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
May 8, 2019

AGENDA

The committee will discuss new drug application (NDA) 202049, for mannitol inhalation powder, for oral inhalation submitted by Chiesi USA, Inc., for the proposed indication of management of cystic fibrosis to improve pulmonary function in patients 18 years of age and older in conjunction with standard therapies.

8:00 a.m.	Call to Order and Introduction of Committee	**David Au, MD** Chairperson, PADAC
8:05 a.m.	Conflict of Interest Statement	**Cindy Chee, PharmD** Designated Federal Officer, PADAC
8:10 a.m.	FDA Introductory Remarks	**Robert H. Lim, MD** Clinical Team Leader Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) Office of Drug Evaluation II (ODE II) Office of New Drugs (OND), CDER, FDA
8:20 a.m.	**APPLICANT PRESENTATIONS**	**Chiesi USA, Inc.**
	Introduction to Bronchitol for Adult Patients with Cystic Fibrosis	**Mark Parry-Billings, PhD** Head of Corporate Drug Development Chiesi Farmaceutici S.p.A.
	Unmet Need and Disease Background	**Scott H. Donaldson, MD** Professor of Medicine University of North Carolina at Chapel Hill School of Medicine; Division of Pulmonary and Critical Care Director, Adult Cystic Fibrosis Center
	Efficacy in Adult Patients with Cystic Fibrosis	**Carmen Dell'Anna, MD** Vice President, Medical Affairs Chiesi USA, Inc.
	Safety of Bronchitol	**W. James Alexander, MD, MPH** Senior Medical Affairs Consultant Chiesi USA, Inc.

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AGENDA (cont.)

	APPLICANT PRESENTATIONS (CONT.)	
	Bronchitol: A Clinician's Perspective	**Patrick A. Flume, MD** Medical University of South Carolina The Powers-Huggins Endowed Chair for Cystic Fibrosis Professor of Medicine and Pediatrics Associate Provost for Research Compliance and Regulatory Affairs
9:50 a.m.	Clarifying Questions	
10:15 a.m.	**BREAK**	
10:30 a.m.	**FDA PRESENTATIONS**	
	Overview of Clinical Program	**Khalid Puthawala, MD** Clinical Reviewer DPARP, ODE II, OND, CDER, FDA
	Statistical Review of Efficacy	**Cesar Torres, PhD** Statistical Reviewer Division of Biometrics II (DBII) Office of Biostatistics (OB) Office of Translational Sciences (OTS) CDER, FDA
	Clinical Review of Efficacy, Safety, and Benefit-Risk Assessment	**Khalid Puthawala, MD**
11:45 a.m.	Clarifying Questions	
12:00 p.m.	**LUNCH**	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Charge to the Committee	**Robert H. Lim, MD**
2:15 p.m.	Questions to the Committee/Committee Discussion	
3:15 p.m.	**BREAK**	

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AGENDA (cont.)

3:30 p.m.	Questions to the Committee/Committee Discussion
5:00 p.m.	**ADJOURNMENT**