Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

Meeting # 100: September 22 - 23, 2004

Committee Members
Dr. Gary Overturf, Chair
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. Peter Palese+
Dr. Steven Self++
Dr. Bonnie M. Word
Dr. Richard Whitley

Consultants
Dr. Peter Densen
Dr. Bruce Gellin
Dr. Pamela McInnes
Dr. David Stephens
Dr. Stephen Petteway**

FDA Participants
Dr. Carl Frasch
Dr. Lucia Lee
Dr. Joseph Toerner

Guest Speakers
Dr. Luc Kuykens, Aventis Pasteur Inc.
Dr. Greg Gilmet, Aventis Pasteur, Inc.
Dr. Michael Decker, Aventis Pasteur, Inc.
Dr. Gary Chikami, Aventis Pasteur, Inc.
LTC Arthur Brown, Office of Surgeon General, US Army
Dr. Prasert Thongcharoen, Thai National AIDS Commission
Dr. Supachai Rerks-Ngarm, Ministry of Public Health, Thailand

Executive Secretary
Christine Walsh, R.N.

Committee Management Specialist
Denise Royster

These summary minutes for the September 22 - 23, 2004 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on _____.

I certify that I participated in the September 22 - 23, 2004 Meeting of the Vaccines and Related Biological Products Advisory Committee and that these minutes accurately reflect what transpired.

_____
Christine Walsh, R.N.
Executive Secretary

_____
Gary D. Overturf, M.D.
Chair

*Consumer Representative
**Acting Industry Representative
+Not Attending
++Not attending September 23, 2004

The Vaccines and Related Biological Products Advisory Committee (VRBPAC) met on September 22 - 23, 2004 at the Holiday Inn Select, 8120 Wisconsin Avenue, Bethesda, MD. In open discussion on September 22, the committee reviewed and made recommendations on the safety and efficacy of a tetravalent meningococcal conjugate vaccine, Menactra, manufactured by Aventis Pasteur, Inc. and on September 23, heard an update on the phase 3 Thai Trial for the prevention of HIV-1 infection. A closed session was held on September 23, 2004.

Following is a summary of the open 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 Vaccines and Related Biological Products Advisory Committee meeting was called to order by the Chair, Dr. Gary Overturf, on September 22, 2004 at 10:00 a.m. EST. Dr. Carl Frasch, FDA, presented an introduction to the License Application for the tetravalent meningococcal conjugate vaccine, Menactra, manufactured by Aventis Pasteur, Inc. Dr. Frasch's presentation included a description of the product, requested indication, and regulatory history. The proposed indication was for the active immunization of adolescents and adults, 11-55 years old, for prevention of invasive disease caused by *Neisseria meningitidis* serogroups A, C, Y and W135. The approach to licensure was based on the demonstration of non-inferiority to Menomune, a US licensed meningococcal polysaccharide vaccine, by immunologic and safety criteria, and demonstration of lot consistency. Serum bactericidal antibody was used for immunologic comparisons. Following Dr. Frasch, the product manufacturer, Aventis Pasteur Inc. made presentations to the committee on clinical data in support of Menactra. Several committee members made comment and asked questions to the manufacturing representatives pertaining to product clinical data. Dr. Lucia Lee, FDA, then made presentation to the committee on the clinical review of safety and efficacy of Menactra. Questions of clarification made by committee members were directed to Dr. Lee following her presentation.

An Open Public Hearing was announced. Public comment was offered by Dr. Paul G. King on behalf of the Coalition for Mercury Free Drugs (CoMeD) and by Mike Kepferle from the National Meningitis Association. Dr. Carl Frasch then presented two questions and two discussion points to the committee.

After review of the data regarding the safety and efficacy of Menactra, manufactured by Aventis Pasteur Inc., the committee recommended:

The committee voted unanimously (13 votes in favor, 0 against, and 0 abstained) on the question "Are the available data adequate to support the efficacy of Menactra, i.e., non-inferiority of the antibody response to Menactra compared to the licensed polysaccharide, Menomune, when administered to individuals 11 – 55 years of age."
The committee voted unanimously (13 votes in favor, 0 against, 0 abstained) on the question "Are the available data adequate to support the safety of Menactra when administered to individuals 11 – 55 years of age."

The committee was also requested to comment on two discussion points presented. Committee members commented on the importance of collecting additional safety data post-licensure and a need for continued evaluation of antibody persistence. Committee members also recommended the evaluation of safety and immunogenicity when Menactra is administered concurrently with other licensed vaccines given to adolescents and travelers in post-marketing studies.

The Chair adjourned Day 1 of the meeting at 3:00 p.m. EST.

The Chair called Day 2 of the meeting to order at 9:00 a.m. EST. In open session, Dr. Joseph Toerner, FDA, presented opening remarks to the committee on the phase 3 Thai Trial of ALVAC vCP 1521 [Aventis Pasteur, Inc.] with AIDSVAX B/E [VaxGen, Inc.] for the prevention of HIV-1 infection. His remarks included a brief update about the study and an overview of some of the US FDA regulatory challenges encountered FDA's review. The sponsor, Office of the Surgeon General, US Army, along with representatives from Thailand presented an overview of the study and rationale for proceeding to Phase III. Several committee members had questions and made comment to the sponsors.

An Open Public Hearing was announced. Public comment was offered by Mr. Richard Jeffreys representing the Treatment Action Group

The Chair adjourned the Open Session at 10:20 A.M. EST.

Closed Session

The Chair called the closed session to order at 10:45 A.M. EST. After discussion, comment, and questions, the meeting was adjourned at 12:00 noon.