FOOD AND DRUG ADMINISTRATION (FDA)
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
ANTIVIRAL DRUGS ADVISORY COMMITTEE MEETING
THE KENNEDY BALLROOM, CROWNE PLAZA HOTEL, 8777 GEORGIA AVENUE,
SILVER SPRING MARYLAND
APRIL 24, 2007

AGENDA

The committee will discuss new drug application (NDA) 022-128, maraviroc 150 and 300 milligram tablets, Pfizer, Inc., proposed for the treatment of antiretroviral-experienced patients with chemokine (c-c motif) receptor 5 (CCR5)– tropic human immunodeficiency virus (HIV).

8: 00 a.m.	Call to Order and Opening Remarks	Lynn A. Paxton, MD, MPH Acting Chair, Antiviral Drugs Advisory Committee
	Introduction of Committee	
	Conflict of Interest Statement	Cicely Reese, PharmD Designated Federal Officer
8: 15 a.m.	FDA Introductory Remarks	Katie Laessig, MD Medical Team Leader, Division of Antiviral Products, CDER, FDA

APPLICANT PRESENTATION

8: 30 a.m.	Introduction, Background and Overview of Maraviroc	Michael Dunne, MD Therapeutic Area Head, Infectious Diseases, Pfizer
8: 45 a.m.	Clinical Efficacy	Howard Mayer, MD Global Clinical Leader, Pfizer
9: 05 a.m.	Safety and Toleration	Steve Felstead, MB ChB Maraviroc Team Leader, Pfizer
9: 30 a.m.	In Vitro and In Vivo Tropism and Resistance Evaluation	Mike Westby, PhD Virology Team Leader, Pfizer
9: 40 a.m.	Medical Need and Place in HIV Armamentarium	Dan Kuritzkes, MD Brigham and Women's Hospital, Boston
9: 55 a.m.	Conclusions	Mike Dunne, MD
10: 00 a.m.	**BREAK**	

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[Page 2]

FDA PRESENTATION

10: 30 a.m.	Clinical Efficacy and Safety	Scott Proestel, MD Medical Officer Division of Antiviral Products, CDER, FDA
11: 10 a.m.	Exposure-Response Modeling	Pravin Jadhav, PhD Pharmacometrician/Clinical Pharmacologist Office of Clinical Pharmacology, CDER, FDA
11: 30 a.m.	Tropism and Resistance	Lisa Naeger, PhD Clinical Virologist 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**	