

**FOOD AND DRUG ADMINISTRATION  
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH  
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE  
May 16-17, 2001  
Holiday Inn, 2 Montgomery Village Avenue, Gaithersburg, Maryland**

**AGENDA**

**Wednesday, May 16**

**8 AM          Session 1 – CLOSED SESSION**

**9:00          Session 2 – OPEN Session – Use of Novel (“Designer”) Cells  
as Substrates for Manufacture of Viral Vaccines**

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|--------------|--|--|
| 9:00         | Call to Order,<br>Introductions, Administrative Matters  | Dr. Robert S. Daum, Committee<br>Chair |
| 9:15         | Introduction to the Session on Designer Cell Substrates  | Dr. Andrew Lewis, FDA                  |
| 9:30         | Designer Cell Substrates for Vaccine Development:<br>Concepts and Issues   | Dr. Steve Hughes                       |
| 9:50         | Adenovirus Biology as Related to Development<br>and Use of Adenovirus Vectors  | Dr. Estuardo Aguilar-Cordova           |
| <b>10:10</b> | <b>Break</b>   |  |
| 10:30        | Adenovirus Transformation of Human Cells and the<br>Development of 293 and PER.C6 Cells for the Manufacture<br>of Defective Adenovirus Vectors | Dr. Alex van der Eb                    |
| 11:00        | Adenovirus Transformed Cell Tumorigenicity and<br>Transformed Cell-Host Interaction that Determine<br>their Tumor-Forming Capability           | Dr. James Cook                         |
| 11:30        | Quantitative Assessment of the Risks of Residual DNA   | Dr. Keith Peden, FDA                   |

**11:55          Lunch**

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**AGENDA**

**Wednesday, May 16, continued**  
**Session 2 – continued**

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|-------------|--|------------------------|
| 1 PM        | Introduction to Adventitious Agent Issues  | Dr. Philip Krause, FDA |
| 1:10        | Transmissible Spongiform Encephalopathy Agents<br>as an Issue in the Use of Neoplastic Cell Substrates                           | Dr. Sue Priola, NIH    |
| 1:30        | Adventitious Agent Testing of Neoplastic Cell Substrates   | Dr. Philip Krause, FDA |
| 2:00        | Review of OVRP-CBER Issues with the Use of<br>Adenovirus-vectored Vaccines and their Complementing<br>“Designer Cell Substrates“ | Dr. Hana Golding, FDA  |
| <b>2:15</b> | <b>Open Public Hearing</b>   |                        |
| <b>3:15</b> | <b>Break</b>   |                        |
| 3:30        | Committee Discussion   |                        |
| <b>6:00</b> | <b>Adjourn for the Day</b>   |                        |

**Thursday, May 17**

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|--------------|--|
| <b>8 AM</b>  | <b><u>Session 3 – CLOSED SESSION</u></b>     |
| <b>12:30</b> | <b>End of Closed Session and Adjournment</b> |