

## **Anti-Infective Drugs Advisory Committee**

Food and Drug Administration  
Center for Drug Evaluation and Research

Parklawn Building, 5600 Fishers Lane, Conference Rooms G, H & I  
and Room 1066, 5630 Fishers Lane, Rockville, MD

Supplemental New Drug Applications(NDA)  
19-537/S038, 19-847/S024, 19-857/S027, 19-858/S021, 20-780/S008  
for Cipro® (ciprofloxacin), Bayer Corporation, Pharmaceutical Division

### **Agenda - July 28, 2000**

- 8:30 Call to Order, Introductions:** Barth Reller, M.D., Chair
- Meeting Statement:** Thomas H. Perez, M.P.H., Executive Secretary
- Opening Comments:** Diane Murphy, M.D., Director, ODE IV
- 9:00 Bayer Corporation Presentation:**  
Andrew S. Verderame, Associate Director, Regulatory Affairs
- 9:30 Anthrax clinical disease and epidemiology** Martin Hugh-Jones, D.V.M.
- 10:00 Human pathology inhalational disease** David Walker, M.D.
- 10:30 Non-human primate model of inhalational anthrax** Arthur Friedlander, M.D.
- 11:10 Break**
- 11:30 FDA Presentation: FDA's Perspective**  
Gary K. Chikami, M.D., Director, Division of Anti-Infective Drug Products  
Andrea Meyerhoff, M.D., Medical Reviewer, Division of Special Pathogens and Immunologic Drug Products.
- 12:00 Lunch**
- 1:30 Open Public Hearing**
- 2:30 Break**
- 2:45 Charge to the Committee, Introduction to Questions:**  
**Discussion and Questions**
- 5:00 Adjourn**

### **Consultants and Guests**

James W. Bayuk, M.D., Director of Environmental Health & Preventive Medicine, U.S. State Department

Scott Deitchman, M.D., National Institute for Occupational Safety and Health

Arthur Friedlander, M.D., U.S. Army Medical Research Institute of Infectious Diseases

Martin Hugh-Jones, D.V.M., School of Veterinary Medicine, Louisiana State University

Jonathan Moreno, Center for Biomedical Ethics, University of Virginia

Ernest Takafuji, M.D., U.S. Army, Office of the Assistant Secretary of Defense

David Walker, M.D., University of Texas Medical Branch

Michael M. Wertz, Operations Officer, U.S. State Department

### **Open Public Hearing**

Itzhak Brook, M.D., Armed Forces Radiobiologic Research Institute