FOOD AND DRUG ADMINISTRATION CENTER FRO BIOLOGICS EVALUATION AND RESEARCH

VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE (VRBPAC)

Committee Questions and Discussions March 15, 2005

Session 1 – Open Committee Discussion

1. Are the available data adequate to support the efficacy of Boostrix TM in individuals 10-18 years of age?

VOTE

2. Are the available data adequate to support the safety of BoostrixTM when administered to individuals 10-18 years of age? VOTE

Discussion item:

Please identify any issues which should be addressed, including post-licensure studies.

Session II – Open Committee Discussion

1. Are the available data adequate to support the efficacy of ADACEL $^{\text{TM}}$ in individuals 11-64 years of age?

VOTE

2. Are the available data adequate to support the safety of $ADACEL^{\rm TM}$ when administered to individuals 11-64 years of age? VOTE

Discussion item:

Please identify any issues which should be addressed, including post-licensure studies.