

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 (represented by 17 votes in favor of retaining the 2002-2003 H3N2 strain; 2 abstained; one vote to change the H3N2 strain) recommended that the influenza A H3N2 component, A/Panama/2007/99 (an A/Moscow/10/99-like strain) should be retained for the 2003-2004 season. Considerable concern was voiced by the committee regarding the emergence of H3N2 variants that were antigenically and immunologically distinct from A/Moscow/10/99 – like strains. However, it has not yet been possible to isolate, for manufacturing purposes, a suitable virus representative of this group of antigenically divergent influenza A H3N2 viruses that have been increasing in prevalence during 2003. Although committee members were concerned that retaining the current vaccine formulation may provide less effective protection if the emerging group of viruses continues to spread, further delay in making a recommendation or awaiting the uncertain

availability of a new variant strain suitable for manufacturing would delay influenza vaccine availability for 2003-2004.

- ?? 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 in the future. The committee also requested that it be informed of progress made in the recovery of an antigenically divergent H3N2 isolate that is suitable for vaccine production, and of the surveillance of the antigenically divergent H3N2 variants.

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.