FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research

Anti-Infective Drugs Advisory Committee (AIDAC) Meeting
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
September 5, 2012

AGENDA

The committee will discuss new drug application (NDA) 201688, tobramycin inhalation powder, application submitted by Novartis Pharmaceuticals Corporation, and the requested indication of management of cystic fibrosis patients infected with the bacterium Pseudomonas aeruginosa.

8:00 a.m.	Call to Order and Introduction of Committee	**Thomas A. Moore, MD, FACP, FIDSA** Chairperson, AIDAC
8:05 a.m.	Conflict of Interest Statement	**Diane Goyette, RPh, JD** Designated Federal Officer, AIDAC
8:10 a.m.	Welcome and Introductory Remarks	**John Farley, MD, MPH** Acting Director Division of Anti-Infective Products (DAIP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	**SPONSOR PRESENTATIONS**	**Novartis Pharmaceuticals Corporation**
	Introduction and Background	**Robert Kowalski, PharmD** Global Head, Drug Regulatory Affairs US Head of Development Novartis Pharmaceuticals Corporation
	Unmet Medical Need in Cystic Fibrosis	**Bonnie Ramsey, MD** Director, Center for Clinical and Translational Research Seattle Children's Research Institute
	Dose Selection and Efficacy	**Olga Santiago, MD** Clinical Science Unit Head Novartis Pharmaceuticals Corporation
	Safety and Benefit Risk	**Linda Armstrong, MD** Therapeutic Area Safety Lead Novartis Pharmaceuticals Corporation
	Clinical Perspective on Benefit/Risk	**Patrick Flume, MD** Professor, Pulmonary and Critical Care Medicine Medical University of South Carolina

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AGENDA (cont.)

9:45 a.m.	Clarifying Questions from the Committee	
10:00 a.m.	**BREAK**	
10:15 a.m.	**FDA PRESENTATIONS**	
	Medical Review Perspective: Trial Design, Safety and Usability	**Shrimant Mishra, MD, MPH** Medical Reviewer DAIP, OAP, OND, CDER, FDA
	Statistical Review Perspective: Efficacy Findings for Studies C2301 and C2303	**Christopher Kadoorie, PhD** Statistical Reviewer Division of Biometrics IV Office of Biostatistics Office of Translational Sciences CDER, FDA
	Microbiology Review Perspective: Increased Tobramycin MICs and Resistance in *Pseudomonas aeruginosa* During Therapy	**Peter Coderre, PhD, MBA** Clinical Microbiology Reviewer DAIP, OAP, OND, CDER, FDA
11:30 a.m.	Clarifying Questions from the Committee	
12:00 p.m.	**LUNCH**	
1:00 p.m.	Open Public Hearing Session	
2:00 p.m.	Charge to the Committee	
2:10 p.m.	Questions to the Committee/Committee Discussion	
3:15 p.m.	**BREAK**	
3:30 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	