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BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE

Meeting #29

April 5-6, 2001

Holiday Inn, Bethesda, MD

Thursday, April 5

9:00 a.m.	Call to Order Dr. Daniel Salomon, Chair
9:10	Conflict of Interest Statement Ms. Gail Dapolito, Executive Secretary
Session I	
9:15	FDA Introduction Overview of March 6, 2000 FDA Gene Therapy Letter Product-Related Issues Dr. Joyce Frey-Vasconcells Division of Cellular and Gene Therapies, CBER
9:30	Responses to Gene Therapy Letter: Multi-Use Facility, QA/QC Issues Ms. Mary Malarkey Division of Case Management, CBER
9:50	Questions from the Committee
10:00	Responses to FDA Gene Therapy Letter: RCR and Different Packaging Cell Lines for Retroviral Vector Manufacture Dr. Carolyn Wilson Divison of Cellular and Gene Therapies, CBER
10:10	Committee Discussion
10:30	Break
10:45	Responses to FDA Gene Therapy Letter: Testing of Plasmids as Manufacturing Intermediates in Gene Therapy Products Dr. Suzanne Epstein Division of Cellular and Gene Therapies, CBER
10:55	Committee Discussion
11:15	Responses to FDA Gene Therapy Letter : Adenovirus Vector Titer Measurements and RCA Levels Dr. Steven Bauer Division of Cellular and Gene Therapies, CBER

Biological Response Modifiers Advisory Committee
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Thursday, April 5 (Cont'd)

11:35 Clinical Issues of Adenovirus Infection in Marrow Transplant Recipients
Dr. Stephen Chanock
Pediatric Oncology Branch, NCI, NIH

12:05 p.m. Committee Discussion

12:30 Lunch

Session II

1:30 p.m. Open Public Hearing

2:00 FDA Introduction
March 6, 2000 FDA Gene Therapy Letter
Preclinical and Clinical Issues
Dr. Karen Weiss, CBER
Division of Clinical Trial Design and Analysis, CBER

2:05 Responses to FDA Gene Therapy Letter:
Preclinical and Clinical Issues
Dr. Patricia Keegan
Division of Clinical Trial Design and Analysis, CBER

Results of Gene Therapy Clinical Site Inspections
Ms. Elaine Cole
Mr. Joseph Salewski
Division of Inspections and Surveillance, CBER

3:05 Break

3:15 Committee Discussion

Update: CBER Intramural Research Programs
Division of Monoclonal Antibodies
4:15 Dr. Jay Siegel, Director
Office of Therapeutics Research and Review

4:20 Dr. Marjorie Shapiro
Laboratory of Molecular and Developmental Immunology

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Thursday, April 5 (Cont'd)

	Division of Cellular and Gene Therapies
4:45	Dr. Philip Noguchi, Director
4:50	Dr. Thomas Eggerman Laboratory of Molecular and Tumor Biology
5:15	Adjourn Open Session
5:30	Closed Session
6:00	Adjourn Closed Session

Friday, April 6

8:30 a.m.	Call to Order Dr. Daniel Salomon, Chair
8:45	Presentation of Certificate of Appreciation for Committee Service Dr. Kathryn Zoon, Director, CBER Dr. Jay Siegel, Director, OTRR, CBER

Session III

9:00	FDA Introduction Long-Term Follow-Up of Gene Therapy Patients Dr. Philippe Bishop Division of Clinical Trial Design and Analysis, CBER
9:05	UNOS Presentation Dr. Mary Ellison Mr. Berkeley Keck United Network for Organ Sharing
9:20 a.m.	FDA Presentation Long-Term Follow-Up of Gene Therapy Patients Dr. Carolyn Wilson Dr. Philippe Bishop
9:50	Break
10:00	Committee Discussion
11:00	Open Public Hearing

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Friday, April 6 (Cont'd)

Session IV

11:30	Introduction - FDA Proposed Rule Availability for Public Disclosure and Submission to FDA for Public Disclosure of Certain Data and Information Related to Human Gene Therapy or Xenotransplantation Dr. Philip Noguchi
12:00 noon	Break
12:10 p.m.	Committee Discussion
1:15	Adjourn