Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

Meeting # 95: March 18, 2003

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

FDA Participants
Dr. Karen Midthun
Dr. William Egan
Dr. Norman Baylor

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

FDA Presenters
Dr. Roland Levandowski

Executive Secretary
Dr. Jody Sachs

CDC Presenters
Dr. Nancy Cox

These summary minutes for the March 18, 2003 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on _____.

I certify that I participated in the March 18, 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 95th Meeting of the Vaccines and Related Biological Products Advisory Committee to order at 10:30 a.m. EST on March 18, 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.

The Meeting was held at Food and Drug Administration, 5515 Security Lane, Conference Room A on the 11th Floor, Suite 1113, Rockville, Maryland 20814 by teleconference.

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/cber03.html#VaccinesandRelatedBiological
A copy of the agenda is attached.

Proceedings were adjourned at approximately 12:00 p.m. EST on March 18, 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 new strains and reagents needed for manufacturing, the committee recommended retaining a trivalent formulation.

?? The committee recommended that the influenza A H3N2 component, A/Panama/2007/99 (an A/Moscow/10/99-like strain), should be retained in view of the fact that it has not yet been possible to isolate for manufacturing purposes a suitable virus representative of a group of antigenically divergent influenza A H3N2 viruses that have been increasing in prevalence during 2003. However, committee members expressed concern that vaccines may provide less effective protection if the emerging group of viruses continues to spread.

?? The committee strongly urged that alternative methods of recovering influenza viruses be considered in manufacturing and that new strains continue to be investigated for changing the influenza strain components next year.

The Committee recommended in February:

- Retaining the influenza A H1N1 component, A/New Caledonia/20/99,
- Retaining the current B/Hong Kong/330/2001-like virus strain.

In Summary:

- 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) H3N2, A/Panama/2007/99 (an A/Moscow/10/99-like virus),
    3) B/Hong Kong/330/2001-like virus strain.