

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Meeting of the Pulmonary-Allergy Drugs Advisory Committee (PADAC)

FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center
(Rm. 1503), Silver Spring, MD

January 30, 2013

AGENDA

The committee will discuss the New Drug Application (NDA) for mannitol inhalation powder (Bronchitol), sponsored by Pharmaxis, for the management of cystic fibrosis (CF) in patients aged 6 years and older to improve pulmonary function.

8:00 a.m.	Call to Order Introduction of Committee	David B. Jacoby, MD Chairperson, Pulmonary-Allergy Drugs Advisory Committee (PADAC)
8:05 a.m.	Conflict of Interest Statement	Cindy Hong, PharmD Designated Federal Officer, PADAC
8:10 a.m.	Opening Remarks	Anthony Durmowicz, 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
8:15 a.m.	<u>Sponsor Presentations</u>	<u>Pharmaxis</u>
	Introduction	Ronald Dundore, PhD VP, US Regulatory Affairs Pharmaxis
	Unmet Medical Need	Felix Ratjen, MD, PhD Professor, Respiratory Medicine University of Toronto Hospital for Sick Children
	Efficacy	Howard Fox, MD Chief Medical Officer Pharmaxis
	Safety	Brett Charlton, MD, PhD Medical Director Pharmaxis
	Risk/Benefit and Clinical Perspective	Patrick Flume, MD Professor, Pulmonary and Critical Care Medicine Medical University of South Carolina
9:30 a.m.	Clarifying Questions to the Presenters	

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AGENDA (cont.)

9:45 a.m. **BREAK**

10:00 a.m. **FDA Presentations**

Overview of the Clinical Program **Kimberly Witzmann, MD**
Clinical Reviewer
DPARP, ODE-II, CDER, FDA

Statistical Review of Efficacy **Feng Zhou, MS**
Statistical Reviewer
Division of Biostatistics II (DB-II)
Office of Biostatistics (OB)
Office of Translational Sciences (OTS), CDER, FDA

Thomas Permutt, PhD
Director, Division of Biostatistics II (DB-II)
Office of Biostatistics (OB)
Office of Translational Sciences (OTS), CDER, FDA

Clinical Review of Efficacy, Safety,
and Risk/Benefit **Kimberly Witzmann, MD**

11:15 a.m. Clarifying Questions to the Presenters

11:30 a.m. **LUNCH**

12:30 p.m. Open Public Hearing

1:30 p.m. Charge to the Committee **Anthony Durmowicz, MD**

1:40 p.m. Questions to the Committee and Committee Discussion

2:30 p.m. **BREAK**

2:45 p.m. Questions to the Committee and Committee Discussion (cont.)

4:00 p.m. **ADJOURNMENT**