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

Pulmonary-Allergy Drugs Advisory Committee (PADAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
July 25, 2018

DRAFT AGENDA

The committee will discuss the supplemental biologics license application (sBLA) 125526 for mepolizumab for injection, submitted by GlaxoSmithKline for add-on treatment to inhaled corticosteroid-based maintenance treatment for the reduction of exacerbations in patients with chronic obstructive pulmonary disease (COPD) guided by blood eosinophil counts.

8:00 a.m.	Call to Order and Introduction of Committee	**Jeffrey S. Wagener, MD** Chairperson, PADAC
8:05 a.m.	Conflict of Interest Statement	**Jennifer Shepherd, RPh** Acting Designated Federal Officer, PADAC
8:10 a.m.	FDA Introductory Remarks	**Banu A. Karimi-Shah, MD** Clinical Team Leader Division of Pulmonary, Allergy, Rheumatology Products (DPARP) Office of Drug Evaluation II (ODE II) Office of New Drugs (OND), CDER, FDA
8:25 a.m.	**APPLICANT PRESENTATIONS**	**GlaxoSmithKline (GSK)**
	Introduction - NUCALA® Mepolizumab for Patients with COPD	**Steven Yancey, MS** Vice President, Medicines Development Leader for Mepolizumab, GSK
	Eosinophilic COPD	**Ian Pavord, MD** Professor of Respiratory Medicine University of Oxford Honorary Consultant Physician University of Oxford Hospitals NHS Trust
	Clinical Efficacy	**Eric Bradford, MD, MSc** Director, Project Physician Lead for Mepolizumab GSK
	Clinical Safety	**Olga Gumieniak, MD, MMSc** Medical Director, Global Clinical Safety and Pharmacovigilance, GSK

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DRAFT AGENDA (cont.)

	APPLICANT PRESENTATIONS (CONT.)	**GSK**
	Physician's Perspective	**Gerard Criner, MD** Professor and Chair, Department of Thoracic Medicine and Surgery Lewis Katz School of Medicine at Temple University
	Closing Comments	**Steven Yancey, MS**
9:55 a.m.	Clarifying Questions	
10:15 a.m.	**BREAK**	
10:30 a.m.	**FDA PRESENTATIONS**	
	Overview of the Clinical Program	**Robert Busch, MD, MMSc** Clinical Reviewer DPARP, ODE II, OND, CDER, FDA
	Statistical Review of Efficacy	**Yu (Jade) Wang, PhD** Statistical Reviewer Division of Biometrics II (DB II) Office of Biometrics (OB) Office of Translational Sciences (OTS) CDER, FDA
	Review of Safety	**Robert Busch, MD, MMSc**
	Clinical Considerations and Benefit-Risk Assessment	**Robert Busch, MD, MMSc**
11:50 a.m.	Clarifying Questions	
12:10 p.m.	**LUNCH**	
1:10 p.m.	Open Public Hearing	
2:10 p.m.	Charge to the Committee	**Banu A. Karimi-Shah, MD**
2:25 p.m.	Questions to the Committee/Committee Discussion	

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DRAFT AGENDA (cont.)

3:00 p.m.	**BREAK**
3:15 p.m.	Questions to the Committee/Committee Discussion
4:00 p.m.	**ADJOURNMENT**