Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

Meeting # 89: January 30, 2002
Holiday Inn, Bethesda
Bethesda, Maryland

Committee Members
Dr. Robert Daum, Chair
Dr. Michael Decker+
Dr. Pamela Diaz
Dr. Walter Faggett
Ms. Barbara Loe Fisher*
Dr. Judith Goldberg
Dr. Diane Griffin
Dr. Sam Katz
Dr. Kwang Sik Kim
Dr. Steve Kohl
Dr. Audrey Manley
Dr. Peter Palese
Dr. Dixie Snider
Dr. David Stephens
Dr. Rich Whitley

Committee Members Absent
Dr. Julie Parsonnet

Temporary Voting Members
Dr. Robert Couch
Dr. Walter Dowdle
Dr. Theodore Eickhoff
Dr. Martin Myers
Dr. Gregory Poland

Guests/Guest Speakers
Ms. Linda Canas
Dr. Nancy Cox
Col. Benedict Diniega
Dr. Keiji Fukuda
Dr. Gregory Slusaw

FDA Participants
Dr. Roland Levandowski
Dr. Zhiping Ye

Acting Executive Secretary
Dr. William Freas

These summary minutes for the January 30, 2002 meeting of the Vaccines and Related Biological Products Advisory Committee were approved on _____ .

I certify that I attended the January 30, 2002 meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

_____
William Freas, Ph.D.
Executive Secretary

_____
Robert S. Daum, M.D.
Chair

*Consumer Representative
+Non-Voting Industry Representative

The 89th meeting of the Vaccines and Related Biological Products Advisory Committee was called to order at 9:00 a.m. on January 30, 2002 by the Chair, Dr. Robert Daum. The meeting addressed a single topic: selection of strains to be included in next year's 2002-2003 influenza virus vaccine. The entire meeting was held in open session.

CBER Director Dr. Kathryn Zoon presented plaques and certificates of appreciation to Drs. Kwang Sik Kim, Steve Kohl, and Dixie Snider whose terms on the committee were ending. Dr. Robert Daum will remain on the committee as Chair for an additional year.

Two Open Public Hearing sessions were announced. No public comment was offered at either session.

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/02acsdocs.htm. A copy of the agenda is attached.

Proceedings were adjourned at approximately 4:00 p.m. on January 30, 2002.

Session #1 – Open Session
Strain Selection for Influenza Virus Vaccine for the 2002-2003 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 2002-2003 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 also recommended that the influenza A H3N2 component, A/Panama/2007/99 (an A/Moscow/10/99-like strain), should be retained unless new information obtained in the next few weeks suggests that another strain might be a better match with naturally circulating viruses.

- The committee also recommended deferring the decision regarding the influenza B virus component. It is very early in the influenza season epidemic and in the data

collection to determine if the influenza B component should be changed from the current strain. The committee felt that it was too early to identify a B virus suitable to support large-scale manufacturing. The committee discussed retaining the current B/Sichuan/379/99-like virus; and adding to, in addition, the B/Victoria/504/2000-like virus strain as a possible candidate if it has the needed characteristics for large-scale production

?? The committee strongly recommended that strain surveillance data be obtained from a pediatric population to study pediatric immunigenicity 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.