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

DRAFT 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 Demming, PhD** Virologist DAVP, OND, CDER, FDA
	SPEAKER PRESENTATION	
	Animal Models for Evaluating Rabies Post-exposure Prophylaxis	**James Ellison, PhD** Microbiologist Poxvirus and Rabies Branch U.S. Center 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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DRAFT 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**