The committees will discuss the supplemental new drug application (sNDA) 204275-S001, for fluticasone furoate and vilanterol inhalation powder (tradename Breo Ellipta) submitted by GlaxoSmithKline for the once daily maintenance treatment of asthma in patients 12 years of age and older. The discussion will include efficacy data, but the focus of the meeting will be safety, including the adequacy of the safety database to support approval and whether a large safety trial to evaluate serious asthma outcomes is recommended.

8:00 a.m.  Call to Order and Introduction of Committee

Erik Swenson, MD
Acting Chairperson, PADAC

8:05 a.m.  Conflict of Interest Statement

Cindy Hong, PharmD
Designated Federal Officer, PADAC

8:15 a.m.  FDA Opening Remarks

Sally Seymour, MD
Deputy Director for Safety
Division of Pulmonary, Allergy, Rheumatology Products (DPARP)
Office of Drug Evaluation (ODE) II
Office of New Drugs (OND), CDER, FDA

8:30 a.m.  APPLICANT PRESENTATIONS

GlaxoSmithKline

BREO ELLIPTA 100/25 and 200/25 (Fluticasone furoate / Vilanterol)
Introduction

Katharine Knobil, MD
Senior Vice President
Research and Development
GlaxoSmithKline

BREO ELLIPTA 100/25 and 200/25 (Fluticasone furoate / Vilanterol)
Asthma: Efficacy and Safety

Courtney Crim, MD
Director, Project Physician Lead
GlaxoSmithKline

Clinical Perspectives on Asthma Management

Eugene Bleecker, MD
Director
Center for Genomics and Personalized Medicine
Research
Professor of Medicine
Wake Forest Baptist Health

Closing Remarks

Katharine Knobil, MD

10:00 a.m.  Clarifying Questions to the Presenters
10:20 a.m.  **BREAK**

10:35 a.m.  **FDA PRESENTATIONS**

Utilization Patterns of Breo Ellipta and Long-Acting Beta2-Adrenergic Agonists (LABAs)  
**Tracy Pham, PharmD**  
Drug Utilization Analyst  
Division of Epidemiology II  
Office of Surveillance and Epidemiology  
CDER, FDA

Clinical Review of Efficacy - 1   
**Banu Karimi-Shah, MD**  
Clinical Team Leader  
DPARP, ODE II, OND, CDER, FDA

Meta-analysis of Asthma Related Serious Adverse Events   
**Janelle K. Charles, PhD**  
Mathematical Statistician  
Division of Biometrics VII  
Office of Biostatistics  
Office of Translational Sciences, CDER, FDA

Efficacy in Subgroups and Risk- Benefit Considerations   
**Banu Karimi-Shah, MD**

Pediatric Perspective   
**Ann McMahon, MD, MS**  
Deputy Director of Science  
Office of Pediatric Therapeutics  
Office of the Commissioner, FDA

11:45 a.m.  Clarifying Questions to the Presenters

12:00 p.m.  **LUNCH**

1:00 p.m.  Open Public Hearing

2:00 p.m.  Charge to the Committee   
**Sally Seymour, MD**

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.)

5:00 p.m.  **ADJOURNMENT**