



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration  
Silver Spring MD 20993

March 31, 2020

David L. Rosen, B.S. Pharm., JD  
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Washington, DC 20007

Sent via email to: [drosen@foley.com](mailto:drosen@foley.com)

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA designate the product identified as ANDA 200644, Acetylcysteine Injection 6gm/30mL by Fresenius Kabi USA LLC, as another reference standard and reference listed in FDA's Orange Book that can serve as the basis for the filing of ANDAs was received by this office on 03/30/2020.

It was assigned docket number FDA-2020-P-1236. 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)