

VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

May 16-17, 2001

Holiday Inn, 2 Montgomery Village Avenue, Gaithersburg, Maryland

QUESTIONS FOR THE COMMITTEE

Wednesday, May 16

Session 2 – Open Session

1. Please discuss OVR/CBER's approach in considering potential risks for the use of 293, PER.C6 and other similar "designer cell substrates" for the production of viral vaccines, including:

- a) Tumorigenicity
- b) Residual cell substrate DNA
- c) Possible contamination with adventitious (including oncogenic) agent testing

2. Please discuss any other safety concerns that should be addressed prior to initiating larger-scale human studies.