

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

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

AGENDA

The committee will discuss the new drug application 214070, for a fixed dose combination of budesonide and albuterol sulfate metered dose inhaler, submitted by AstraZeneca and Bond Avillion 2 Development LP. The proposed indication is as-needed treatment or prevention of bronchoconstriction and for the prevention of exacerbations in patients with asthma 4 years of age and older.

10:00 a.m.	Call to Order	David H. Au, MD, MS Chairperson, PADAC
10:10 a.m.	Introduction of Committee and Conflict of Interest Statement	Takyiah Stevenson, PharmD Designated Federal Officer, PADAC
10:15 a.m.	FDA Introductory Remarks	Kelly Stone, MD, PhD Associate Director for Therapeutic Review Division of Pulmonology, Allergy, and Critical Care Office of Immunology and Inflammation Office of New Drugs, CDER, FDA
10:20 a.m.	APPLICANT PRESENTATION	Bond Avillion 2 Development LP/AstraZeneca
	Summary	Ed Piper, MBBS Global Franchise Head Core Inhaled Products AstraZeneca
	Clinical Perspective	Neil Skolnik, MD Professor of Family and Community Medicine Sidney Kimmel Medical College Thomas Jefferson University Jefferson Health
10:50 a.m.	Clarifying Questions to the Applicant	
11:10 a.m.	FDA PRESENTATION	
	FDA Summary Presentation	Kelly Stone, MD, PhD
11:40 a.m.	Clarifying Questions to the FDA	
12:00 p.m.	LUNCH	
1:00 p.m.	Open Public Hearing	

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

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

AGENDA (cont.)

- | | | |
|-----------|---|-----------------------------|
| 2:00 p.m. | FDA Charge to the Committee | Kelly Stone, MD, PhD |
| 2:05 p.m. | Questions to the Committee/Committee Discussion | |
| 3:00 p.m. | BREAK | |
| 3:15 p.m. | Questions to the Committee/Committee Discussion (cont.) | |
| 4:30 p.m. | ADJOURNMENT | |