

**FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)**

*Antimicrobial Drugs Advisory Committee (AMDAC) Meeting
Tommy Douglas Conference Center
10000 New Hampshire Avenue, Silver Spring, Maryland
April 25, 2019*

AGENDA

The committee will discuss one or more possible pathways for approval of rabies virus monoclonal antibodies for use as the passive-immunization component of post-exposure prophylaxis (PEP).

8:30 a.m.	Call to Order and Introduction of Committee	Lindsey Baden, MD Chairperson, AMDAC
8:35 a.m.	Conflict of Interest Statement	Lauren Tesh Hotaki, PharmD, BCPS Designated Federal Officer, AMDAC
8:40 a.m.	FDA Opening Remarks	Jeffrey Murray, MD Deputy Director Division of Antiviral Products (DAVP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA
8:45 a.m.	FDA PRESENTATIONS	
	Background on Rabies and Why Monoclonal Antibodies (mAbs) are Being Developed for Rabies PEP	Tanvir Bell, MD, FACP, FIDSA Medical Officer DAVP, OND, CDER, FDA
	Neutralizing Activity of Anti-Rabies Virus Antibodies in Cell Culture	Damon Deming, PhD Virologist DAVP, OND, CDER, FDA
	SPEAKER PRESENTATION	
	Use of Animal Models in Rabies Product Development	James A Ellison, PhD Microbiologist Poxvirus and Rabies Branch U.S. Centers for Disease Control and Prevention
9:45 a.m.	BREAK	
10:00 a.m.	FDA PRESENTATIONS (cont.)	
	Clinical Trials to Evaluate Rabies mAb Cocktails as a Component of Post-Exposure Prophylaxis & A Proposed Development Pathway	Stephanie Troy, MD Medical Officer DAVP, OND, CDER, FDA

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AGENDA (cont.)

- 10:45 a.m. Clarifying Questions
- 11:45 a.m. **LUNCH**
- 1:00 p.m. **OPEN PUBLIC HEARING**
- 2:00 p.m. Questions to the Committee/Committee Discussion
- 3:00 p.m. **BREAK**
- 3:15 p.m. Questions to the Committee/Committee Discussion (cont.)
- 4:30 p.m. **ADJOURNMENT**