



ANNUAL REPORT
OF THE
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE
For the period
October 1, 2003 through September 30, 2004

FUNCTION

The Committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related products which are intended for use in the prevention, treatment, or diagnosis of human diseases, and, as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Food and Drugs.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The Committee met four times during the reporting period. Meetings were held in Bethesda, Maryland. Two meetings were held by teleconference.

The dates of those meetings were February 18-19, 2004, March 17, 2004, May 6, 2004, and September 22-23, 2004.

The meetings on May 6, 2004, and September 22-23, 2004 included closed sessions to permit discussion of secret or confidential commercial information or matters of a personal nature.

ACCOMPLISHMENTS

February 18-19, 2004: The topic was the strain selection for the Influenza Virus Vaccine for the 2004-2005 season including strain characterization.

March 17, 2004 teleconference on the National Institutes of Health campus in Bethesda, Maryland: The topic was the influenza B component for the strain selection of the Influenza Virus Vaccine for the 2004-2005 season. FDA used the recommendations from the February and March meetings to make formal recommendations to industry for the composition of the 2004-2005 Influenza Virus Vaccine.

May 6, 2004 teleconference on the National Institutes of Health campus in Bethesda, Maryland: The topics was an overview of the Laboratory of DNA Viruses, Division of Viral Products, Office of Vaccines Research and Review. In the afternoon of May 6, 2004, the Committee held a closed session to make recommendations on personnel and program actions for the Laboratory of DNA. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6). The recommendations were utilized by FDA as part of its independent intramural program review.

September 22-23, 2004: The topics was Aventis Pasteur Inc.'s Tetavalent Meningococcal Conjugate Vaccine, Menactra, including clinical data, safety and efficacy, and an overview of the Thailand HIV Vaccine Phase 3 Trial. On September 23, 2004, the Committee held a closed session to permit a discussion and review of trade secrets and/or confidential information 5 U.S.C. 552b(c)(4). These issues are under consideration by FDA.

Detailed information related to these meetings is available in the annual report.

9/30/04
Date

Paul Dapocito for
Christine A. Walsh, R.N.
Executive Secretary

Vaccines and Related Biological Products Advisory Committee

Chair

Gary D. Overturf, M.D.

Expertise: Pediatrics
Term: 02/01/02 - 01/31/06
Professor of Pediatrics and Pathology
University of New Mexico Center
Ambulatory Care Center, 3rd Floor
2211 Lomas Avenue, N.E.
Albuquerque, New Mexico 87131

Chair

David S. Stephens, M.D.

Expertise: Bacterial Pathogenesis
Term: 02/01/99 - 01/31/04
Professor of Medicine
Division of Infectious Diseases
Department of Medicine
Emory University School of Medicine
1364 Clifton Road, N.E., Suite H-153
Atlanta, Georgia 30322

Michael Decker, M.D.

Expertise: Infectious Diseases
Term: 06/20/01- 05/28/04
Vice President
Scientific and Medical Affairs
Aventis Pasteur
Discovery Drive
Swiftwater, Pennsylvania 18370

Pamela S. Diaz, M.D.

Expertise: Pediatrics, Infectious Disease
Term: 07/11/00 - 01/31/04
Director, Infectious Diseases
Chicago Department of Public Health
West Side Center for Disease Control
2160 West Ogden Avenue
Chicago, Illinois 60612

Executive Secretary

Christine Walsh, R.N.

Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike (HFM-71)
Rockville, Maryland 20852
E-mail: walshc@cber.fda.gov
Phone: 301-827-0314
Facsimile: 301-827-0294

Audrey F. Manley, M.D., M.P.H.

Expertise: Neonatology
Term: 07/11/00 - 01/31/04
President Emeritus
Spelman College
Rear Admiral (Ret)
U.S. Public Health Services
Washington, DC 20009

David M. Markovitz, M.D.

Expertise: Infectious Diseases
Term: 02/01/02 - 01/31/06
Professor
Division of Infectious Diseases
Department of Internal Medicine
University of Michigan Medical Center
1150 West Medical Center Drive, Room 5220
Ann Arbor, Michigan 48109

Monica M. Farley, M.D.

Expertise: Bacterial Infectious Diseases
Term: 02/01/04 - 01/31/08
Professor of Medicine
Department of Medicine
Emory University School of Medicine
VA Medical Center
Research - Infectious Diseases (151)
1670 Clairmont Road
Atlanta, Georgia 30033

Judith D. Goldberg, Sc.D.

Expertise: Biostatistics, Clinical Trials
Term: 07/11/000 - 01/31/04
Director, Division of Biostatistics
New York University School of Medicine
650 First Avenue, Room 506
New York, New York 10016

Ruth A. Karron, M.D.

Expertise: Pediatrics & Infectious Diseases
Term: 02/01/03 - 01/31/07
Associate Professor
Division of International Health
Johns Hopkins School of Hygiene and
Public Health
624 N. Broadway
Hampton House, Room 117
Baltimore, Maryland 21205

Samuel L. Katz, M.D.

Expertise: Pediatrics, Infectious Disease
Term: 07/11/00 - 01/31/04
Wilburt C. Davidson Professor and
Chairman Emeritus, Department of
Pediatrics
Duke University Medical Center, Box 2925
Durham, North Carolina 27710

Philip S. LaRussa, M.D.

Expertise: Pediatrics / Virology
Term: 02/01/04 - 01/31/08
Professor of Clinical Pediatrics
Columbia University, PH-4 West - 462
622 West 168th Street
New York, New York 10032

Peter Palese, Ph.D.

Expertise: Molecular Biology
Term: 06/20/01 - 01/31/05
Chairman and Professor
Department of Microbiology
Mt. Sinai School of Medicine
New York University
One Gustave L. Levy Place
New York, New York 10029

Julie Parsonnet, M.D.

Expertise: Enteric Pathogens
Term: 06/20/01 - 02/01/04
Associate Professor of Medicine and Health
Research Policy
Stanford University
Grant Building, Room S156
Stanford, California 94305

Cindy Lyn Province, R.N., M.S.N.*

Expertise: Consumer Representative
Term: 04/10/03 - 01/31/05
Associate Director
Bioethics Center of St. Louis
P.O. Box 6134
Chesterfield, Missouri 63006

Walter Royal, III, M.D.

Expertise: Infectious Diseases / Neurology
Term: 02/01/03 - 01/31/07
Associate Professor of Medicine
Morehouse School of Medicine
720 Westview Drive, S.W.
Atlanta, Georgia 30310

Steven Self, Ph.D.

Expertise: Biostatistics
Term: 02/01/04 - 01/31/08
Professor, Department of Biostatistics
University of Washington
Fred Hutchinson Cancer Research Center
1100 Fairview Avenue, S., MS MW 500
P.O. Box 19024
Seattle, Washington 98109

Richard Whitley, M.D.

Expertise: Pediatrics & Infectious Diseases

Term: 06/20/01 - 01/31/05

Professor

Pediatrics, Microbiology and Medicine

Department of Pediatrics and Microbiology

University of Alabama at Birmingham

Suite 616, Children's Hospital

1600 7th Avenue South

Birmingham, Alabama 35233

Bonnie M. Word, M.D.

Expertise: Pediatric Infectious Diseases

Term: 02/01/04 - 01/31/08

Assistant Professor of Pediatrics

Baylor College of Medicine

Texas Children's Hospital

Clinical Care Center

6621 Fannin Street, Suite 1740.01

Houston, Texas 77030