

Beckloff Associates

7400 West 110th Street, Suite 300
Overland Park, Kansas, 66210
913.451.3955 tel
913.451.3846 fax



www.beckloff.com

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June 30, 2006

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 3-, 5-, 15-, and 30-mL Water for 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 the Commissioner of the Food and Drug Administration (FDA) to declare that the drug product, Water for Injection, *USP*, in 3-, 5-, 15-, and 30-mL volumes (strengths), is suitable for submission as an abbreviated new drug application (ANDA).

A. Action Requested

The petitioner requests that the Commissioner of FDA declare that Water for Injection, *USP*, in 3-, 5-, 15-, and 30-mL volumes (strengths), is suitable for submission as an ANDA. The reference listed drug product upon which this petition is based is Water for Injection, *USP*, approved in 10-, 20-, and 50-mL dosage strengths, under New Drug Application (NDA) No. 18-801. This petition is submitted for a change in dosage strength from the reference listed drug product. Water for Injection, *USP*, will be marketed in the dosage strengths of 3, 5, 10, 15, 20, 30, and 50 mL (three of these strengths are the same as the reference listed drug). The drug, the route of administration, and the recommendations for use are the same as those of the reference listed drug product. The proposed product would differ only in dosage strength from the Water for Injection, *USP*, marketed product.

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 listed drug, 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 reference listed drug.

2006P-0273

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The proposed package insert for Water for Injection, *USP*, 3, 5, 10, 15, 20, 30, and 50 mL, will be consistent with the reference listed drug labeling.

In summary, the proposed change in strength (volume) of Water for Injection, *USP*, from that of the reference listed drug (i.e., a change from 10, 20, and 50 mL to 3, 5, 10, 15, 20, 30, and 50 mL) will not raise questions of safety or efficacy of the proposed product.

The proposed product will differ from the reference listed drug only in dosage strength (volume). The indications, route of administration, intended patient population, and recommendations for use will remain the same as for the reference listed Water for Injection, *USP* product. Therefore, there will be no difference in the safety and efficacy of the proposed strengths of Water for Injection, *USP*.

The package insert for the reference listed drug, Water for Injection, *USP* (10, 20, and 50 mL), is provided in Attachment 1 of this petition. The draft package insert for the proposed Water for Injection, *USP* (3, 5, 10, 15, 20, 30, and 50 mL), is provided in Attachment 2.

C. 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 listed drug, Water for Injection, *USP*, states that "Safety and effectiveness have been established in pediatric patients. In the neonates or very small infants, the volume of fluid may affect fluid and electrolyte balance". Water for Injection, *USP* (3, 5, 10, 15, 20, 30, and 50 mL), will provide the same information for pediatric use as the reference product, and, because the proposed change is a change in strength, no additional studies should be required.

D. Environmental Impact

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

Division of Dockets Management
Re: Suitability Petition for 3-, 5-, 15-, and 30-mL
Water Injection, USP
June 30, 2006
Page 3

E. 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.

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
President
Beckloff Associates, Inc.

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Enclosures

cc: G. Buehler; Director, Office of Generic Drugs; FDA