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June 13, 2022

VIA ELECTRONIC SUBMISSION

Division of Dockets Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

SUITABILITY PETITION

Dear Sir/Madam,

The undersigned hereby submits this Suitability petition pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), and in accordance with 21 CFR 314.93 & 21 CFR 10.30 requesting the Commissioner of the Food and Drug Administration ("FDA") 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").

A. ACTION REQUESTED

The Petitioner requests the Commissioner of the FDA declare that the proposed drug product, Sugammadex Injection 1000 mg/10 mL (100 mg/mL) is suitable for submission as an ANDA.

The Reference Listed Drug product (RLD), upon which this petition is based, is 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. NDA# N022225.

Currently the RLD BRIDION® is available as 2 mL vial (total drug content 200mg/2mL) and 5 mL vial (total drug content 500mg/5mL). Therefore, the petitioner seeks a change in strength, from 200 mg/2 mL and 500mg/5mL single-dose vial to 1000 mg/10 mL single-dose pre-filled syringe.

B. STATEMENT OF GROUNDS

The FD&C Act provides for the submission of an ANDA for a drug product that differs in dosage strength and or dosage form from that of the listed drug provided the FDA has approved a petition that proposed filing such an application.

The RLD, BRIDION® by ORGANON USA INC. is an injection product containing Sugammadex injection 200mg/2mL and 500 mg/5mL (i.e. 100mg base/mL). Please refer to listing in the current electronic edition of Approved Drug Products with Therapeutic Equivalence Evaluations (Attachment 1) and the last approved Package Insert (Attachment 2). The proposed drug product represents a change in total drug content and proposes the 1000 mg/10 mL (100 mg/mL) strength in single-dose pre-filled syringe. Thus, this petition is seeking a change in strength (total drug content) from 200 mg/2 mL or 500 mg/5 mL single-dose vial to 1000 mg/10mL single dose pre-filled syringe. Note this is only a change in presentation and not in concentration.

Like BRIDION (Sugammadex Injection) 100 mg/mL, 2mL and 5mL vial of ORGANON USA INC., the proposed drug product would be a sterile, non-pyrogenic aqueous solution that is clear, colorless to slightly yellow-brown for intravenous injection and infusion with a formulation containing 100 mg of Sugammadex per mL. The proposed applicant's product has similar condition of use, qualitative & quantitative ingredient content, route of administration, and dosage form with that of current reference listed drug BRIDION (Sugammadex Injection) 100 mg/mL of ORGANON USA INC.,

According to the currently approved Package Insert, BRIDION (Sugammadex Injection) 100 mg/mL of ORGANON USA INC., Sugammadex is indicated for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults and pediatric patients aged 2 years and older undergoing surgery. The dosing regimens for each indication are as follows:

DOSAGE AND ADMINISTRATION Dosing is based on actual body weight Monitor for twitch responses to determine the timing and dose for BRIDION administration	
Indication	**Recommended Dosage**
Administer as a single bolus injection	
For rocuronium and vecuronium:	4 mg/kg is recommended if spontaneous recovery of the twitch response has reached 1 to 2 post-tetanic counts (PTC) and there are no twitch responses to train-of-four (TOF) stimulation. 2 mg/kg is recommended if spontaneous recovery has reached the reappearance of the second twitch in response to TOF stimulation.
For rocuronium only:	16 mg/kg is recommended if there is a clinical need to reverse neuromuscular blockade soon (approximately 3 minutes) after administration of a single dose of 1.2 mg/kg of rocuronium. Immediate reversal in pediatric patients has not been studied.

The body weight of an average adult is 70 kg. Therefore, an adult patient would generally require a

maximum dose of 1120 mg for therapy in consideration to the highest dose of 16 mg/kg. The intention to propose higher fill volume of 10 mL is to avoid use of multiple drug product containers by offering a higher amount of drug product in a single presentation (for adult patients) which can be used in cases where a higher dose is to be used (i.e. 16 mg/kg for neuromuscular blockade due to rocuronium injection). Below is a table detailing the advantage achieved with availability of a 10 mL fill volume in achieving a total dose of 1120 mg.

Dosage [in mg/kg]	**Total dose**	**Presentations utilized to provide dosage [on the basis of existing fill volumes]**	**Presentations utilized to provide dosage [on the basis of applicant's proposed fill volumes]**
16	1120	5 mL + 5 mL + 2 mL	10 mL + 2 mL

The Petitioner's proposed labeling will be in line with RLD labeling with some acceptable modifications (i.e. changes in strength/fill volume presentation sought in this petition, manufacturer/distributor details and adverse reaction reporting contact details). The proposed drug product (1000 mg/10mL) is not intended for use in the pediatric patients; accordingly, information related to the pediatric patients will be removed from prescribing information sections (i.e. indication and preparation of dilution for pediatric use). Draft labeling for the proposed product is provided herewith as (Attachment 3).

Therefore, the petitioner's request for the Commissioner to find that a modification in presentation (i.e. inclusion of higher fill volume 10 mL) for Sugammadex Injection 100 mg/mL should raise no questions of safety or effectiveness, and the Agency should approve this petition.

C. ENVIRONMENTAL IMPACT

The Petitioner claims a categorical exclusion from the requirement of an environmental assessment or environmental impact statement pursuant to 21 CFR § 25.31.

D. ECONOMIC IMPACT STATEMENT

The petitioner does not believe that an economic impact assessment is applicable in this case; however, pursuant to 21 C.F.R. § 10.30(b), the Petitioner will, upon request by the Commissioner, submit economic impact information.

E. CERTIFICATION

The undersigned certifies that to the best of knowledge and belief of the undersigned, this petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the petition.

Sincerely,

Michelle R. Ryder

Digitally signed by Michelle R. Ryder
Date: 2022.06.13 14:56:08 -05'00'

Michelle R. Ryder
Executive Director
Lachman Consulting Services, Inc.

List of Attachments

Sr. No.	Document
Attachment 1	Copy of Orange Book
Attachment 2	Current labeling of RLD
Attachment 3	Proposed labeling of applicant