

Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

Meeting # 103: September 22, 2005
Teleconference Meeting

Committee Members

Dr. Gary D. Overturf, Chair
Dr. Walter Royal III
Dr. Ruth A. Karron
Dr. David Markovitz
Dr. Monica M. Farley
Dr. Philip S. LaRussa
Dr. Steven Self
Ms. Cindy Lyn Province, R.N., M.S.N.*

FDA Participants

Dr. Hana Golding
Dr. Bruce D. Meade
Dr. Drusilla L. Burns
Dr. Ira Berkower
Dr. Kathryn Carbone
Dr. Norman Baylor
Dr. Jerry Weir
Dr. Richard Walker
Dr. Philip Krause
Dr. Michael Brennan

Absent:

Dr. Bonnie M. Word

Executive Secretary

Christine Walsh, R.N.

Committee Management Specialist

Denise Royster

These summary minutes for the September 22, 2005 Meeting of the Vaccines and Related Biological products Advisory Committee were approved on _____.

I certify that I participated in the September 22, 2005 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

The Chair, Dr. Gary D. Overturf, called the one hundred and third Meeting of the Vaccines and Related Biological Products Advisory Committee to order at 1:35 p.m. ET on September 22, 2005. The meeting addressed the April 18 – 19, 2005 site visit of the intramural research programs of the Laboratory of Retroviruses and the Laboratory of Immunoregulation, Division of Viral Products, and the June 16, 2005 site visit of the Laboratory of Respiratory & Special Pathogens and the Laboratory of Methods Development & Quality Control, Division of Bacterial Parasitic & Allergenic 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/cber05.html#VaccinesandRelatedBiological>.

Proceedings were adjourned at approximately 4:00 p.m. ET on September 22, 2005.

Open Session

The telephone conference meeting focused on the intramural research programs of the Laboratory of Retroviruses and the Laboratory of Immunoregulation, Division of Viral Products, and the Laboratory of Respiratory & Special Pathogens and the Laboratory of Methods Development & Quality Control, Division of Bacterial Parasitic & Allergenic Products, Office of Vaccines Research and Review (OVR). The committee heard presentations, to include overviews of each research laboratory, from Dr. Hana Golding, Laboratory of Retroviruses; Dr. Ira Berkower, Laboratory of Immunoregulation; Dr. Drusilla L. Burns, Laboratory of Respiratory & Special Pathogens; and Dr. Bruce D. Meade, Laboratory of Methods Development & Quality Control.

Closed Session

The committee discussed the site visit reports from the April 18 -19, 2005 Laboratory of Retroviruses and Laboratory of Immunoregulation and the June 16, 2005 Laboratory of Respiratory and Special Pathogens and Laboratory of Methods Development & Quality Control site visits.

