

**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 26, 2019

**DRAFT AGENDA**

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*The committee will discuss the safety and effectiveness of bacitracin for intramuscular injection for the treatment of infants with pneumonia and empyema caused by staphylococci shown to be susceptible to the drug, which is the only approved indication for bacitracin for intramuscular injection. The committee will also consider whether there are other uses for bacitracin for intramuscular injection that could be studied. FDA will present background information on the regulatory history of bacitracin for intramuscular injection and information on the current use of bacitracin for intramuscular injection.*

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8:30 a.m.	Call to Order and Introduction of Committee	<b>Lindsey Baden, MD</b> Chairperson, AMDAC
8:35 a.m.	Conflict of Interest Statement	<b>Lauren Tesh Hotaki, PharmD, BCPS</b> Designated Federal Officer, AMDAC
8:40 a.m.	FDA Opening Remarks	<b>Thomas Smith, MD</b> Clinical Team Leader Division of Anti-Infective Products (DAIP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA
8:50 a.m.	<b>FDA PRESENTATIONS</b>	
	Bacitracin for Intramuscular Injection: Labeled Indication and Current Uses	<b>Caroline J. Jjingo, MD, MPH</b> Clinical Reviewer DAIP, OAP, OND, CDER, FDA
9:10 a.m.	Clarifying Questions	
9:25 a.m.	<b>INDUSTRY PRESENTATION</b>	<b>Xellia Pharmaceuticals USA, LLC</b>
	Safety and Effectiveness of Bacitracin for Intramuscular Injection	<b>Tatjana Anic-Milic, MD</b> Director, Medical Affairs Xellia Pharmaceuticals USA, LLC
9:45 a.m.	Clarifying Questions	
10:15 a.m.	<b>BREAK</b>	
10:30 a.m.	<b>OPEN PUBLIC HEARING</b>	
11:30 a.m.	Questions to the Committee/Committee Discussion	
1:00 p.m.	<b>ADJOURNMENT</b>	