Exubera® (insulin [rDNA origin] powder for inhalation
NDA 21-868
Advisory Committee Questions
September 8, 2005

1. **Efficacy in type 1 diabetes**: Is there sufficient clinical trial evidence that Exubera® can be effectively applied to an "intensive" glycemic control regimen?
2. **Efficacy in type 2 diabetes**: Has the efficacy of Exubera® been adequately assessed in patients with Type 2 diabetes?
3. **Hypoglycemia**: Has the safety of Exubera® regarding hypoglycemia been adequately assessed?
    a. In Type 1 diabetes in "intensive" control regimens?
    b. In Type 2 diabetes?
4. **Pulmonary effects**:
    a. Are there sufficient data to assess the pulmonary safety of Exubera® in patients without underlying lung disease?
        i. If yes, do the data suggest an acceptable pulmonary safety profile in patients without underlying lung disease?
        ii. If no, what additional information is needed?
    b. Are there sufficient data to assess the pulmonary safety of Exubera® in patients with underlying lung disease?
        i. If yes, do the data suggest an acceptable pulmonary safety profile in patients with underlying lung disease?
        ii. If no, what additional information is needed?
5. **Comments/discussion**:
    a. Comment on clinical concerns and recommendations about the use of Exubera in the setting of pulmonary pathology or exogenous factors affecting pulmonary function:
        i. Viral upper respiratory infection
        ii. Asthma
        iii. COPD
        iv. Smoking
    b. Comment on clinical concerns and recommendations regarding dose adjustment (titration) and switching between inhaled and subcutaneous insulin.
    c. Other issues

6. **Should Exubera® be approved for the proposed indications?**
    a. Type 1 diabetes
    b. Type 2 diabetes as monotherapy, in combination with basal insulin, in combination with oral agents
7. **Additional investigations:** What, if any, recommendations does the committee have for additional investigations of Exubera®?