Mitul Chatterjee
Head, Regulatory Affairs
Baxter Healthcare Corporation
1 Baxter Parkway
Deerfield, IL 60015

Sent via email to: mitul_chatterjee@baxter.com

June 7, 2021

Re: Docket No. FDA-2020-P-2317

Dear Ms. Chatterjee:

This letter responds to your citizen petition received on December 21, 2020 (Petition). In the Petition you request that the Food and Drug Administration (FDA) determine whether QUELICIN PRESERVATIVE FREE (succinylcholine chloride) Injection, 20 milligrams (mg)/ milliliter (mL), 50 mg/mL, and 100 mg/mL, has been withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and determined that QUELICIN PRESERVATIVE FREE (succinylcholine chloride) Injection, 20 mg/ mL, 50 mg/mL, and 100 mg/mL, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain QUELICIN PRESERVATIVE FREE (succinylcholine chloride) Injection, 20 mg/ mL, 50 mg/mL, and 100 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 call me at (301) 796-3601.

Sincerely,

Nicole K. Mueller -S

Digitally signed by Nicole K. Mueller -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300170462, cn=Nicole K. Mueller -S
Date: 2021.06.07 11:42:23 -04'00'

Nikki Mueller
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure