

**DRAFT**

**DRAFT**

**DRAFT**

**BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE**

**Meeting #30**

**Holiday Inn, Bethesda, MD**

**July 13, 2001**

**8:30 a.m.**

Welcome and Introductions  
Dr. Daniel Salomon, Chair

**8:40**

Conflict of Interest Statement  
Ms. Gail Dapolito, Executive Secretary

**OPEN COMMITTEE DISCUSSION**

**8:45**

**FDA Introduction**

Responses to March 6, FDA Gene Therapy Letter:  
Adenovirus Vector Titer Measurements and RCA Levels  
Dr. Steve Bauer  
Office of Therapeutics Research and Review  
Center for Biologics Evaluation and Research

**9:15**

**Guest Presentations**

Dr. Estuardo Aguilar-Cordova  
Harvard Gene Therapy Initiative  
Harvard University Medical School

**9:30**

Questions from the Committee

**9:35**

Dr. Beth Hutchins  
Process Scientist  
Canji

**9:50**

Questions from the Committee

**9:55**

Dr. Richard Sublett  
Director, Quality Systems  
Introgen Therapeutics, Inc.

**10:10**

Questions from the Committee

**10:15**

Break

**Biological Response Modifiers Advisory Committee  
Meeting #30  
Agenda - Page 2**

**July 13, 2001**

**Guest Presentations (Cont'd)**

- 10:30 a.m.** Dr. Phyllis Flomenberg  
Thomas Jefferson University Medical School
- 10:50** Questions from the Committee
- 11:00** **Open Public Hearing**
- 12:00 noon** Lunch
- 1:00 p.m.** **Committee Discussion of Questions**
- 2:55** **Committee Update**  
NIH Final Action on Serious Adverse Event Reporting
- Dr. Amy Patterson  
Office of Biotechnology Activities  
National Institutes of Health
- 3:15** Questions from the Committee
- 3:30** Adjourn