FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
PULMONARY-ALLERGY DRUGS ADVISORY COMMITTEE MEETING

AGENDA

May 1, 2007

The Committee will discuss the benefit to risk considerations for the approved product Advair Diskus 500/50 (fluticasone propionate/salmeterol inhalation powder) to increase survival and reduce exacerbations in patients with chronic obstructive pulmonary disease (COPD) (NDA 21-077 efficacy supplement).

8:00 a.m.	Call to Order and Opening Remarks	Mark L. Brantly, M.D. Chair, Pulmonary-Allergy Drugs Advisory Committee
	Introduction of Committee	
	Conflict of Interest Statement	Teresa A. Watkins, PharmD Designated Federal Official, PADAC
8:15 a.m.	FDA Introductory Remarks	Badrul Chowdhury, M.D., Ph.D. Director, Division of Pulmonary-Allergy Products
8:30 a.m.	**Sponsor Presentation**	Glaxo Smith Kline
	Pulmonary-Allergy Drugs Advisory Committee Meeting	Christine Elaine Jones, Ph.D. Vice President, US Regulatory Affairs GlaxoSmithKline
	Efficacy and Safety Data from the Advair Diskus 500/50 Clinical Program	Katharine Knobil, M.D. Vice President, Respiratory Medicine Development Center GlaxoSmithKline
	Clinician's Perspective	Bartolome Celli, M.D. Professor of Medicine, Tufts University
10:15 a.m.	Break	
10:30 a.m.	**FDA Presentation**	
	History of the Clinical Program for Advair Diskus 500/50 and Introduction to the Efficacy Data	Carol H. Bosken, M.D., ScM, MPH Medical Reviewer Division of Pulmonary and Allergy Products
	Efficacy Data for Advair Diskus 500/50	Feng Zhou, M.S. Statistical Reviewer DBII/ Office of Biostatistics

	Safety Data for Advair Diskus 500/50 and Summary	Carol H. Bosken, M.D., ScM, MPH Medical Reviewer Division of Pulmonary and Allergy Products
12:00 p.m.	Lunch	
1:00 p.m.	**Open Public Hearing**	
2:00 p.m.	Clarifying questions	
2:45 p.m.	Break	
3:00 p.m.	Committee Discussion/vote	
5:30 p.m.	Adjourn	