



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

December 26, 2019

Jennifer Gross
Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

Sent via email to: Jennifer.Gross@fresenius-kabi.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration to determine 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 Abbreviated New Drug Application was received by this office on 12/19/2019.

It was assigned docket number FDA-2019-P-6047. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Supervisory Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of Operations (OO)