FOOD AND DRUG ADMINISTRATION (FDA)
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Pulmonary-Allergy Drugs Advisory Committee (PADAC)
FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center (Rm. 1503), Silver Spring, MD
March 8, 2011

Agenda

The Committee will discuss new drug application (NDA) 022-383, indacaterol maleate (Arcapta™ Neohaler™) by Novartis Pharmaceuticals Corporation, for the long-term once daily maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

8:00 a.m.	Call to Order Introduction of Committee	**Peter Terry, M.D.** Chair (Acting), PADAC
	Conflict of Interest Statement	**Kristine Khuc, Pharm.D.**, Designated Federal Officer, PADAC
8:15 a.m.	Opening Remarks	**Badrul Chowdhury, M.D., Ph.D.** Director, Division of Pulmonary, Allergy, and Rheumatology Products Center for Drug Evaluation and Research (CDER), FDA
8:30 a.m.	**Sponsor Presentation**	**Novartis Pharmaceuticals Corporation**
	Introduction and Background	**Trevor Mundel, M.D., Ph.D.** Head of Development Novartis Pharma AG
	Perspectives on COPD	**James Donohue, M.D.** Professor and Chief, Division of Pulmonary and Critical Care Medicine University of North Carolina at Chapel Hill
	Dose Selection, Efficacy	**David Morris, M.D.** Franchise Head, Respiratory Novartis Pharma AG
	Safety, Risk Mitigation	**Linda Armstrong, M.D.** Drug Safety and Epidemiology Novartis Pharmaceuticals Corporation
	Benefit-Risk, Clinical Perspective	**James Donohue, M.D.**
10:00 a.m.	Questions for clarification for Sponsor	
10:15 a.m.	Break	
10:30 a.m.	**FDA Presentation**	
	Overview of Clinical Program and Statistical Perspective – Efficacy	**Dongmei Liu, Ph.D.** Mathematical Statistician, Division of Biometrics II CDER, FDA

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Agenda- *continued-*

11:00 a.m.	Clinical Perspective – Safety	**Anya Harry, M.D., Ph.D.** Medical Officer, Division of Pulmonary, Allergy, and Rheumatology Products CDER, FDA
11:20 a.m.	Meta-analysis Discussion	**Banu Karimi-Shah, M.D.** Medical Officer, Division of Pulmonary, Allergy, and Rheumatology Products CDER, FDA
11:30 a.m.	Risk Benefit Discussion	**Theresa Michele, M.D.** Clinical Team Leader, Division of Pulmonary, Allergy, and Rheumatology Products, CDER, FDA
11:45 a.m.	Questions for Clarification for FDA	
12:00 p.m.	Lunch	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Charge to the Committee	**Theresa Michele, M.D.**
2:15 p.m.	Discussion and Questions	
3:00 p.m.	Break	
3:15 p.m.	Continue Discussion and Questions	
5:00 p.m.	Adjourn	