Center for Biologics Evaluation & Research

Vaccines and Related Biological Products Advisory Committee

December 14-15, 2005

Consultants

DAY 1

Bruce Gellin, M.D., M.P.H. ***
Director
National Vaccine Program Office (NVPO)
Hubert Humphrey Building, Rm. 725H
200 Independence Ave., SW
Washington, DC 20201

Samuel Maldonado, M.D., M.P.H. **
Senior Director
Global Regulatory Affairs
Chairman, Pediatric Drug Development Committee
Johnson & Johnson Pharmaceutical Research and
Development L.L.C.
920 Route 202 South
Raritan, NJ 08869

Pamela McInnes, D.D.S. ***
National Institute of Allergy and Infectious Diseases (NIAID)
Deputy Director, Division of Microbiology and Infectious Diseases (DMID)
National Institutes of Health
6610 Rockledge Drive, Room 6113
Bethesda, MD 20892

Melinda Wharton, M.D., M.P.H. ***
Acting Deputy Director of the National Immunization Program
National Immunization Program
Centers for Disease Control and Prevention
1600 Clifton Road, N.E. (MS E05)
Atlanta, GA 30333

^{**} Acting Industry Representative *** Temporary Voting Members

Center for Biologics Evaluation & Research

Vaccines & Related Biological Products Advisory Committee

December 14-15, 2005

Speakers

Day 1

Mark Bagarazzi, M.D.
Director, World Wide Regulatory Affairs
Vaccines/Biologics
Merck Research Laboratories
P.O. Box 4, BLB-22
West Point, PA 19486

Penny Heaton, M.D., M.P.H. Director, Department of Biologics Clinical Research Merck Research Laboratories P.O. Box 4, BLB-22 West Point, PA 19486

FDA Participant

Rosemary Tiernan, M.D., M.P.H. Medical Officer Division of Vaccines and Related Product Applications OVRR/CBER 1401 Rockville Pike, HFM-485 Rockville, MD 20852

Hector Izurieta, M.D., M.P.H. Epidemiologist Division of Epidemiology OVRR/CBER 1401 Rockville Pike, HFM-222 Rockville, MD 20852

Center for Biologics Evaluation & Research

Vaccines and Related Biological Products Advisory Committee

December 14-15, 2005

Consultants

DAY 2

Bruce Gellin, M.D., M.P.H. ***
Director
National Vaccine Program Office (NVPO)
Hubert Humphrey Building, Rm. 725H
200 Independence Ave., SW
Washington, DC 20201

Thomas Fleming, Ph.D. ***
Professor and Chairman
Department of Biostatstics, SC-32
University of Washington
Seattle, WA 98195

Seth Hetherington, M.D. **
Chief, Medical Officer
VP Clinical Development
Inhibitex, Inc.
1165 Sanctuary Pkwy., Suite 400
Alpharetta, GA 30004

Pamela McInnes, D.D.S. ***
National Institute of Allergy and Infectious
Diseases (NIAID)
Deputy Director Division of Microbiology
and Infectious Diseases (DMID)
National Institutes of Health
6610 Rockledge Drive, Room 6113
Bethesda, MD 20892

Michael Rowbotham, M.D. ***
Professor of Clinical Neurology and Anesthesia
Director, UCSF Pain Clinical Research Center
1701 Divisadero Street, Suite 480
University of California San Francisco
San Francisco, CA 94115

Daniel Scharfstein, Sc.D. ***
Associate Professor
Department of Biostatistics
Johns Hopkins Bloomberg School of
Public Health
615 North Wolfe Street
Baltimore, MD 21205

Melinda Wharton, M.D., M.P.H. ***
Acting Deputy Director of the National Immunization Program
National Immunization Program
Centers for Disease Control and
Prevention
1600 Clifton Road, N.E. (MS E05)
Atlanta, GA 30333

^{**} Acting Industry Representative

^{***} Temporary Voting Members

Center for Biologics Evaluation & Research

Vaccines & Related Biological Products Advisory Committee

December 14-15, 2005

Speakers

Day 2

David Gutsch, M.D. Director, Regulatory Affairs Merck Research Laboratories P.O. Box 4, BLB-22 West Point, PA 19486

Jeffrey Silber, M.D. Senior Director, Clinical Research Merck Research Laboratories P.O. Box 4, BLB-22 West Point, PA 19486

FDA Participant

Patricia Rohan, M.D.
Medical Officer
Division of Vaccines and Related
Product Applications
OVRR/CBER
1401 Rockville Pike, HFM-485
Rockville, MD 20852