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VIA ELECTRONIC SUBMISSION

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

ANDA SUITABILITY PETITION

Foley & Lardner LLP (the "Petitioner") submits this ANDA Suitability Petition under the provisions of section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act and 21 CFR § 314.93 requesting that the Commissioner of Food and Drugs allow the submission and filing of an Abbreviated New Drug Application ("ANDA") for Succinylcholine Chloride Injection USP, 20mg/mL, 5 mL vials as discussed below.

A. Action Requested

The Petitioner requests that the Commissioner of Food and Drugs allow 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. Currently Succinylcholine Chloride Injection USP, 20mg/mL, is available as 10mL vials from Hospira, Inc. and is sold under the brand name Quelicin®. The total amount of drug per vial is 200mg.

The proposed change in the vial size 5 mL (total amount of drug per vial is 100mg) is the type of change that has been expressly authorized in the statute and by FDA regulations. The Agency has approved many other ANDA Suitability Petitions requesting a similar type of change in vial size. Further discussion is provided below. Draft labeling is enclosed with this Suitability Petition.

B. Statement of Grounds

1. As noted above, Succinylcholine Chloride Injection USP, 20mg/mL, is available only in a 10mL vial (total amount of drug per vial is 200mg) from Hospira, Inc. and is sold under the brand name Quelicin®. Quelicin® (Succinylcholine Chloride Injection

USP) 20mg/mL, 10mL vials, is approved by FDA under NDA 008845 is designated as the reference listed drug ("RLD") in the publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") for the purpose of serving as the RLD for generic products.

2. The proposed product, for Succinylcholine Chloride Injection USP, 20mg/mL, 5 mL vials, is quantitatively and qualitatively the same as the RLD.

   A chart comparing the formulations of the RLD and the proposed drug is presented below:

Ingredient	**Quelicin® - RLD**	**Proposed Drug**
Succinylcholine Chloride	20mg/mL	20mg/mL
Sodium Chloride to adjust tonicity	As needed	As needed
Hydrochloric Acid or Sodium Hydroxide to adjust pH	As needed	As needed
Methylparaben	0.18% (18mg/mL)	0.18% (18mg/mL)
Propylparaben	0.02% (2mg/mL)	0.02% (2mg/mL)
Water for Injection	QS	QS

3. The company will be seeking a waiver of *in vivo* bioavailability requirements under 21 CFR 320.22 (b)(1).

4. The proposed change in vial size (a change in the total amount of drug per vial) is the type of change that has been expressly authorized in the statute and by FDA regulation. In the past, the Agency has approved numerous ANDA Suitability Petitions for similar types of changes.

5. The INDICATIONS AND USAGE is the same for both the RLD and the proposed drug, as follows:

   Succinylcholine chloride is indicated as an adjunct to general anesthesia, to facilitate tracheal intubation, and to provide skeletal muscle relaxation during surgery or mechanical ventilation.

6. The proposed 5 mL vial size of the drug provides a sufficient amount of drug that is recommended in the dosage and administration section of the currently approved package insert.

Adults

1. For Short Surgical Procedures

   The average dose required to produce neuromuscular blockade and to facilitate tracheal intubation is 0.6 mg/kg Succinylcholine Chloride Injection given intravenously. The optimum dose will vary among individuals and may be from 0.3 to 1.1 mg/kg for adults. Following administration of doses in this range, neuromuscular blockade develops in about 1 minute; maximum blockade may persist for about 2 minutes, after which recovery takes place within 4 to 6 minutes. However, very large doses may result in more prolonged blockade. A 5 to 10 mg test dose may be used to determine the sensitivity of the patient and the individual recovery time (see PRECAUTIONS).

2. For Long Surgical Procedures

   The dose of succinylcholine administered by infusion depends upon the duration of the surgical procedure and the need for muscle relaxation. The average rate for an adult ranges between 2.5 and 4.3 mg per minute.

   Solutions containing from 1 to 2 mg per mL succinylcholine have commonly been used for continuous infusion. The more dilute solution (1 mg per mL) is probably preferable from the standpoint of ease of control of the rate of administration of the drug and, hence, of relaxation. This IV solution containing 1 mg per mL may be administered at a rate of 0.5 mg (0.5 mL) to 10 mg (10 mL) per minute to obtain the required amount of relaxation. The amount required per minute will depend upon the individual response as well as the degree of relaxation required. Avoid overburdening the circulation with a large volume of fluid. It is recommended that neuromuscular function be carefully monitored with a peripheral nerve stimulator when using succinylcholine by infusion in order to avoid overdose, detect development of Phase II block, follow its rate of recovery, and assess the effects of reversing agents (see PRECAUTIONS).

   Intermittent IV injections of succinylcholine may also be used to provide muscle relaxation for long procedures. An IV injection of 0.3 to 1.1 mg/kg may be given initially, followed, at appropriate intervals, by further injections of 0.04 to 0.07 mg/kg to maintain the degree of relaxation required.

Pediatrics

For emergency tracheal intubation or in instances where immediate securing of the airway is necessary, the IV dose of succinylcholine is 2 mg/kg for

infants and small children; for older children and adolescents the dose is 1 mg/kg (see BOX WARNING and PRECAUTIONS: Pediatric Use).

Rarely, IV bolus administration of succinylcholine in infants and children may result in malignant ventricular arrhythmias and cardiac arrest secondary to acute rhabdomyolysis with hyperkalemia. In such situations, an underlying myopathy should be suspected.

Intravenous bolus administration of succinylcholine in infants or children may result in profound bradycardia or, rarely, asystole. As in adults, the incidence of bradycardia in children is higher following a second dose of succinylcholine. The occurrence of bradyarrhythmias may be reduced by pretreatment with atropine (see PRECAUTIONS: Pediatric Use).

Intramuscular Use

If necessary, succinylcholine may be given intramuscularly to infants, older children, or adults when a suitable vein is inaccessible. A dose of up to 3 to 4 mg/kg may be given, but not more than 150 mg total dose should be administered by this route. The onset of effect of succinylcholine given intramuscularly is usually observed in about 2 to 3 minutes.

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The proposed 5 mL vial size of the drug provides a sufficient amount of drug (100mg/vial) to meet the majority of dosage recommendations for the indications set forth above. Of course, a second vial could be used if additional drug is needed for dosing larger individuals or for longer surgical procedures. For example, at the average dose of 0.6mg/kg, an 80 kg person would require 48mg.

C. Environmental Impact

The Petitioner claims a categorical exclusion under 21 CFR § 25.31.

D. Economic Impact

By allowing the submission and filing of an ANDA for Succinylcholine Chloride Injection USP, 20mg/mL, 5 mL vials healthcare professionals practicing in a hospital setting and the public will be afforded access to the same concentration, 20mg/mL but for a different total amount of drug per vial for the proposed product. The availability of a smaller vial size will reduce drug waste. This smaller vial size has been requested by numerous healthcare professionals.

E. Certification

The undersigned certifies, that, to the best 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.

Respectfully submitted,

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