DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

November 5, 2020

Michelle Ryder
Lachman Consulting Services, Inc.
1600 Stewart Ave., Suite 604
Westbury, NY 11590

Sent via email to: m.ryder@lachmanconsultants.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA declare that the proposed drug products, Succinylcholine Chloride Injection, 100 mg/5 mL (20 mg/mL) and 200 mg/10 mL (20 mg/mL) single dose Prefilled Syringes (PFS) are suitable for submission as an Abbreviated New Drug Application. The listed reference drug product (RLD), upon which this petition is based, is QUELICIN® (Succinylcholine Chloride) Injection, 200 mg/10 mL (20 mg/mL) multiple-dose vials by Hospira NDA # 008845, Product Number 006 was received by this office on 11/05/2020 and it was assigned docket number FDA-2020-P-2175.

Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham -bigby - S

Digitally signed by Dynna Gorham-bigby - S
Date: 2020.11.06 10:56:49 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of Operations (OO)