

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

QUESTIONS

1. **VOTE:** Do the benefits of bacitracin for intramuscular injection outweigh the risks for its approved indication of the treatment of infants with pneumonia and empyema caused by staphylococci shown to be susceptible to the drug?
 - If yes, please provide any recommendations concerning labeling.
 - If no, please provide your rationale.
 - Please provide any additional comments or thoughts on your vote.

2. **DISCUSSION:** Are there uses for bacitracin for intramuscular injection other than for treatment of infants with pneumonia and empyema caused by staphylococci that could be studied?