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January 19, 2007

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

Re: Supplement to 1-mL 0.9% Sodium Chloride Injection, *USP*, Suitability Petition, Docket No. 2006P-0302/CPI

Supplement to Suitability Petition, Docket No. 2006P-0302/CPI

Reference is made to 1-mL 0.9% Sodium Chloride Injection, *USP*, Suitability Petition, submitted on July 28, 2006, by Beckloff Associates, Inc. (BAI), and subsequently assigned Docket No. 2006P-0302/CPI. Reference is also made to the discussion between Ms. Cecelia Parise, Office of Generic Drugs, and Mr. Wayne Vallee, BAI, on September 29, 2006, regarding the petition.

Ms. Parise asked for a list of drugs that the 1-mL 0.9% Sodium Chloride Injection, *USP*, could be used with as a diluent. She also indicated that the labeling provided in the petition was for Application No. 018803, which was not a reference listed drug (RLD) at that time. Application No. 018803 is now an RLD.

A. Action Requested

The petitioner requests that the Commissioner of FDA declare that 0.9% Sodium Chloride Injection, *USP*, in a 1-mL prefilled syringe, is suitable for submission as an ANDA. The RLD product upon which this petition is based is 0.9% Sodium Chloride Injection, *USP*, approved in 10-, 20-, and 50-mL dosage strengths in plastic containers, under NDA No. 18-803. Hospira Inc. is the applicant holder of this RLD product. Refer to United Sates Food and Drug Administration, Electronic Orange Book entry for sodium chloride in plastic container (accessed on January 9, 2007) provided in Attachment 1. This petition is submitted for a change in dosage strength (volume) from the RLD product. Sodium Chloride Injection, *USP*, will be marketed in the dosage strength of 1 mL in prefilled syringes. The active ingredient, the route of administration, and the recommendations for use are the same as those of the RLD product. The proposed product will differ only in dosage strength (volume) from the Sodium Chloride Injection, *USP*, marketed product.

2006P-0302

Sup 1

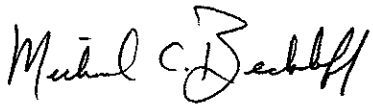
In response to C. Parise's question regarding compatible products, Attachment 2 provides a partial listing of commercially available products with which a 1-mL volume of 0.9% Sodium Chloride Injection, *USP*, could be used as a diluent.

All other aspects of the original petition remain the same.

F. Certification

The undersigned certifies that to the best of his knowledge, 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,



Michael C. Beckloff
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ffw

ecc: C. Parise; FDA

Attachment 1

Electronic Orange Book Entry

Search results from the "OB_Rx" table for query on "018803."

Active Ingredient:	SODIUM CHLORIDE
Dosage Form;Route:	INJECTABLE; INJECTION
Proprietary Name:	SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
Applicant:	HOSPIRA
Strength:	9MG/ML
Application Number:	018803
Product Number:	001
Approval Date:	Oct 29, 1982
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	**AP**

Patent and Exclusivity Info for this product: View

Return to Electronic Orange Book Home Page

FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:

Orange Book Data - **Monthly**

Generic Drug Product Information & Patent Information - **Daily**

Orange Book Data Updated Through November, 2006

Patent and Generic Drug Product Data Last Updated: January 09, 2007

Attachment 2

Partial Listing of Commercially Available Products That Could Be Reconstituted With a Prefilled Syringe of 1-mL 0.9% Sodium Chloride

Product Name	Pharmaceutical Form	Active Ingredient	Diluent Required
REFLUDAN® (Berlex)	Freeze-dried powder for injection or infusion	Lepirudin (rDNA)	Reconstitute one vial (50 mg of lepirudin) with 1 mL of WFI or Sodium Chloride 0.9% Injection. The final concentration of 5 mg/mL is obtained by transferring the contents of the vial into a sterile, single-use syringe (of at least 10-mL capacity) and diluting the solution to a total volume of 10 mL using WFI or Sodium Chloride 0.9% or Dextrose 5%.
BOTOX® (Allergan)	Powder for injection	Vacuum-dried clostridium botulinum type A neurotoxin complex	Prior to injection, reconstitute vacuum-dried BOTOX with sterile normal saline without a preservative; 0.9% Sodium Chloride Injection with the following dilutions: 1 mL (10 units), 2 mL (5 units), 4 mL (2.5 units), and 8 mL (1.25 units).
ROCEPHIN® (Roche)	Powder for injection and infusion	Ceftriaxone sodium	IM use: Reconstitute Rocephin powder with the appropriate diluent (includes Sodium Chloride 0.9%): 0.9 mL (250-mg vial), 1.8 or 1.0 mL (500-mg vial), 3.6 or 2.1 mL (1-g vial), and 7.2 or 4.2 mL (2-g vial).
INDOCIN®	Lyophilized powder for injection	Indomethacin for injection	The solution should be prepared only with 1 to 2 mL of sterile Sodium Chloride Injection 0.9% or WFI.
BLENOXANE®	Powder for solution for injection	Bleomycin sulphate	The Blenoxane 15-unit vial should be reconstituted with 1 to 5 mL of Sterile WFI, *USP*; Sodium Chloride for Injection, 0.9%, *USP*; or Sterile Bacteriostatic WFI, *USP*.