FOOD AND DRUG ADMINISTRATION (FDA)
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
ANTIVIRAL DRUGS ADVISORY COMMITTEE MEETING
HILTON WASHINGTON, DC/SILVER SPRING; 8727 COLESVILLE ROAD, SILVER SPRING, MARYLAND
SEPTEMBER 5, 2007

AGENDA

The committee will discuss new drug application (NDA) 22-145, raltegravir potassium, integrase inhibitor 400 mg tablets / Merck & Co., Inc., for treatment of HIV-1 infection in combination with other antiretroviral agents in treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy.

8: 00 a.m.	Call to Order and Opening Remarks	Lynn A. Paxton M.D., M.P.H. Acting Chair, Antiviral Drugs Advisory Committee
	Introduction of Committee	
	Conflict of Interest Statement	Cicely Reese, Pharm.D. Designated Federal Officer
8: 15 a.m.	FDA Introductory Remarks	Debra B. Birnkrant, M.D. Director, Division of Antiviral Products, CDER, FDA

APPLICANT PRESENTATION

8: 30 a.m.	Introduction	Robert A. Fromtling, Ph.D. Director, Regulatory Affairs Merck & Co., Inc
	Raltegravir Background	Bach-Yen Nguyen, M.D. Senior Director, Clinical Research Merck & Co., Inc.
	Clinical Development Program Overview	
	Clinical Trials Results: Efficacy, Resistance, and Safety	
	Drug-Drug Interactions	Robin Isaacs, M.D. Executive Director, Clinical Research Merck & Co., Inc.
	Risk Management Plan	
	Conclusions	
10: 00 a.m.	**BREAK**	

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FDA PRESENTATION

10: 30 a.m.	Clinical Efficacy, Resistance and Clinical Safety	Sarah Connelly, M.D. Medical Officer Division of Antiviral Products, CDER, FDA
12: 00 p.m.	Clarifications / Questions	
12: 30 p.m.	**LUNCH**	
1: 30 p.m.	Open Public Hearing	
2: 30 p.m.	Discussion / Questions	
4: 00 p.m.	**ADJOURNMENT**	