

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Pulmonary-Allergy Drugs Advisory Committee (PADAC) Meeting
November 8, 2022

QUESTIONS

1. **DISCUSSION:** Discuss the data to support the efficacy of fixed dose combination of budesonide and albuterol sulfate metered dose inhaler (BDA) for the as-needed treatment or prevention of bronchoconstriction and for the prevention of exacerbations in patients with asthma 4 years of age and older.
 - a. For adolescents (12 to <18) and young children (4 to <12), discuss if extrapolation of adult data to pediatric subjects is appropriate and, if so, discuss the appropriate degree of extrapolation in these age groups.
2. **DISCUSSION:** Discuss the safety data for BDA for the proposed indication. Discuss any specific pediatric safety concerns.
3. **VOTE:** Do the data support a favorable benefit risk assessment for use of BDA in patients ≥ 18 years of age with asthma?
 - a. If not, what additional data are needed?
4. **VOTE:** Do the data support a favorable benefit risk assessment for use of BDA in patients ≥ 12 to <18 years of age with asthma?
 - a. If not, what additional data are needed?
5. **VOTE:** Do the data support a favorable benefit risk assessment for use of BDA in patients ≥ 4 to <12 years of age with asthma?
 - a. If not, what additional data are needed?