



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

Re: Docket No. FDA-2020-P-2304

April 26, 2021

Dear Ms. Pashyan:

This letter responds to your citizen petition received on December 16, 2020, requesting that the Food and Drug Administration (FDA) determine whether sodium chloride 14.6%, 50 milliequivalents (mEq)/20 milliliters (mL), in plastic containers, approved under new drug application 18897, was withdrawn from sale for safety or efficacy reasons.

FDA has reviewed its records and determined that sodium chloride 14.6%, 50 mEq/20 mL, in plastic containers, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain sodium chloride 14.6%, 50 mEq/20 mL, in plastic containers, in the “Discontinued Drug Product List” section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).¹

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) 402-4191.

Sincerely,

Ayako Sato -
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Digitally signed by Ayako Sato -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=Ayako Sato -S,
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Date: 2021.04.26 08:44:57 -04'00'

Ayako Sato
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

¹ The Orange Book is available at <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>.