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**Food and Drug Administration  
Center for Biologics Evaluation and Research  
BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE  
AGENDA  
Meeting #31, Holiday Inn, Gaithersburg, MD  
October 25-26, 2001**

**Thursday, October 25**

- 8:00 a.m.            Opening Remarks  
                            Dr. Daniel Salomon, Chair
- 8:15                    Conflict of Interest Statement  
                            Gail Dapolito, Executive Secretary
- 8:20                    Introduction of Committee

**Topic 1 – Lentivirus Vectors in Gene Transfer Clinical Trials**

**Introduction**

- 8:30                    Dr. Inder Verma, Salk Institute  
9:00                    Q&A

**FDA Perspective**

- 9:15                    Dr. Daniel Takefman  
9:45                    Q&A

- 10:00                  Break

**Guest Presentations**

- 10:15                  Dr. Dale Ando, Cell Genesys, Inc.  
                            Dr. Gabor Veres, Cell Genesys, Inc.
- 11:00                  Q&A
- 11:15                  Dr. Jeffrey Kordower, Rush Presbyterian Medical Center  
12:00                  Q&A
- 12:15 p.m.            Lunch
- 1:15                    Dr. Susan Kingsman, Oxford BioMedica (UK) Ltd.  
2:00                    Q&A

**BRMAC Meeting #31**  
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**Thursday, October 25 (cont'd)**

2:15 p.m.	Dr. John Kappes, University of Alabama at Birmingham
2:45	Q&A
3:00	<b>Open Public Hearing</b>
3:15	Break
3:30	<b>Committee Discussion of Questions</b>
5:30 – 6:00	Adjourn

**Friday, October 26**

8:00 a.m.	Opening Remarks Dr. Daniel Salomon, Chair
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**Topic 2 – Lentivirus Vector Gene Transfer Product for Treatment of People with HIV**

	<b>Guest Presentation</b>
8:15	Dr. Boro Dropulic, VIRxSYS Corp.
9:45	Q&A
10:00	Break
10:15	<b>Open Public Hearing</b>
10:30	<b>Committee Discussion of Questions</b>
12:00 noon	Lunch
12:30 p.m.	Committee Discussion (cont'd)
2:00	Adjourn