

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

DRAFT 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 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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DRAFT 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

Medical Officer
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 p.m. Clarifying Questions

12:00 p.m. **LUNCH**

1:00 p.m. Open Public Hearing

2:00 p.m. Charge to the Committee

Robert Lim, MD

2:15 p.m. Questions to the Committee/Committee
Discussion

3:15 p.m. **BREAK**

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DRAFT AGENDA (cont.)

3:30 p.m. Questions to the Committee/Committee
Discussion

5:00 p.m. **ADJOURNMENT**

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