Pulmonary-Allergy Drugs Advisory Committee

17 January 2002

Advair Diskus and Flovent Diskus for Long-term, Maintenance Treatment of COPD

POINTS FOR DISCUSSION AND QUESTIONS

- Please discuss the patient population studied in clinical trials FLTA3025, SCFA3006, and SCFA3007 with regard to how typical or "representative" they are of US COPD patients in general, and how this would or would not impact on the generalizability of the results of these trials to all COPD patients.

- Please discuss the clinical relevance for the COPD population of the primary endpoint "change from baseline in [pre-dose] FEV_1 over 24 weeks" and the resultant primary efficacy data. .

- Please discuss the sufficiency of the safety database to support the use of these products for the long-term, maintenance treatment of COPD.

QUESTIONS:

1. Do the data provide sufficient evidence of efficacy of Flovent Diskus (at a dose of 250 mcg twice daily, 500 mcg twice daily or both) for the indication of "long-term, twice-daily maintenance treatment of COPD (including emphysema and chronic bronchitis)"?

2. Do the data provide sufficient evidence of efficacy of Advair Diskus (at a dose of 250/50 mcg twice daily, 500/50 mcg twice daily or both) for the indication of "long-term, twice-daily maintenance treatment of COPD (including emphysema and chronic bronchitis)"?

3. Do the data provide sufficient evidence of safety of Flovent Diskus for the indication of "long-term, twice-daily maintenance treatment of COPD (including emphysema and chronic bronchitis)"?

4. Do the data provide sufficient evidence of safety of Advair Diskus for the indication of "long-term, twice-daily maintenance treatment of COPD (including emphysema and chronic bronchitis)"?

5. Do you recommend approval of Flovent Diskus for the indication of "long-term, twice-daily maintenance treatment of COPD (including emphysema and chronic bronchitis)"?

If Yes:

- At both doses or only one dose?

- Are there any labeling restrictions or changes needed?
- Are there any phase 4 studies you would recommend?

If No, what safety and/or efficacy data would the sponsor need to provide to allow for approval?

1. Do you recommend approval of Advair Diskus for the indication of "long-term, twice-daily maintenance treatment of COPD (including emphysema and chronic bronchitis)"?

If Yes:

- At both doses or only one dose?
- Are there any labeling restrictions or changes needed?
- Are there any phase 4 studies you would recommend?

If No, what safety and/or efficacy data would the sponsor need to provide to allow for approval?