



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration  
Silver Spring MD 20993

December 26, 2019

Jennifer Gross  
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Lake Zurich, IL 60047

Sent via email to: [Jennifer.Gross@fresenius-kabi.com](mailto:Jennifer.Gross@fresenius-kabi.com)

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration to determine whether drug product Sodium Chloride 0.9% Irrigation 250 ml and 1500 mL fill sizes in flexible plastic containers (bottles) are suitable for submission in an Abbreviated New Drug Application was received by this office on 12/20/2019.

It was assigned docket number FDA-2019-P-6048. 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)