U.S. FOOD & DRUG ADMINISTRATION

Jennifer Boysen
Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

Re: Docket No. FDA- 2019-P-0466

AUG 2 1 2019

Dear Ms. Boysen:

This letter responds to your citizen petition received on January 29, 2019, requesting that the Food and Drug Administration (FDA) determine whether Dextrose, 20 grams (g)/100 milliliters (mL), and Dextrose, 50 g/100 mL (Dextrose 20%, and Dextrose 50%), in plastic containers (new drug application (NDA) 017521), were withdrawn for reasons of safety or efficacy.

FDA has reviewed its records and determined that Dextrose, 20 g /100 mL, and Dextrose, 50 g /100 mL, in plastic containers, were not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Dextrose, 20 g /100 mL, and Dextrose, 50 g /100 mL, in plastic containers (NDA 017521), 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 (301) 796-3946.

Sincerely,

Heather A. Dorsey
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

U.S. Food & Drug Administration
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