

January 8, 2020

BY ELECTRONIC DELIVERY

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

The undersigned submits this petition under 505(j) of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to designate ANDA 202496 as the reference standard for Ipratropium Bromide and Albuterol Sulfate Inhalation Solution, 0.5 mg/3 mg per 3 mL.

A. Action Requested

The undersigned hereby requests that the Commissioner of the Food and Drug Administration designate ANDA 202496 as the reference standard for Ipratropium Bromide and Albuterol Sulfate Inhalation Solution, 0.5 mg/3 mg per 3 mL.

B. Statement of Grounds

The reference listed drug, DUONEB® (NDA 020950), has been discontinued in the *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* and a reference standard has not been designated. Therefore, the undersigned is requesting designation of ANDA 202496 as the reference standard for Ipratropium Bromide and Albuterol Sulfate Inhalation Solution, 0.5 mg/3 mg per 3 mL because ANDA 202496 is the market leader based on units sold.

Refer to the IQVIA (formerly IMS Health) data in Appendix 1 which demonstrates that ANDA 202496 is the market leader per units sold. Note that the drug product is private label manufactured under ANDA 202496 for American Health Packaging, GSMS, Mylan Pharmaceuticals, Ritedose Pharmaceuticals, Teva Pharmaceuticals, and Sandoz.

C. Environmental Impact

The action requested in this petition is subject to categorical exclusion under 21 CFR 25.30.

D. Economic Impact

Information on the economic impact of this proposal will be submitted upon request of the Commissioner.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



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