

Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

Meeting # 108: November 16, 2006
Teleconference Meeting

Committee Members

Dr. Ruth Karron, Chair
Dr. Walter Royal III
Dr. Philip LaRussa
Dr. Bonnie Word
Dr. John Modlin
Dr. Lisa Jackson
Dr. Jack Stapleton
Ms. Cindy Lyn Province, R.N., M.S.N.*
Dr. Seth Hetherington**

FDA Participants

Dr. Kathryn Carbone
Dr. Norman Baylor
Dr. Jerry Weir
Dr. Richard Walker
Dr. Willie Vann
Dr. Lewis Markoff
Dr. Stephen Feinstone
Dr. Michael Brennan

Absent:

Dr. Monica Farley
Dr. Steven Self

Executive Secretary

Christine Walsh, R.N.

Committee Management Specialist

Denise Royster

These summary minutes for the November 16, 2006 Meeting of the Vaccines and Related Biological products Advisory Committee were approved on _____.

I certify that I participated in the November 16, 2006 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

Christine Walsh, R.N.
Executive Secretary

Ruth Karron, M.D.
Chair

*Consumer Representative

**Industry Representative

The Chair, Dr. Ruth Karron, called the one hundred and eighth Meeting of the Vaccines and Related Biological Products Advisory Committee to order at 1:07 p.m. ET on November 16, 2006. The meeting addressed the December 6, 2005 site visit of the intramural research programs of the Laboratory of Bacterial Toxins, Division of Bacterial, Parasitic, & Allergenic Products; and the January 11, 2006 site visit of the Laboratory of Vector-Borne Virus Diseases/Laboratory of Hepatitis Viruses and the June 29, 2006 Laboratory of Respiratory Viral Diseases, Division Viral Products, Office of Vaccines Research and Review (OVR), Center for Biologics and Research (CBER).

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, Building 29B, Conference Room C, Bethesda, MD. A speakerphone was provided at the specified location for public participation.

An Open Public Hearing was announced. Public comment was offered via an electronic message from B. Sachau. Copies of the comment were provided to committee members, displayed in the public notebook at the meeting, and posted on the FDA website. No other 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/cber06.html#VaccinesandRelatedBiological>.

Proceedings were adjourned at approximately 3:21 p.m. ET on November 16, 2006.

Open Session

The telephone conference meeting focused on the intramural research programs of the Laboratory of Bacterial Toxins, Division of Bacterial, Parasitic & Allergenic Products; and the Laboratory of Vector-Borne Virus Diseases/Laboratory of Hepatitis Viruses and the Laboratory of Respiratory Viral Diseases, Division of Viral Products, Office of Vaccines Research and Review (OVR). The committee heard presentations, to include overviews of each research Laboratory, from Dr. Willie Vann, Laboratory of Bacterial Toxins; Dr. Lewis Markoff, Laboratory of Vector-Borne Virus Diseases; Dr. Stephen Feinstone, Laboratory of Hepatitis Viruses; and Dr. Jerry Weir, Director, Division of Viral Products on behalf of the Laboratory of Respiratory Viral Diseases.

Closed Session

The committee discussed the site visit reports from the December 6, 2005, Laboratory of Bacterial Toxins, the January 11, 2006 Laboratory of Vector-Borne Virus Diseases/Laboratory of Hepatitis Viruses and the June 29, 2006 Laboratory of

Respiratory Viral Diseases site visits. The committee approved the site visit reports as written.