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

QUESTIONS

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

1. Has cilomilast at a dose of 15 mg twice daily shown a magnitude and consistency of efficacy that is sufficient to support approval of cilomilast for the maintenance of lung function (FEV1) in patients with COPD?

a) If not, what further efficacy data should be obtained?

2. Is the safety database (aside from the concern for vasculitis) for cilomilast for the maintenance of lung function (FEV 1) in patients with COPD sufficient to support approval?

a) If not, what further safety data should be obtained?

3. Do you feel that the concern of mesenteric vasculitis has been adequately studied to be dismissed as a safety concern in humans?

a) If not, what further data should be obtained?

4. Do the efficacy and safety data provide substantial and convincing evidence that support the approval of cilomilast at a dose of 15 mg twice daily for the maintenance of lung function (FEV1) in patients with COPD?