

# Questions

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1. Do the data provide substantial convincing evidence that Advair Diskus (fluticasone/salmeterol inhalation powder) 500/50 mcg increases survival when used in the chronic treatment of patients with COPD?



# Questions

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**1a.** If not, what additional data should be obtained?

# Questions

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**1b.** Is additional dosing information needed (e.g., efficacy of Advair 500/50 vs. Advair 250/50)?



# Questions

2. Do the data provide substantial convincing evidence that Advair Diskus (fluticasone/salmeterol inhalation powder) 500/50 mcg provides a clinically meaningful decrease in the incidence of COPD exacerbations when used in the chronic treatment of patients with COPD?



# Questions

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**2a.** If not, what additional data should be obtained?

# Questions

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**2b.** Is additional dosing information needed (e.g., efficacy of Advair 500/50 vs. Advair 250/50)?



# Questions

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- 3.** Do the data provide sufficient evidence that Advair Diskus (fluticasone/salmeterol inhalation powder) 500/50 mcg provides substantial advantage for the treatment of patients with COPD when compared to salmeterol alone?



# Questions

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4. Does the increased incidence of respiratory infections and pneumonia seen in these studies warrant additional evaluation?



# Questions

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**4a.** If so, what additional data should be obtained?