

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Meeting of the Pulmonary-Allergy Drugs Advisory Committee (PADAC)

FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center
(Rm. 1503), Silver Spring, MD

April 17, 2013

AGENDA

The committee will discuss the new drug application (NDA) 204275 for fluticasone furoate and vilanterol dry powder inhaler (proposed tradename BREO Ellipta) sponsored by GlaxoSmithKline, for the long-term maintenance treatment of airflow obstruction and for reducing exacerbations in patients with chronic obstructive pulmonary disease (COPD).

8:00 a.m.	Call to Order Introduction of Committee	David Jacoby, MD Chairperson, Pulmonary-Allergy Drugs Advisory Committee (PADAC)
8:05 a.m.	Conflict of Interest Statement	Cindy Hong, PharmD Designated Federal Officer, PADAC
8:10 a.m.	Member Appreciation	Susan Limb, MD Clinical Team Leader, Division of Pulmonary, Allergy, and Rheumatology Products (DPARP), Office of Drug Evaluation II (ODE-II), Office of New Drug (OND), CDER, FDA
8:15 a.m.	Opening Remarks	Susan Limb, MD
8:25 a.m.	<u>Sponsor Presentations</u>	<u>GlaxoSmithKline</u>
	BREO ELLIPTA 100/25 (Fluticasone furoate/Vilanterol) Introduction	Katharine Knobil, MD Vice President, Clinical Development GlaxoSmithKline
	BREO ELLIPTA 100/25 (Fluticasone furoate/Vilanterol) Efficacy	Courtney Crim, MD Director of Clinical Development GlaxoSmithKline
	BREO ELLIPTA 100/25 (Fluticasone furoate/Vilanterol) Safety	Tjark Reblin, MD Vice President, Global Clinical Safety and Pharmacovigilance GlaxoSmithKline
	Clinician's Perspective	Stephen I. Rennard, MD Larson Professor of Medicine Division of Pulmonary, Critical Care, Sleep and Allergy University of Nebraska Medical Center Omaha, NE
	Closing Remarks	Katharine Knobil, MD

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AGENDA (cont.)

9:55 a.m. Clarifying Questions to the Presenters

10:25 a.m. **BREAK**

FDA Presentations

10:40 a.m. Overview of Clinical Program **Sofia Chaudhry, MD**
Clinical Reviewer, DPARP, ODE-II, OND, CDER, FDA

Statistical Review of Efficacy **Kiya Hamilton, PhD**
Statistical Reviewer
Division of Biostatistics II (DB-II)
Office of Biostatistics (OB)
Office of Translational Sciences (OTS), CDER, FDA

Clinical Review of Efficacy, Safety,
and Risk/Benefit **Sofia Chaudhry, MD**

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 **Susan Limb, MD**

2:05 p.m. Questions to the Committee and Committee Discussion

3:00 p.m. **BREAK**

3:15 p.m. Questions to the Committee and Committee Discussion (cont.)

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