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

Re: Suitability Petition for a 1-mL 0.9% Sodium Chloride Injection, *USP*

### SUITABILITY PETITION

This petition is submitted pursuant to 21 CFR 10.20 and 10.30, as provided for in 21 CFR 314.93 and Section 505(j)(2)(c) of the Federal Food, Drug, and Cosmetic Act, to request permission from the Commissioner of the Food and Drug Administration (FDA) to submit an Abbreviated New Drug Application (ANDA) for a proposed drug product that differs from the reference listed drug (RLD) in strength (volume) only.

#### 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. 19-217. Hospira is the Applicant Holder of this RLD product. Refer to United States Food & Drug Administration, Electronic Orange Book entry for Sodium Chloride in plastic container (accessed on 24 July 2006) 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 from the Sodium Chloride Injection, *USP*, marketed product only in dosage strength (volume).

#### B. Statement of Grounds

The Federal Food, Drug, and Cosmetic Act provides for the submission of an ANDA for a new drug that differs in dosage strength from that of a RLD, provided FDA has approved a petition that proposed the filing of such an application. This petition requests a change in strength for the proposed drug from that of the RLD.

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The proposed drug product is a different strength of the RLD product (different volume of drug product in single dose container) at the same concentration. The justification to change the packaging from a plastic vial to a prefilled syringe is that prefilled syringes offer several advantages for a diluent product over traditional packaging in vials. This is discussed below:

- Market studies have been conducted and suggest that health professionals are increasingly demanding prefilled syringes due to the convenience and safety of use they provide. Prefilled syringes ease administration and are more convenient for health professionals and end users. In addition, they may facilitate use at home and in emergency situations.
- The prefilled syringe is made from Type I glass. The stoppers and tip of the syringe are elastomeric closures.
- Prefilled syringes provide an accurate premeasured dose. They eliminate the need to withdraw from a larger container. This results in fewer dosing errors compared to the use of a system where the volume of sodium chloride solution required is measured by the user and where an overfill of up to 25% is used. Prefilled syringes contain the exact deliverable dose desired. They have the potential to enhance patient compliance and reduce misidentification leading to medication errors.
- Prefilled syringes can help lower the injection costs since they require less preparation, fewer materials, and ease storage and disposal.
- Fewer manipulation steps are required, therefore, the prefilled syringe is faster to use and will have a reduced risk of microbial contamination.

The proposed package insert for 0.9% Sodium Chloride Injection, *USP*, 1-mL, will be consistent with the RLD labeling.

In summary, the proposed change in strength (volume) of 0.9% Sodium Chloride Injection, *USP*, from that of the RLD (i.e., a change from 10, 20, and 50-mL to 1-mL) will not raise questions of safety or efficacy of the proposed product.

The proposed product will differ from the RLD only in dosage strength. The active ingredient, indication, route of administration, intended patient population, and recommendations for use will remain the same as for the reference listed 0.9% Sodium Chloride Injection, *USP*, product. Therefore, there will be no difference in the safety and efficacy of the proposed strength of 0.9% Sodium Chloride Injection, *USP*.

The package insert for the RLD, 0.9% Sodium Chloride Injection, *USP* (10, 20, and 50-mL), is provided in Attachment 2 of this petition. The draft package insert for the proposed 0.9% Sodium Chloride Injection, *USP* (1-mL), is provided in Attachment 3, with changes highlighted for ease of review.

### **C. Environmental Impact**

A claim for a categorical exclusion of an environmental assessment report based upon 21 CFR 25.31 is hereby made.

**D. Economic Impact**

The petitioner does not believe that this is applicable in this case but will agree to provide such an analysis if requested by the Agency.

**E. Pediatric Use Information**

The Pediatric Research Equity Act, passed in December 2003, requires that applications submitted under Section 505 of the Act be evaluated for safety and efficacy in pediatric populations when the application is submitted for the following: a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration. The proposed petition seeks a change in dosage strength from that of the reference listed product, and therefore, under the provisions of the Pediatric Research Equity Act, it is not necessary to evaluate the safety or efficacy in pediatric populations or seek a waiver or deferral for pediatric studies.

The package insert of the RLD, 0.9% Sodium Chloride Injection, *USP*, states that "The safety and effectiveness in the pediatric population are based on the similarity of the clinical conditions of the pediatric and adult populations. In neonates or very small infants, the volume of fluid may affect fluid and electrolyte balance". 0.9% Sodium Chloride Injection, *USP* (1-mL), will provide the same information for pediatric use as the reference product, and because the proposed change is a change in strength (volume), no additional studies should be required.

**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,



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Enclosures

cc: G. Buehler; Director, Office of Generic Drugs; Food and Drug Administration