Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

Meeting # 94: February 20, 2003

Committee Members
Dr. David Stephens, Chair
+Dr. Michael Decker
Dr. Pamela Diaz
Dr. Judith Goldberg
Dr. Sam Katz
Dr. David Markovitz
Dr. Gary Overturf
Dr. Peter Palese
Dr. Julie Parsonnet
Dr. Ruth Karron
Dr. Walter Royal, III

Members Not Present
Dr. Rich Whitley
Dr. Audrey Manley

FDA Presenters
Dr. Roland Levandowski
Dr. Zhiping Ye

DOD Presenter
Ms. Linda Canas

CDC Presenters
Dr. Nancy Cox

FDA Participants
Dr. Karen Midthun
Dr. Norman Baylor
Dr. Kathryn Carbone

Consultants
Dr. Robert Couch
Dr. Nancy Cox
Col. Benedict Diniega
Dr. Walter Dowdle
*Ms. Barbara Loe Fisher
Dr. Bruce Gellin
Dr. Pamela McInnes
Dr. Martin Myers

Executive Secretary
Dr. Jody Sachs

These summary minutes for the February 20, 2003 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on _____.

I certify that I participated in the February 20, 2003 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

_____
Jody Sachs, D.P.M.
Executive Secretary

_____
David Stephens, M.D.
Chair

* Consumer Representative
+ Non-Voting Industry Representative

The Chair, Dr. David Stephens, called the 94th Meeting of the Vaccines and Related Biological Products Advisory Committee to order at 8:30 a.m. EST on February 20, 2003. The meeting addressed the review and discussed the selection of strains to be included in the influenza virus vaccine for the 2003-2004 Season and the intramural research program of the Laboratory of Bacterial Polysaccharides (LBP), Office of Vaccines Research and Review (OVRR).

The Meeting was held at the Holiday Inn, 8120 Wisconsin Ave., Bethesda, Maryland 20814.

An Open Public Hearing session 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/cber02.htm#Vaccines%20and%20Related%20Biological.
A copy of the agenda is attached.

Proceedings were adjourned at approximately 3:40 p.m. EST on February 20, 2003.

Open Session
Strain Selection for Influenza Virus Vaccine for the 2003-2004 Season

The panel heard presentations on strains of circulating influenza virus. After discussion, the committee made the following recommendations for the influenza virus strains to be included in vaccine for use during the 2003-2004 Season in the United States.

Based on information about the appearance and epidemiology of new influenza virus variants, responses to current vaccines and the availability of strains and reagents needed for manufacturing, the committee recommended a trivalent formulation.

- The committee recommended that for the influenza A H1N1 component, A/New Caledonia/20/99, should be retained.

- Based on current information, the committee decided to defer the influenza A H3N2 component, in order to review new information obtained in the next few weeks suggesting that another strain might be a better match with naturally circulating viruses.

- The committee recommended retaining the current B/Hong Kong/330/01-like virus strains (B/Hong Kong/330/01 and B/Hong Kong/1434/2002.)

?? The committee strongly recommended that data be obtained from a pediatric population to study pediatric immunogenicity and efficacy of the influenza vaccine, as this group is relatively unprimed and may display a distinct pattern of susceptibility to the circulating strains compared to the adult population.

?? The 2003-2004 vaccine recommendation from the committee would be to continue with a trivalent vaccine consisting of:
   1) H1N1, A/New Caledonia/20/99,
   2) B/Hong Kong/330/2001-like virus strain,
   3) postponing the H3N2 component selection until further information can be collected and reviewed.

Session 2 – OPEN Session
Laboratory of Bacterial Polysaccharides

An overview of the Division of Bacterial, Parasitic, & Allergenic Products was presented by Dr. Richard Walker, FDA, CBER, DBPAP, OVRR, followed by a presentation of laboratory research activities and accomplishments by the Laboratory of Bacterial Polysaccharides (LBP), by Dr. Carl Frasch, Laboratory Chief.

Session 2 – CLOSED Session

After discussion, the members voted unanimously to accept the Site Visit Report as written.