Food and Drug Administration
Center for Drug Evaluation and Research

Summary Minutes of the Antiinfective Drugs Advisory Committee

July 28, 2000

Parklawn Building
5600 Fishers Lane
Rockville, MD

Members Present
Barth L. Reller, M.D.
Keith A.Rodvold, Pharm.D.
Joan P. Chesney, M.D.
Celia Christie-Samuels, M.D.,M.P.H., F.A.A.P
David E. Soper, M.D.
Murray Wittner, M.D., Ph.D.
Gordon L. Archer, M.D.
Judith O'Fallon, M.D.

FDA Participants
Diane Murphy, M.D.
Renata Albrecht, M.D.
Gary Chikami, M.D.
Andrea Meyerhoff, M.D.
Sandra Kweder, M.D.

Guest Experts to the GIDAC
Martin Hugh-Jones
David Walker
Arthur Friedlander
Scott Deitchman
Ernest Takafuji
Jonathan Moreno
Michael M. Wertz
James W. Bayuk

These summary minutes for the July 28 meeting of the Antiinfective Drugs Advisory Committee were approved on 9 November 2000.

I certify that I attended the July 28 meeting of the Antiinfective Drugs Advisory Committee and that these minutes accurately reflect what transpired.

Thomas H. Perez, M.P.H., R.Ph.
Executive Secretary

Barth L. Reller, M.D.
Chair

L. BARTH RELLER, M.D.

This report contains public information that has not been reviewed by the agency or AntiInfective Drugs Advisory Committee. The official summary minutes will be prepared, circulated, and certified as usual. Transcripts will be available in about 12 days. External requests should be submitted to the Freedom of Information office.

The AntiInfective Drugs Advisory Committee of the Food and Drug Administration, Center for Drug Evaluation and Research met on July 28, 2000 at the : Parklawn Building, 5600 Fishers Lane, Conference Rooms G, H, & I, Rockville, MD.

The committee discussed 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, for post-exposure prophylaxis of clinical disease from inhaled *Bacilllus anthracis.*

The Committee had received a briefing document from the FDA.

There were approximately 150 persons in the audience. The meeting was called to order at 9:00am by the Chair, Barth Reller, M.D. The Committee members and discussants introduced themselves. Thomas H. Perez, Executive Secretary of the AntiInfective Drugs Advisory Committee read the Meeting Statement. Diane Murphy, M.D., Director, Office of Drug Evaluation IV, provided opening comments.

Bayer Corporation's presentation began at 9:30 am and was provided by:

Andrew S. Verderame, Associate Director, Regulatory Affairs

At approximately 10:00 the following invited speakers gave their presentations:

Anthrax clinical disease and epidemiology	- Martin Hugh-Jones, D.V.M.
Human pathology inhalational disease	- David Walker, M.D.
Non-human primate model of inhalational anthrax	- Arthur Friedlander, M.D.

At approximately 12:00 the FDA, CDER presentation was made by:

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.

The Open Public Hearing portion of the meeting included one participant, Itzhak Brook, M.D., representing the Armed Forces Radiobiology Research Institute.

The Committee discussed the following questions.

1) Do the data presented support the safety and efficacy of ciprofloxacin for post-exposure prophylaxis of inhalational anthrax?
   Yes 8 *No 0*

2) If yes, is 60 days an appropriate duration of ciproflaxacin administration for this indication?
   Yes 8 *No 0*

The committee also expressed the sentiment that in relation to their answers to the questions there is clear recognition of the special circumstances surrounding the use of this drug in the context of the discussions held and the available science.

The meeting was adjourned at 2:40 p.m.