Peter Baer
Senior Regulatory Specialist
Fresenius Kabi USA, LLC
Three Corporate Dr.
Lake Zurich, IL 60047

August 27, 2024

Re: Docket No. FDA-2024-P-1131

Dear Mr. Baer:

This letter responds to your citizen petition received on March 5, 2024, requesting that the Food and Drug Administration (FDA) determine whether Diltiazem Hydrochloride in Dextrose 5% (diltiazem hydrochloride (HCl)) solution, 125 milligrams (mg)/125 milliliters (mL) (1 mg/mL) and 250 mg/250 mL (1 mg/mL) has been withdrawn for reasons of safety or efficacy.

FDA has reviewed its records and determined that Diltiazem Hydrochloride in Dextrose 5% (diltiazem HCl) solution, 125 mg/125 mL (1 mg/mL) and 250 mg/250 mL (1 mg/mL), was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Diltiazem Hydrochloride in Dextrose 5% (diltiazem HCl) solution, 125 mg/125 mL (1 mg/mL) and 250 mg/250 mL (1 mg/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 email me at Neerja.Razdan@fda.hhs.gov.

Sincerely,

Neerja Razdan -S

Digitally signed by Neerja Razdan -S
Date: 2024.08.27 11:31:58 -04'00'

Neerja Razdan
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

U.S. Food & Drug Administration
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w ww.fda.gov