

**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

**DRAFT AGENDA**

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*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).*

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

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**DRAFT AGENDA (cont.)**

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

DRAFT