FOOD AND DRUG ADMINISTRATION (FDA)
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Antiviral Drugs Advisory Committee (AVDAC)
The Inn and Conference Center, University of Maryland University College
3501 University Boulevard, East, Adelphi, MD
October 8, 2009
AGENDA

The committee will discuss an efficacy supplement for new drug application (NDA) 022–128, maraviroc 300 milligram tablets, Pfizer, Inc., proposing a new indication for the treatment of antiretroviral-naive patients with chemokine (c-c motif) receptor 5 (CCR5)-tropic human immunodeficiency virus (HIV).

8:00 a.m. – 8:10 a.m.	Call to Order Introduction of Committee	**Craig W. Hendrix, M.D.** Acting Chair, AVDAC
8:10 a.m. – 8:15 a.m.	Conflict of Interest Statement	**Paul T. Tran, R.Ph.** Designated Federal Official, AVDAC
8:15 a.m. – 8:30 a.m.	FDA Opening Remarks	**Debra B. Birnkrant, M.D.** Director Division of Antiviral Drug Products (DAVP) Office of New Drugs (OND), CDER, FDA **Scott Proestel, M.D.** Medical Team Leader DAVP, OND, CDER, FDA
8:30 a.m. – 9: 30 a.m.	**Sponsor Presentation**	
	Introductions, Background and Overview of Maraviroc's Role in Treatment-Naïve Patients	**Howard Meyer, M.D.**
	Study A4001026 Efficacy	**Jayvant Heera, M.D.**
	Study A4001026 Safety	**James Goodrich, M.D., Ph.D.**
	Study A4001026 Microbiology	**Michael Westby, BSc, Ph.D.**
	Conclusions	**Howard Meyer, M.D.**
9:30 a.m. – 10:00 a.m.	Questions of Clarification to Sponsor	
10:00 a.m. – 10:15 a.m.	**Break**	

FOOD AND DRUG ADMINISTRATION (FDA)
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Antiviral Drugs Advisory Committee (AVDAC)
The Inn and Conference Center, University of Maryland University College
3501 University Boulevard, East, Adelphi, MD
October 8, 2009
AGENDA

The committee will discuss an efficacy supplement for new drug application (NDA) 022–128, maraviroc 300 milligram tablets, Pfizer, Inc., proposing a new indication for the treatment of antiretroviral-naive patients with chemokine (c-c motif) receptor 5 (CCR5)-tropic human immunodeficiency virus (HIV).

10:15 a.m. – 10:45 a.m.	**FDA Presentation**	**Poonam Mishra, M.D.** Medical Officer DAVP, OND, CDER, FDA
10:45 a.m. – 11:00 a.m.	Clarifying Questions for FDA	
11:00 a.m. – 12:00 p.m.	Open Public Hearing (OPH) Session	
12:00 p.m. – 1:00 p.m.	**Lunch**	
1:00 p.m. – 1:15 p.m.	Charge to the Committee	**Debra B. Birnkrant, M.D.** Director Division of Antiviral Drug Products Office of New Drugs, CDER, FDA
1:15 p.m. – 4:00 p.m.	Questions for Discussions	
4:00 p.m.	**Adjournment**	