

Fresenius Kabi USA, LLC

Three Corporate Drive Lake Zurich, Illinois 60047 T 847-550-2300 T 888-391-6300

September 22, 2023

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

REQUEST FOR WITHDRAWAL - CITIZEN PETITION DOCKET NUMBER FDA-2019-P-6047

Dear Sir/Madam:

Reference is made to the Fresenius Kabi USA LLC's (FK USA) Suitability Petition submitted to the Agency on 19 December 2019.

FK USA respectfully requests a withdrawal of the Suitability Petition (docket number FDA-2019-P-6047).

In the aforementioned Suitability Petition, FK USA requested if the 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 Abbreviated New Drug Application (ANDA).

Should you have any questions, please feel free to contact the undersigned or Irina Pashyan, Senior Manager, Regulatory Affairs, at (224) 221-6370 or Irina.Pashyan@fresenius-kabi.com.

Sincerely,

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