

Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

Meeting # 102: March 15, 2005

Committee Members

Dr. Gary Overturf, Chair
Dr. Ruth A. Karron
Dr. David Markovitz
Ms. Cindy Lyn Province, R.N., M.S.N.*
Dr. Walter Royal III
Dr. Monica M. Farley
Dr. Philip S. LaRussa
Dr. Steven Self
Dr. Bonnie M. Word

Consultants

Dr. Bruce Gellin
Dr. Pamela McInnes
Dr. Trudy Murphy (non-voting)
Dr. Melinda Wharton
Dr. David Stephens

Executive Secretary

Christine Walsh, R.N.

FDA Participants

Dr. Theresa Finn
Dr. Ann Schwartz
Ms. Martha Monser
Dr. ChrisAnna Mink

Sponsor Presenters

Dr. Vincent Ahonkhai, GSK
Dr. Barbara Howe, GSK
Dr. Leonard Friedland, GSK
Dr. Luc Kuykens, A..P.
Dr. Michael Decker, A.P.
Dr. David Johnson, A.P.

Acting Industry Representative

Dr. Seth Hetherington

Committee Management Specialist

Denise Royster

These summary minutes for the March 15, 2005 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on _____.

I certify that I participated in the March 15, 2005 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

The Vaccines and Related Biological Products Advisory Committee (VRBPAC) met on March 15, 2005 at the Holiday Inn Select, 8120 Wisconsin Avenue, Bethesda, MD. In open discussion during the morning session, the committee heard presentations and held discussions on the safety and immunogenicity for a Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed (Tdap) manufactured by GlaxoSmithKline Biologicals. In open discussion during the afternoon session, the committee heard presentations and held discussions on the safety and immunogenicity for a Tdap vaccine manufactured by Aventis Pasteur Ltd.

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/05acdocs.htm>.

Open Session

The Vaccines and Related Biological Products Advisory Committee meeting was called to order by the Chair, Dr. Gary Overturf, on March 15, 2005 at 8:34 a.m. EST. In the morning session, Dr. Theresa Finn, FDA, provided an introduction to the day's sessions, including a summary of a VRBPAC meeting held June 1997, during which members discussed licensure of acellular pertussis vaccines for use in older individuals based on serologic criteria. A presentation was then made by GlaxoSmithKline representatives regarding the manufacturer's proposed product, Boostrix™. Dr. Ann Schwartz, FDA, then presented CBER's review of the immunogenicity and safety data contained in GlaxoSmithKline's license application for Boostrix™.

Prior to vote, the Committee recommended unanimously (12 votes in favor, 0 against, 0 abstained, 1 member not present at vote) of modifying question 1, "Are the available data adequate to support the efficacy of Boostrix™ in individuals 10 – 18 years of age" to reflect the following "Are the available data adequate to support the effectiveness of Boostrix™ in individuals 10 –18 years of age". The Committee recommended the same change for question 1 of the afternoon session.

Based on information presented to the committee regarding the availability of data adequate to support the effectiveness of Boostrix™ in individuals 10 –18 years of age, the Committee recommended:

- The Committee unanimously recommended (12 votes in favor, 0 against, 0 abstained, 1 member not present for the vote) that the available data were adequate to support the effectiveness of Boostrix™ in individuals 10 – 18 years of age.

Based on information presented to the Committee regarding the availability of data to support the safety of Boostrix™ when administered to individuals 10 –18 years of age, the Committee recommended:

The Committee unanimously recommended (12 votes in favor, 0 against, 0 abstained, 1 member not present for the vote) that the available data were adequate to support the safety of Boostrix™ when administered to individuals 10 – 18 years of age.

The Committee had questions and discussed points of clarification after each slide presentation and held further discussion during the question and vote portion of the meeting. Discussion points included the possibility of herd immunity, the incidence of disease in adult populations including pregnant women and the elderly, and whether GSK was considering seeking an indication for older subjects. Committee members suggested that antibody persistence studies may provide insight into intervals for revaccination. A concomitant vaccination study particularly with the meningococcal conjugate vaccine was advocated. A study to evaluate the use of Tdap vaccines in adolescents primed with all acellular vaccines in childhood was discussed. Members asked manufacturers to consider development of stand-alone acellular pertussis vaccines. The importance of epidemiologic studies to determine impact of vaccination on disease prevalence was also emphasized.

An Open Public Hearing was announced . Public comment was offered via an electronic mail message from B. Sachau. No other comment was offered. This completed the morning session.

Ms. Martha Monser, FDA opened the afternoon session. Ms. Monser provided an introduction to ADACEL™, manufactured by Aventis Pasteur Limited. Ms. Monser was followed by a presentation from Aventis Pasteur Limited representatives regarding their product, ADACEL™. Dr. ChrisAnna Mink, FDA, then provided an overview of the safety and immunogenicity results contained in the license application for ADACEL™.

Based on information presented to the committee regarding the availability of data adequate to support the effectiveness of ADACEL™ in individuals 10 –18 years of age, the Committee recommended:

- The Committee unanimously recommended (13 votes in favor, 0 against, 0 abstained) that the available data were adequate to support the effectiveness of ADACEL™ in individuals 11 – 64 years of age.

Based on information presented to the Committee regarding the availability of data to support the safety of ADACEL™ when administered to individuals 10 –18 years of age, the Committee recommended:

- The Committee unanimously recommended (13 votes in favor, 0 against, 0 abstained) that the available data were adequate to support the safety of ADACEL™ when administered to individuals 11 – 64 years of age.

The Committee then held a discussion pertaining to the discussion item to identify any further issues that should be addressed. The committee noted that the items raised during the morning's discussion also pertained to the afternoon discussion. The committee

advocated further studies to provide more data regarding immune responses and safety in older adult populations, particularly for subjects on concurrent medications and/or having other illnesses, and continued safety monitoring particularly for neurological complications.

An Open Public Hearing was announced. No public comment was offered.

This completed the committee discussion and recommendations. The Chair adjourned the meeting at 3:36 p.m.