

Pulmonary Allergy Drugs Advisory Committee
September 6, 2002
Holiday Inn Gaithersburg
Questions

1. Is the safety database for tiotropium bromide inhalation powder for the treatment of COPD patients adequate?
 - A) If not, what further safety data should be obtained?
 - B) Which of the safety data should be obtained prior to approval?
2. Are there specific safety concerns regarding the use of tiotropium bromide inhalation powder in the COPD patient population that merit specific attention in the product label?
3. Do the data provide substantial and convincing evidence that tiotropium bromide inhalation powder provides a clinically meaningful bronchodilator effect when used in the chronic treatment of patients with COPD?
4. Do the data provide substantial and convincing evidence that tiotropium bromide inhalation powder provides a clinically meaningful effect for the symptom of dyspnea in patients with COPD?
5. In general, what quality and quantity of data would constitute substantial and convincing evidence of a clinically meaningful benefit for the symptom of dyspnea in patients with COPD?