

**FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
RESEARCH REVIEW SUBCOMMITTEE OF THE
VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE**

**OFFICE SITE VISIT
OFFICE OF VACCINES RESEARCH AND REVIEW**

May 19, 2006
Hilton Hotel, Washington DC North/Gaithersburg,
620 Perry Parkway, Gaithersburg, MD 20877

AGENDA

Open Committee Discussion

- 8:00 a.m.** Welcome and Introduction of Committee
Walter Royal, M.D., Chair
- 8:10** Conflict of Interest Statement
Christine Walsh, R.N., Executive Secretary
- 8:15** Introduction/Charge to Committee
Jesse L. Goodman, M.D., M.P.H.
Director, Center for Biologics Evaluation and Research
CBER Mission
CBER Program Structure
- 8:35** Overview of CBER Research Programs
Kathryn Carbone, M.D.
Associate Director for Research, CBER
- 9:00** Overview of the Office of Vaccines Research and Review (OVRR)
Norman Baylor, Ph.D., Director
Office Mission and Structure
Regulatory Activities and Priorities
Research Program Introduction
- 9:30** Q & A
- 9:50 a.m.** Break

**Research Review Subcommittee of the
Vaccines and Related Biological Products Advisory Committee
Site Visit Review
Office of Vaccines Research and Review
May 19, 2006**

AGENDA (Cont'd)

Open Committee Discussion

- 10:05 a.m.** Office of Vaccines Research and Review Research Program
Michael Brennan, Ph.D., Associate Director of Research, OVRR
Research Management, Accomplishments and Future Plans
- 10:40 a.m.** Overview of the Division of Viral Products
Jerry Weir, Ph.D., Director DVP
Mission/Philosophy/Regulatory Activities and
Public Health Impact
Regulatory and Research Expertise
Research Program Structure and Research
Activities and Priorities
- 11:15 a.m.** Overview of the Division of Bacterial Parasitic and Allergenic Products
Richard Walker, Ph.D., Director DBPAP
Mission/Philosophy/Regulatory Activities and
Public Health Impact
Regulatory and Research Expertise
Research Program Structure and Research
Activities and Priorities
- 11:45 a.m.** Q&A
- 12:00 p.m.** **Open Public Hearing**
- 1:00 p.m.** **Adjourn Open Session/Lunch**
- 2:00 p.m.** **Closed Committee Discussion**
- 4:30 p.m.** Adjourn Closed Session
- .