Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

Meeting # 97: February 18 – 19, 2004

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

Consultants
Dr. Nancy Cox
Dr. Walter Dowdle
Dr. Theodore Eickhoff
Dr. Bruce Gellin
Judith D. Goldberg, ScD.
Dr. Arnold S. Monto
Dr. Martin Meyers
Dr. Stephen C. Phillips++
Dr. Pamela McInnes

FDA Participants
Dr. Karen Midthun
Dr. Roland Levandowski
Dr. Zhiping Ye

Guest Speakers
Dr. Carolyn Bridges
Ann Moen
Col. James Neville
Linda Canas
Dr. Greg Slusaw
Dr. Maria Zambon
Dr. Linda Lambert
Dr. Phil Minor
Dr. Antoine Flahault

Committee Management Specialist
Denise Royster

Acting Executive Secretary
William Freas, PhD

These summary minutes for the February 18 – 19, 2004 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on _____.

I certify that I participated in the February 18 – 19, 2004 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

_____
William Freas, PhD
Acting Executive Secretary

_____
Gary D. Overturf, M.D.
Chair

*Consumer Representative
**Industry Representative
+Not Attending
++Not present February 18, 2004

The Vaccines and Related Biological Products Advisory Committee (VRBPAC) met on February 18 – 19, 2004 at the Sheraton Four Points Hotel, 8400 Wisconsin Avenue, Bethesda, MD. In open discussion, the committee reviewed and discussed the selection of strains to be included in the influenza virus vaccine for the 2004-2005 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/cber04.htm#VaccinesandRelatedBiological

Open Session

The Vaccine and Related Biological Products Advisory Committee meeting was called to order by the Chair, Dr. Gary Overturf, on February 18, 2004 at 8:30 a.m. EST. Dr. Roland Levandowski, FDA discussed last years selection of the components of the influenza vaccine and the constraints, importance and deadlines for the selection of this year's vaccine components. Subsequent presentations included vaccine effectiveness, U.S. and world surveillance of influenza activity, strain characterization, vaccine responses, availability of strains, comments from manufacturers, and an update on influenza A(H5N1) activity in Asia. An Open Public Hearing was announced. No public comment was offered. The Chair adjourned Day 1 of the meeting at 6:10 p.m. EST.

The Chair called Day 2 of the meeting to order at 8:30 a.m. EST. An Open Public Hearing was announced. No public comment was offered. The panel heard an overview of their options for strain selection of the components of next season's influenza vaccine. **After discussion, the committee made the following recommendations for the influenza virus strains to be included in vaccine for use during the 2004-2005 season in the United States**. Based on information about the appearance and epidemiology of new influenza virus strains, responses to current vaccines, and the availability of new candidate strains for manufacturing, the committee recommended:

- **The Committee unanimously recommended (17 votes in favor, 0 against, and 0 abstained) retaining the 2003-2004 influenza A H1N1 component, New Caledonia 20/99 for the 2004-2005 season.**
- **The Committee unanimously recommended (17 votes in favor, 0 against, and 0 abstained) changing the influenza A H3N2 component of the influenza vaccine to the A/Fujian-like strain for the 2004-2005 season.**
- **The Committee recommended (16 votes in favor of a change or provisional change, 1 vote to defer, and 0 abstained) a change of the 2003-2004 influenza B component to a Yamagata lineage, B/Shanghai – like strain for the 2004-2005 season with a provision to meet via teleconference on March 17, 2004 review any further data gathered in the interim period, and make their decision final at that time if no new information would contradict the recommendation.**

The panel heard presentations from both the FDA and National Institute for Biological Standards and Control (NIBSC) UK and had discussions on the use of mammalian cell lines for the use in preparation of reference influenza viruses.

This completed the committee discussion and recommendations and the meeting was adjourned at 12:20 p.m. EST