FRESENIUS KABI

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

SUITABILITY PETITION

Dear Sir/Madam:

Fresenius Kabi USA, LLC (FK USA) submits this petition pursuant to Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act, and in accordance to 21 CFR 10.30 requesting the Commissioner of the Food and Drug Administration (FDA) to provide a determination whether drug product Sterile Water for Irrigation, USP 250 ml and 1500 mL fill sizes in flexible plastic containers (bottles) are suitable for submission in an Abbreviated New Drug Application (ANDA).

A. Action Requested

FK USA requests that the Commissioner of the FDA determines whether Sterile Water for Irrigation, USP 250 ml and 1500 mL fill sizes in single dose flexible plastic containers (bottles) are suitable for submission in an ANDA. The Reference Listed Drug (RLD) upon which this petition is based is Sterile Water for Irrigation, USP, in 500 mL, 1000 mL, 2000 mL and 4000 mL flexible plastic containers (bottles) held by B Braun Medical, NDA 016734. Therefore, FK USA is seeking a change in strength (total drug content per container).

B. Statement of Grounds

FD&C Act § 505(j)(2)(A) permits the submission of an ANDA for a drug product that differs in dosage strength from that of the listed drug provided the FDA has approved a petition submitted pursuant to FD&C Act § 505(j)(2)(C) that proposed submitting such an application.

The RLD is Sterile Water for Irrigation, USP, in 500 mL, 1000 mL, 2000 mL and 4000 mL flexible plastic containers (bottles). Reference a copy of the listing in the current electronic Edition of the Approved Drug Products with Therapeutic Equivalence Evaluations (Attachment 1) and the current RLD labeling (Attachment 2). Fresenius Kabi proposed drug product in a 250 mL and 1500 mL single dose flexible plastic container represents a change in strength (total drug content).

Pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, the abbreviated new drug application (ANDA) for a proposed drug product is not obligated to use the same container closure system as the one used by the applicant of the reference-listed drug. However, the ANDA is required to provide appropriate information to ensure that the proposed drug product has the same conditions of use and the same labeling as the RLD pursuant to Section 505(j)(2)(A)(v) of the FD&C Act.

Sterile Water for Irrigation USP is a sterile, hypotonic, nonpyrogenic irrigating fluid or pharmaceutic aid (solvent) entirely composed of Sterile Water for Injection USP. It is prepared by distillation and contains no antimicrobial or bacteriostatic agents or added buffers. The pH is 5.7 (5.0–7.0).

Please note that the changes proposed by Fresenius Kabi in strength and container size do not affect dosing, administrations and conditions of use. The indications, warnings and directions for use will remain the same as that of the RLD. According to the Dosage and Administration in the currently approved RLD package insert the dose is "us as directed by physician".

The 250 mL and 1500 mL fill sizes would provide an appropriate single dose presentations when these volumes of drug product are required in different clinical settings. This availability will help minimize the unused portions waste.

Fresenius Kabi draft labeling for the proposed product is included in Attachment 3, and the RLD's approved labeling is provided in Attachment 2. No changes from the RLD are proposed in labeling for 250 mL and 1500 mL fill sizes with the exception of the obvious changes in strength (total drug content) sought in this petition, administrative information and container closure size.

Therefore, the petitioner's request for the Commissioner to find that a change in strength (i.e., a change in total drug content to include 250 mL and 1500 mL in flexible plastic containers) should raise no questions of safety or effectiveness, and the Agency should approve the petition.

C. Environmental Impact

In Accordance with the requirements set forth in 21 CFR 25.31, the petitioner hereby requests a Categorical Exclusion from the requirements to prepare an Environmental Impact Assessment.

D. Economic Impact

Pursuant to 21 CFR 10.30(b) an economic impact analysis will be provided upon request.

E. Certification

FK USA certifies that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and includes representative data and information known to the petitioner, which is unfavorable to the petition.

Should you have any questions, please feel free to contact the undersigned or Irina Pashyan, Manager, Regulatory Affairs, at (847) 550-5731 or Irina.Pashyan@fresenius-kabi.com.

Sincerely,

Jennifer Gross

Digitally signed by Jennifer Gross
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Attachment 1: Orange Book Listing of Sterile Water for Irrigation (RLD NDA 016734)
Attachment 2: Reference Listed Drug Labeling Sterile Water for Irrigation USP
Attachment 3: Fresenius Kabi Proposed Package Insert