**FOOD AND DRUG ADMINISTRATION (FDA)**
**CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)**
**ANTIVIRAL DRUGS ADVISORY COMMITTEE MEETING**
FDA ADVISORS AND CONSULTANTS STAFF CONFERENCE ROOM, RM 1066
5630 FISHERS LANE; ROCKVILLE, 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).

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

**APPLICANT PRESENTATION**

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

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# AGENDA

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**FDA PRESENTATION**

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