The committee will discuss pathways for the development of drugs intended to treat variola virus infection (smallpox) in the event of an outbreak, including the use of animal models of other orthopoxviruses (the group of viruses that includes smallpox) as potential evidence of efficacy.

Day 1: Wednesday, December 14, 2011

8:00 a.m. Call to Order and Introduction of Committee
Acting Chair, AVDAC

8:05 a.m. Conflict of Interest Statement
Paul T. Tran, R.Ph
Designated Federal Officer, AVDAC

8:10 a.m. FDA PRESENTATIONS
Debra Birnkrant, M.D.
Director
Division of Antiviral Products (DAVP)
Office of Antimicrobial Products (OAP)
Office of New Drugs (OND), CDER, FDA
Health and Human Services (HHS)

Welcome and Introduction

Historical Perspective on Smallpox

8:40 a.m. SPEAKER PRESENTATIONS
Smallpox Antiviral for Treatment: Public Health Perspective and Considerations

8:55 a.m. HHS Smallpox Antiviral Program

9:10 a.m. FDA PRESENTATION
The Animal Rule

9:20 a.m. GUEST SPEAKER PRESENTATION
Orthopoxvirus Phylogeny and Replication Cycle
9:55 a.m. **BREAK**

10:10 a.m. **GUEST SPEAKER PRESENTATIONS**

Mousepox (Ectromelia virus) Challenge Model

Animal Models of Poxvirus Infection
Elucidate Novel Aspects of Host-Virus Interaction

11:00 a.m. **SPEAKER PRESENTATIONS**

Susceptibility of Marmosets (Callithrix jacchus) to Monkeypox Virus

Non-Human Primate (NHP) Monkeypox Model Development

Animal Models of Smallpox NHP Challenge/Variola Virus

12:10 p.m. Clarifying Questions

12:30 p.m. **LUNCH**

1:30 p.m. **INDUSTRY PRESENTATION**  
Chimerix, Inc.

. Developing CMX001 for the Treatment of Smallpox Under the “Animal Rule”

2:00 p.m. Clarifying Questions from Committee to Chimerix

2:15 p.m. **INDUSTRY PRESENTATION**  
SIGA Technologies, Inc.

Towards Approval of a Smallpox Antiviral Drug: Challenges and Progress

2:45 p.m. Clarifying Questions from the Committee to SIGA
DAY 2: Thursday, December 15, 2011

8:00 a.m. Call to Order and Introduction of Committee

8:05 a.m. Conflict of Interest Statement

8:15 a.m. Charge to the Committee

8:45 a.m. Questions to the Committee/Committee Discussion

10:15 a.m. BREAK

10:30 a.m. Questions to the Committee/Committee Discussion

12:00 p.m. ADJOURNMENT