose 30 g/100 mL (dextrose 30%), 40 g/100 mL (dextrose 40%), and 60 g/100 mL (dextrose 60%), under the same NDA, were withdrawn for reasons of safety or effectiveness.

[2] FDA made the same determination on dextrose 30%, 40%, and 60%.