

**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

AGENDA

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.

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	Thomas Smith, MD 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.	FDA PRESENTATION	
	Bacitracin for Intramuscular Injection Labeled Indication and Current Uses	Caroline J. Jjingo, MD, MPH Clinical Reviewer DAIP, OAP, OND, CDER, FDA
9:10 a.m.	Clarifying Questions	
9:30 a.m.	INDUSTRY PRESENTATION	Xellia Pharmaceuticals USA, LLC
	Safety and Effectiveness of Bacitracin for Intramuscular Injection	Tatjana Anic-Milic, MD Director, Medical Affairs Xellia Pharmaceuticals USA, LLC
9:50 a.m.	Clarifying Questions	
10:15 a.m.	BREAK	
10:30 a.m.	OPEN PUBLIC HEARING	
11:30 a.m.	Questions to the Committee/Committee Discussion	
1:00 p.m.	ADJOURNMENT	