

Food and Drug Administration
Center for Biologics Evaluation and Research

SUMMARY MINUTES
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

Meeting # 92: November 18, 2002

Committee Members

Dr. Robert Daum, Chair
Dr. Walter Faggett
*Ms. Barbara Loe Fisher
Dr. Judith Goldberg
Dr. Audrey Manley
Dr. Diane Griffin
Dr. Sam Katz
Dr. David Markovitz
Dr. Gary Overturf
Dr. Peter Palese
Dr. Julie Parsonnet
Dr. David Stephens
Dr. Rich Whitley

Members Not Present

+Dr. Michael Decker
Dr. Pamela Diaz

FDA Presenters

Dr. Richard Walker
Dr. Dennis Kopecko
Dr. Scott Stibitz
Dr. Philip Boucher

FDA Participants

Dr. Karen Midthun
Dr. Neil Goldman

Consultants

Dr. Estuardo Aguilar-Cordova

Executive Secretary

Dr. Jody Sachs

These summary minutes for the November 18, 2002 Meeting of the Vaccines and Related Biological Products Advisory Committee were approved on _____ .

I certify that I participated in the November 18, 2002 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

Robert S. Daum, M.D.
Chair

* Consumer Representative

+ Non-Voting Industry Representative

The Chair, Dr. Robert Daum, called the 92nd Meeting of the Vaccines and Related Biological Products Advisory Committee to order at 1:00 p.m. EST on November 18, 2002. The meeting addressed the review of intramural research programs of the Laboratory of Enteric and Sexually Transmitted Diseases (LESTD), Office of Vaccines Research and Review (OVRR).

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

This meeting was held by a telephone conference call. The public was welcome to attend the open portion of the meeting at the Food and Drug Administration, Bldg 29B, Conference Room C, 29 Lincoln Drive, Bethesda, MD., for public participation. A speakerphone was provided at the specified location.

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 2:40 p.m. EST on November 18, 2002.

Open Session

Brief Overview of the CBER Laboratories that underwent a Site Visit:

Dr. Richard Walker, Director of the Division of Bacterial, Parasitic & Allergenic Products presented an overview of the Division of Bacterial, Parasitic & Allergenic Products. Dr. Neil Goldman, Assoc. Director for Research in the Office of the Center Director, and Dr. Karen Midthun, Director, Office of Vaccines Research and Review responded to questions regarding the site visit process.

Dr. Dennis Kopecko, Chief of the Laboratory Enteric and Sexually Transmitted Diseases, (LESTD), presented an overview of all research and accomplishments from LESTD Laboratory.

Dr. Scott Stibitz and Dr. Philip Boucher then presented their laboratory research activities to the committee, followed by discussion.

The Closed Session followed.