FDA/FCHR COLLABORATIVE PUBLIC MEETING ON LONG-TERM SAFETY CONCERNS ASSOCIATED WITH CCR5 ANTAGONIST DEVELOPMENT

MAY 31, 2006
WASHINGTON, DC
THE GEORGE WASHINGTON UNIVERSITY MARVIN CENTER
The Marvin Center, 800 21st Street, N.W., Washington, DC 20052

8:30 – 10:30	**SESSION I: CHEMOKINE ANTAGONISTS IN DEVELOPMENT: CURRENT STATUS**	**Chair: Debra Birnkrant**
8:30	**WELCOME & INTRODUCTIONS**	**Debra Birnkrant**
8:35	**CHEMOKINE RECEPTORS AND ANTAGONISTS: SUMMARY OF CLINICAL EXPERIENCE** ✓ Tropism assay, tropism changes, and safety issues	**Roy Gulick**
9:05	**RECAP OF FCHR CHEMOKINE ANTAGONIST WORKING GROUP MEETINGS**	**Veronica Miller**
9:20	**REGULATORY PERSPECTIVE** ✓ Current Requirements for Approval ✓ Proposed Monitoring plans ✓ Summary of Responses	**Scott Proestel**
09:50 10:10	**LONG-TERM SAFETY MONITORING** ✓ ACTG experience ✓ Long-term safety monitoring of HIV patients in an observational setting	**Dan Kuritzkes** **Jens Lundgren**
10:30- 10:45	**BREAK**	
	SESSION II: PANEL DISCUSSION AND PUBLIC RESPONSE	**Chairs: Roy Gulick & Joe Eron**
10:45– 12:30	PANEL A: MONITORING & SAFETY	**Moderator: Roy Gulick** Panelists: **Judith Millard** **John Doweiko** **Tom Gegeny** **David Haerry** **Katherine Laessig** **Richard Little** **Howard Mayer** **William Olson** **Paul Skolnik** **Kate Squires** **Robert Yarchoan**
12:30 –	**LUNCH**	

1:30		
1:30 – 3:00	PANEL B: VIRAL TROPISM & RESISTANCE	**Moderator: Joe Eron** Panelists: **Stephen Becker** **Richard Colvin** **Lynda Dee** **Steve Deeks** **Jim Demarest** **Wayne Greaves** **John Moore** **Lisa Naeger** **Neil Parkin** **Jonathan Schapiro** **Mani Subramanian**
3:00-4:00	PANEL C: CLINICAL EFFICACY AND STRATEGY	**Moderators: Roy Gulick and Joe Eron** Panelists from Panel A & B plus pediatrics **Andy Wiznia**
4:00 – 4:15	**WRAP-UP**	