

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

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

**AGENDA**

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*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.*

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

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**AGENDA (cont.)**

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