

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

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting
DoubleTree by Hilton Hotel Bethesda – Washington DC, Grand Ballroom
8120 Wisconsin Avenue Bethesda, Maryland
May 1, 2018

AGENDA

The committee will discuss new drug application (NDA) 208627 for tecovirimat, sponsored by SIGA Technologies Inc., for the proposed indication of the treatment of smallpox disease caused by variola virus in adults and pediatric patients. This product was developed under the Animal Rule (21 CFR part 314, subpart I).

10:00 a.m.	Call to Order and Introduction of Committee	Lindsey R. Baden, MD Acting Chairperson, AMDAC
10:05 a.m.	Conflict of Interest Statement	Cindy Chee, PharmD Acting Designated Federal Officer, AMDAC
10:10 a.m.	FDA Opening Remarks	Debra Birnkrant, MD Director, Division of Antiviral Products (DAVP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA
10:15 a.m.	APPLICANT PRESENTATIONS	SIGA Technologies, Inc.
	Introduction	Annie Frimm Vice President, Regulatory, Clinical and Quality SIGA Technologies, Inc.
	Unmet Need Efficacy Safety Benefit/Risk	Dennis Hruby, PhD Chief Scientific Officer SIGA Technologies, Inc.
11:00 a.m.	FDA PRESENTATIONS	
	Animal Efficacy and Human Safety	Kirk Chan-Tack, MD Medical Officer DAVP, OND, CDER, FDA
	Selection of an Effective Dose in Humans	Su Young Choi, PharmD, PhD Clinical Pharmacology Reviewer Division of Clinical Pharmacology IV (DCP IV) Office of Clinical Pharmacology (OCP) Office of Translational Sciences (OTS), CDER, FDA
11:45 a.m.	Clarifying Questions	
12:15 p.m.	LUNCH	

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AGENDA (cont.)

- 1:15 p.m. **OPEN PUBLIC HEARING**
- 2:15 p.m. Questions to the Committee/Committee Discussion
- 3:30 p.m. **ADJOURNMENT**