FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE
Meeting #28, November 16-17, 2000
Holiday Inn, Bethesda, MD

Thursday, November 16, 2000

8:30 a.m.	Call to Order Daniel Salomon, M.D., Chair
8:40	Conflict of Interest Statement Gail Dapolito, Executive Secretary
8:45	Presentation of Certificates to Retiring Members Kathryn Zoon, Ph.D., Director, CBER Jay Siegel, M.D, Director, OTRR, CBER

Session I

9:05	FDA Introduction - Current Policy on Sequence Characterization of Gene Transfer Products Steven Bauer, Ph.D., CBER
9:25	Questions from the Committee
9:30	Identification and Characterization of Unexpected DNA Found in Adenovirus Vectors Louis Zumstein, Ph.D., Introgen Therapeutics Inc.
9:45	Questions from the Committee
9:50	Instability of Mini-Adenovirus Vectors Jeffrey Chamberlain, Ph.D., University of Michigan Medical School
10:05	Questions from the Committee
10:10	Break
10:20	The CMV Promoter is Copied as "Extra DNA" from DNA Vaccine Plasmids (Generation of Plasmid Replication Intermediates in Host E.coli) John Levy, CTL ImmunoTherapies Corp.
10:35	Questions from the Committee
10:40	Committee Discussion of FDA Questions
12:15 p.m.	Lunch

Thursday, November 16, 2000

Session II

1:15 p.m.	Open Public Hearing
1:45	FDA Introduction - Preclinical Models Anne Pilaro, Ph.D., CBER
2:10	Questions from the Committee
2:15	Advantages and Disadvantages of the Use of Non-Human Primates Estella Z. Jones, D.V.M., CBER
2:40	Questions from the Committee
2:45	Use of the Canine Model of Hemophilia Katherine High, M.D., Children's Hospital of Philadelphia
3:10	Questions from the Committee
3:15	Break
3:30	Use of Aotus Monkeys to Assess Neurovirulence of Replication-Selective Herpes Vectors Richard Whitley, M.D., University of Alabama
3:55	Questions from the Committee
4:00	Committee Discussion of FDA Questions
5:30	Adjourn

Friday, November 17, 2000

8:30 a.m.	Call to Order Daniel Salomon, M.D, Chair
8:40	Open Public Hearing
	Session III
9:10	FDA Introduction - Vector Classes with Potential for Long-Term Risks Carolyn Wilson, Ph.D., CBER
9:25	FDA Perspective - Long-Term Follow-Up Philippe Bishop, M.D., CBER
9:40	Committee Discussion of FDA Questions
11:00	Break
	Session IV
11:30	FDA Introduction - Issues in Germ Line Transmission Mercedes Serabian, M.S., CBER
11:45	Preclinical and Clinical Findings with Retroviral Vector Encoding Factor VIII Gene Deborah Hurst, M.D., Chiron
12:05 p.m.	Questions from the Committee
12:10	Committee Discussion of FDA Questions
1:30	Adjourn