

AKORN-STRIDES, LLC

2500 Millbrook Drive ▼ Buffalo Grove, IL 60089-4694
847-279-6100 ▼ Fax: 847-279-6123

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Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

CITIZEN PETITION

Akorn-Strides, LLC. submits this petition under section 505(j)(2)(c) of the Federal Food and Drug and Cosmetic Act. We seek approval to file an Abbreviated New Drug Application (ANDA) for Dexamethasone Sodium Phosphate Injection USP, 10 mg/mL -- 1 mL fill size, using Sicom Pharmaceuticals RLD for Dexamethasone Sodium Phosphate Injection, 10 mg/mL -- 10 mL fill size.

Dexamethasone Sodium Phosphate Injection 10 mg/mL (RLD) is currently marketed as a sterile injection by Sicom in one configuration as 10 mL fill size.

Along with 10 mL presentation, Akorn-Strides is proposing Dexamethasone Sodium Phosphate Injection USP, 10 mg/mL as 1 mL fill single dose vial for the convenience of administration by the hospitals. This size also offers cost savings as the 1 mL vial costs less than the 10 mL vial and minimizes the waste (multiple dose vial has to be discarded after some period of time once opened).

Draft copy of package insert for the proposed product, Dexamethasone Sodium Phosphate Injection USP, 10 mg/mL (1 mL fill) is included along with a copy of the package insert for the RLD Dexamethasone Sodium Phosphate Injection USP, 10 mg/mL by SICOR Pharmaceuticals, Inc. (**Attachment A**).

A. Action Requested

The petitioner requests the Commissioner to declare Dexamethasone Sodium Phosphate Injection USP, 10 mg/mL in 1 mL vial (1 mL fill size) suitable for consideration in an abbreviated new drug application based on RLD by Sicom formulation, 10 mg/mL in 10 mL vial (10 mL fill size).

2007P.0167

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B. Statement of Grounds

Akorn Strides wishes to state that the proposed product was developed in line with the Sicor RLD for Dexamethasone Sodium Phosphate Injection USP, 10 mg/mL (10 mL fill) and pharmaceutical equivalence was established with the RLD by Sicor. RLD by Sicor does not have a presentation in 1 mL single dose vial.

Very recently Baxter ANDA #87-702 has been listed as the RLD for Dexamethasone Sodium Phosphate Injection, 10 mg/mL, 1 mL fill. However, the concentration of **Sodium Citrate**, inactive ingredient, in Baxter's product (16.5 mg/mL) differs as compared to Sicor's product (10 mg/mL). The proposed product is formulated to have 10 mg/mL of Sodium Citrate as in Sicor RLD.

The comparison of the formulations of Sicor RLD, proposed product and Baxter RLD are given below:

	Composition (Quantity/mL)		
	RLD (SICOR Pharmaceuticals Inc.) formula ANDA # 81-126	AKORN-STRIDES Proposed formula	RLD (BAXTER INC) formula ANDA # 87-702
Active Ingredient: Dexamethasone Sodium Phosphate	10.0 mg	10.0 mg	10.0 mg
Inactive Ingredients:			
Preservative *	Benzyl alcohol: 10.0 mg	Methylparaben: 1.5 mg Propylparaben:0.2 mg	Benzyl alcohol: 10.42 mg
Antioxidant *	Sodium metabisulfite: 1 mg	Edetate Disodium: 0.11 mg	Sodium sulfite: 1.5 mg
Isotonicity agent: Sodium Citrate	10 mg	10 mg	16.5 mg
pH adjustment agents: Citric Acid Sodium Hydroxide	q.s. to adjust pH	q.s. to adjust pH	q.s. to adjust pH
Vehicle: Water for Injection	q.s. to 1 mL	q.s. to 1 mL	q.s. to 1 mL

** Akorn Strides LLC's formulation differs in the Preservative and Anti-oxidant as permitted by 21 CFR 314.94(a)(9)(iii)*

Akorn-Strides would like to submit an ANDA for Dexamethasone Sodium Phosphate Injection, USP 10 mg/mL in 1 mL vial (1 mL fill size) as supported by the following:

- 1) The proposed formulation is pharmaceutically equivalent to the Sicor's RLD product (10 mL fill).
- 2) Baxter product has an approved ANDA # 87-702 for 1 mL fill size and is also listed as RLD. However, Akorn-Strides would like to file the ANDA for 1 mL fill size using Sicor ANDA #81-126 as RLD, instead of Baxter RLD product.
- 3) The dosage and administration of the proposed drug product is the same as that for the Sicor and Baxter RLDs, as recommended in the DOSAGE AND ADMINISTRATION Section of the proposed package insert (**Attachment A**).
- 4) The 1 mL single dose vial is more cost-efficient than 10 mL multiple dose vial. The waste of the product is minimized as the multiple dose vial contents have to be discarded after some period of time once they are opened for the first time use. Besides, 1 mL fill size is the subject of another approved ANDA (Baxter RLD).

Based on this, we request the Agency to allow us to file ANDA for Dexamethasone sodium phosphate 10 mg/mL (1mL fill) based on Sicor's RLD, in addition to the approved 10 mL size for RLD.

C. Environmental Impact

An environmental Impact Analysis Report for the action requested (i.e., the determination that Dexamethasone Sodium Phosphate Injection USP, 10 mg/mL (1 mL fill) is suitable for ANDA status) is not required as cited under 21 CFR 25.24(c)(1).

D. Economic Impact

Information regarding economic impact will be made upon request.

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 petitioner.

Sincerely,



Sam Boddapati, Ph.D.
Vice President, Regulatory Affairs
Akorn-Strides, LLC
2500 Millbrook Drive
Buffalo Grove, IL 60089
Phone: (847) 353-4909
Fax: (847) 279-6196
E-mail: sam.boddapati@akorn.com