

Food and Drug Administration  
Center for Drug Evaluation and Research  
**Pulmonary-Allergy Drugs Advisory Committee**  
**September 5, 2003**  
Holiday Inn, Gaithersburg

**Agenda**

**NDA 21-573, Ariflo™ (cilomilast) Tablets 15mg, by GlaxoSmithKline, for use in Chronic Obstructive Pulmonary Disease (COPD)**

8:00	Introductions Conflict of Interest Statement	Polly Parsons, M.D. Kimberly L. Topper, M.S.
8:20	Topic Introduction	Badrul Chowdhury, M.D.
8:30	<b>GlaxoSmithKline Presentation</b> Introduction Rationale for the Use of Ariflo in COPD Efficacy Data from Ariflo Clinical Program Safety of Ariflo Assessment of Outcome in COPD Conclusion	David Wheadon, M.D. Katharine Knobil, M.D. Katharine Knobil, M.D. Kathy Rickard, M.D. Frank Scieurba, M.D. David Wheadon, M.D.
9:30	Committee Discussion and Clarification	
10:00	Break	
10:15	<b>Food and Drug Administration Presentation</b> Introduction Preclinical Pharmacology-Toxicology Dose-Finding Statistics Efficacy & Safety	Raymond Anthracite, M.D. Virgil Whitehurst, Ph.D. Sandra Suarez-Sharp, Ph.D. James Gebert, Ph.D. Raymond Anthracite, M.D.
11:15	Committee Discussion and Clarification	
11:45	Lunch	
1:00	Open Public Hearing	
2:00	Committee Discussion	
3:00	Break	
3:15	Questions	
5:30	Adjourn	