



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration  
Silver Spring MD 20993

January 8, 2020

Linda Valentine  
The Ritedose Corporation  
1 Technology Circle  
Columbia, SC 29203

Sent via email to: [valentinel@ritedose.com](mailto:valentinel@ritedose.com)

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that FDA designate ANDA 202496 as the reference standard for Ipratropium Bromide and Albuterol Sulfate Inhalation Solution, 0.5 mg/3 mg per 3 mL was received by this office on 01/08/2020.

It was assigned docket number FDA-2020-P-0102. 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)