



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

January 10, 2019

Jennifer Boysen
Regulatory Specialist
Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

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

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug Administration determine whether the drug product Sterile Water for Injection, USP, in a 250 mL fill size is suitable for submission in an ANDA was received by this office on 1/9/2019.

It was assigned docket number FDA-2019-P-0175. 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,

Karen Kennard

Karen Kennard
Acting Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)