

**Developing New Pneumococcal Vaccines
Indicated for Adults for US Licensure
November 17, 2005**

DRAFT questions to the committee:

1. Please discuss whether the efficacy of a new pneumococcal vaccine against pneumococcal disease in adults should be demonstrated in a clinical endpoint efficacy study to support licensure of the vaccine for an adult indication. In this regard, please discuss the appropriate target population and endpoint(s) for the study.

2. Please discuss whether efficacy against invasive disease in adults can be inferred from non-inferiority immune response trials comparing a new pneumococcal vaccine with the licensed 23-valent pneumococcal vaccine.
 - a. Please discuss what immunological parameter(s) should be used in such trials.

 - b. Please discuss required data to support approval of an adult indication for a new pneumococcal vaccine that would contain a subset of the serotypes in Pneumovax® 23.