March 17, 2020

Irina Pashyan
Manager, Regulatory Affairs
Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

Re: Docket No. FDA-2019-P-4523

Dear Ms. Pashyan:

This letter responds to your citizen petition (Petition) received on September 26, 2019, requesting that the Food and Drug Administration (FDA) determine whether Potassium Chloride (5 milliequivalents (mEq), 10 mEq, 15 mEq, 20 mEq, 30 mEq, and 40 mEq) in Dextrose 5% and Sodium Chloride 0.225%, in Plastic Containers, approved under new drug application 018365, held by ICU Medical Inc., was withdrawn from the market place for reasons other than safety or efficacy (Petition at 2).

FDA has reviewed its records and determined that the following Potassium Chloride products were not withdrawn from sale for reasons of safety or effectiveness:

- Potassium Chloride (5 mEq) in Dextrose 5% and Sodium Chloride 0.225%, in Plastic Container, 5 grams (g)/100 milliliters (mL); 74.5 milligrams (mg)/100 mL; 225 mg/100 mL
- Potassium Chloride (5 mEq) in Dextrose 5% and Sodium Chloride 0.225%, in Plastic Container, 5 g/100 mL; 149 mg/100 mL; 225 mg/100 mL
- Potassium Chloride (10 mEq) in Dextrose 5% and Sodium Chloride 0.225%, in Plastic Container, 5 g/100 mL; 74.5 mg/100 mL; 225 MG/100 mL
- Potassium Chloride (10 mEq) in Dextrose 5% and Sodium Chloride 0.225%, in Plastic Container, 5g/100 mL; 149 mg/100 mL; 225 mg/100 mL
- Potassium Chloride (15 mEq) in Dextrose 5% and Sodium Chloride 0.225%, in Plastic Container, 5 g/100 mL; 224 mg/100 mL; 225 mg/100 mL
- Potassium Chloride (20 mEq) in Dextrose 5% and Sodium Chloride 0.225%, in Plastic Container, 5 g/100 mL; 298 mg/100 mL; 225 mg/100 mL
- Potassium Chloride (30 mEq) in Dextrose 5% and Sodium Chloride 0.225%, in Plastic Container, 5 g/100 mL; 224 mg/100 mL; 225 mg/100 mL
- Potassium Chloride (40 mEq) in Dextrose 5% and Sodium Chloride 0.225%, in Plastic Container, 5 g/100 mL; 298 mg/100 mL; 225 mg/100 mL

Thus, FDA will maintain these products 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) 796-3977.

Sincerely,

Linda Jong

Linda Jong
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure