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

Re: Docket No. FDA-2020-P-0102

Dear Ms. Valentine: July 13, 2020

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on January 8, 2020. Your petition requests that the Agency designate ANDA 202496 as the reference standard (RS) for Ipratropium Bromide and Albuterol Sulfate Inhalation Solution, 0.5 mg/3 mg per 3 mL because according to your petition, the reference listed drug, DUONEB® (NDA 020950), has been discontinued and an RS has not been designated.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
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Date: 2020.07.13 09:43:37 -04'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research