DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

September 30, 2019

David L. Rosen, B.S. Pharm., JD
Foley & Lardner LLP
3000 K Street, NW, Suite 500
Washington, DC 20007-5143

Sent via email to: drosen@foley.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that the submission and filing of an ANDA for Succinylcholine Chloride Injection USP, 20mg/mL, 5 mL vials (total vial content 100mg) pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act and 21 CFR §314.93 was received by this office on 09/27/2019.

It was assigned docket number FDA-2019-P-4540. 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: 2019.09.30 13:32:21 -04'00'

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