Food and Drug Administration Center for Biologics Evaluation and Research BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE

Meeting #33, October 10, 2002

Hilton Hotel, Gaithersburg, MD

Draft Agenda

Topic I: Retroviral Gene Therapies for the Treatment of Patients with Severe Combined Immunodeficiency – Safety Issues

8:00 a.m. Welcome and Introductions

Dr. Daniel Salomon, Chair The Scripps Research Institute

8:10 Conflict of Interest Statement

Ms. Gail Dapolito, Executive Secretary Center for Biologics Evaluation and Research

8:15 FDA Introduction to the Topic

Dr. Philip Noguchi

Center for Biologics Evaluation and Research, FDA

Guest Presentations

8:20 Dr. Alain Fischer (audioconference)

Hospital Necker, France

Dr. Christof Kalle

University of Cincinnati School of Medicine

9:20 Q&A

9:35 Dr. Rebecca Buckley

Duke University Medical Center

9:50 Q&A

10:00 Dr. Linda Wolff

National Cancer Institute

10:30 Q&A

10:45 Break

11:00 Dr. Christopher Baum

Hannover Medical School, Germany

11:20 Q&A

6:00 p.m.

Adjourn

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Agenda (Cont'd) 11:30 a.m. 11:50		Dr. Stuart Orkin Harvard Medical School Q&A
12:00 noon	Lunch	
12:45 p.m.		Dr. Donald Kohn U.S.C. Keck School of Medicine
1:15		Dr. Brian Sorrentino Dr. John Cunningham St. Jude Children's Research Hospital
1:30		Dr. Harry Malech National Institute for Allergy and Infectious Diseases
1:45		Q&A
2:00	Open l	Public Hearing
3:00	Commi	ittee Discussion of Questions
5:00	Break	
To	pic II:	Update – Research Programs, Division of Cell and Gene Therapies, Division of Therapeutic Proteins, CBER
5:10		Dr. Raj Puri Chief, Laboratory of Molecular Tumor Biology
5:20		Dr. David Essayan Laboratory of Molecular Tumor Biology
5:25		Dr. Michael Norcross Laboratory of Gene Regulation
5:35 Clo	osed Sessio	on .