June 14, 2022

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

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

Dear Petitioner:

Your submission requesting the Commissioner of Food and Drug to declare that the proposed drug product, Sugammadex Injection 1000 mg/10 mL (100 mg/mL), is suitable for consideration in an Abbreviated New Drug Application ("ANDA") based upon BRIDION® (sugammadex) injection 200mg/2mL and 500 mg/5mL (i.e. 100mg base/mL) by ORGANON USA INC A SUB OF MERCK AND CO INC., approved under NDA N022225, as Reference Listed Drug ("RLD") was received and processed under CFR 10.30 by this office on 6/13/2022.

It was assigned docket number FDA-2022-P-1153. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the suitability petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen P. Malvin -S
Digitally signed by Karen P. Malvin -S
Date: 2022.06.14 15:44:25 -04'00'

Karen Malvin
Acting Director
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)