# FOOD AND DRUG ADMINISTRATION

Center for Biologics Evaluation and Research

*130th Meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC)*

FDA White Oak Campus, Bldg. 31, Great Room

Silver Spring, Maryland

September 19, 2012

# DRAFT AGENDA

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|---|---|---|
| 8:00 a.m. | Call to Order and Opening Remarks<br>Introduction of Committee | Robert Daum, M.D.<br>Chair, VRBPAC |
| | Conflict of Interest Statement | Donald W. Jehn, M.S.<br>Designated Federal Officer, VRBPAC |

**Topic: Consideration of the Appropriateness of Cell Lines Derived from Human Tumors for Vaccine Manufacture**

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| 8:15 | Introduction and History of Vaccine Cell Substrates | Phil Krause, M.D.<br>Acting Deputy Director<br>OVRR/CBER |
| 9:00 | A549: A Novel Cell Substrate Enabling Production of New Vaccine Candidates | Tim Mayall, Ph.D.<br>Senior Director of R&D<br>PaxVax, Inc. |
| 9:20 | History and Characterization of the A3.01 Cell Line and its Tumorigenic Evaluation | Seung Ho Choo<br>Director, Process Development & GMP Manufacturing<br>Sumagen Co., Ltd |
| 9:40 | Are HeLa Cells an Acceptable Vaccine Substrate? | Rebecca Sheets, Ph.D.<br>CAPT, USPHS<br>NIH/NIAID |
| 10:00 | Break | |
| 10:15 | Issues Associated with Tumorigenic Cells or Cells Derived from Human Tumors | Keith Peden, Ph.D.<br>Chief, LDNAV<br>DVP/OVRR/CBER |
| 11:00 | Adventitious Agents and Human Tumors | Patrick Moore, M.D., Ph.D.<br>Director<br>Cancer Virology Program<br>University of Pittsburgh Cancer Insititute |

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| 11:45 a.m. | Regulatory Approaches for the Characterization of Cell Substrates | Arifa Khan, Ph.D.<br>Senior Investigator<br>DVP/OVRR/CBER |
| 12:30 p.m. | Lunch | |
| 1:30 | Open Public Hearing | |
| 2:30 | Committee Discussion and Recommendations | |
| 4:00 | Adjourn Meeting | |