

Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY
COMMITTEE

Meeting # 99: May 6, 2004
Teleconference

Committee Members

Dr. Gary Overturf, Chair
Dr. Walter Royal III
Dr. Peter Palese
Dr. Ruth A. Karron
Dr. David Markovitz
Dr. Monica M. Farley
Dr. Bonnie M. Word
Dr. Richard Whitley
Dr. Philip S. LaRussa
Dr. Steven Self
Dr. Michael Decker**+
Cindy Province, R.N., M.S.N.*

FDA Participants

Dr. Kathryn Carbone
Dr. William Egan
Dr. Norman Baylor
Dr. Andrew Lewis

Executive Secretary

Christine Walsh, R.N.

Committee Management Specialist

Denise Royster

These summary minutes for the May 6, 2004 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on

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I certify that I participated in the May 6, 2004 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

Christine Walsh, R.N.
Executive Secretary

Gary D. Overturf, M.D.
Chair

*Consumer Representative
+Present for Open Session Only

**Industry Representative

The Chair, Dr. Gary D. Overturf, called the ninety-ninth Meeting of the Vaccines and Related Biological Products Advisory Committee to order at 1:40 p.m. EST on May 6, 2004. The meeting addressed the site visit of the intramural research program of the Laboratory of DNA Viruses, Division of Viral Products, Office of Vaccines Research and Review (OVRR), Center for Biologics and Research (CBER), completed on March 4, 2004.

The meeting was held by telephone conference call. The public was welcome to attend the open session of the meeting at the Food and Drug Administration, Bldg. 29B, Conference Room C, Bethesda, MD. A speakerphone was provided at the specified location for public participation.

An Open Public Hearing was announced. No public comment was offered.

Following is a summary of the discussion. Additional information and specific details may be obtained from the transcript of the meeting. The transcript may be viewed on the World Wide Web at:

<http://www.fda.gov/ohrms/dockets/ac/cber04.htm#VaccinesandRelatedBiological>

Proceedings were adjourned at approximately 2:50 p.m. EST on May 6, 2004.

Open Session

The telephone conference meeting focused on the intramural research program of the Laboratory of DNA Viruses, Division of Viral Products, Office of Vaccines Research and Review (OVRR). The Committee heard a presentation from Dr. Andrew Lewis, FDA to include an overview of the Unit on Cell Substrate and Adventitious Agents, Unit of Viral Latency, Unit of Viral Gene Expression, and Unit on Poxvirus Biology.

Closed Session

After discussion, the Committee members voted unanimously to accept the Laboratory of DNA Viruses Site Visit Report as written.