Food and Drug Administration
Center for Biologics Evaluation and Research
SUMMARY MINUTES
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE
Meeting # 106: February 17, 2006
NIH campus, Building 29B, Conference Room A&B, and C

Committee Members
Dr. Ruth A. Karron, Acting Chair
Dr. Walter Royal III
Dr. Philip S. LaRussa
Ms. Cindy Lyn Province, R.N., M.S.N.*
Dr. Monica M. Farley
Dr. Steven Self
Dr. Bonnie M. Word
Dr. John Modlin
Dr. Seth Hetherington**

FDA Participants
Dr. Jerry Weir
Dr. Zhiping Ye
Dr. Norman Baylor
Dr. Karen Midthun

Consultants
Dr. Bruce Gellin
Dr. Pamela McInnes
Dr. Melinda Wharton
Dr. Robert Couch
Dr. Nancy Cox
Dr. Theodore Eickhoff
LTC Wayne Hachey

Guest Speakers
Albert Thomas, Sanofi Pasteur

Executive Secretary
Christine Walsh, R.N.

Committee Management Specialist
Denise Royster

These summary minutes for the February 17, 2006 Teleconference Meeting of the Vaccines and Related Biological products Advisory Committee were approved on 3/9/06.

I certify that I participated in the February 17, 2006 Teleconference 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 A. Karron, M.D.
Acting Chair

*Consumer Representative
**Industry Representative

The Vaccines and Related Biological Products Advisory Committee (VRBPAC) met via teleconference on February 17, 2006 on the NIH campus, Building 29B, Conference Room A&B, and C, Bethesda, MD. In open session the committee discussed and made recommendations on the strain selections to be included in the influenza virus vaccine for the 2006 – 2007 season.

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.

Open Session

The Vaccines and Related Biological Products Advisory Committee meeting was called to order via teleconference by the Acting Chair, Dr. Ruth A. Karron at 1:00 p.m. The meeting presentations began with Dr. Jerry Weir, FDA, who presented an introduction to the committee on the agenda topic; strain selections to be included for the 2006 – 2007 flu season. Dr. Weir's presentation also included committee discussion questions for consideration. Following Dr. Weir, Dr. Nancy Cox, CDC, presented to the committee. In her presentation, Dr. Cox included U.S. and world surveillance data related to epidemiology and antigenic characteristics. Dr. Zhiping Ye, FDA presented following Dr. Cox and included serological responses to 2005/2006 vaccines and availability of candidate strains and reagents. Concluding the presentations was Mr. Albert Thomas, Sanofi Pasteur, who discussed vaccine manufacturing critical factors, timelines, and current manufacturing status of the vaccine strain.

An Open Public Hearing was announced. A written comment had been received from B. Sachau which was made part of the official record. No other public comment was offered.

After being presented an overview of options for strain selection of the components for next season's influenza vaccine, the committee held discussion and made the following recommendations for the influenza virus strains to be included in the vaccine for use during the 2006 – 2007 season in the United States. Based on information regarding the appearance and epidemiology of new influenza virus strains, response to current vaccines, and the availability of new candidate strains for manufacturing, the committee recommended:

- The Committee recommended (13 votes in favor, 0 against, 0 abstained, 1 member not present for vote) retaining the current A/New Caledonia/20/99 (H1N1)-like virus. Industry opinion agreed with committee vote.
- The Committee recommended (13 votes in favor, 0 against, 0 abstained, 1 member not present for vote) replacing the current strain with an

A/Wisconsin/67/2005 (H3N2)-like virus (A/Wisconsin/67/2005 and A/Hiroshima/52/2005 strains). Industry opinion agreed with committee vote.

- The Committee recommended (13 votes in favor, 0 against, 0 abstained, 1 member not present for vote) replacing the current strain with a B/Malaysia/2506/2004-like virus (B/Malaysia/2506/2004 and B/Ohio/01/2005 strains). Industry opinion agreed with committee vote.

After recommendations were made, Dr. Nancy Cox presented a short update on the Influenza A(H5N1) Viruses to the committee.

A recommendation was also made by the panel for the FDA to convene a workshop to discuss the possibility of having the annual influenza vaccine comprised of two B strains rather than the current one.

This concluded the committee discussions and recommendations. The meeting was adjourned by the Acting Chair at 4:30 p.m.