

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 13, 2017

QUESTIONS

1. **DISCUSSION:** Discuss the unmet medical need for single species specific products and the risks and benefits of the development proposals presented; please provide any additional recommendations you might have for developing such products.

2. **DISCUSSION:** While every effort will be made to perform human clinical trials, performing clinical trials for antibacterial drugs that treat a single species of bacteria when the target species infrequently causes infections will be challenging and data collected may not be interpretable or may be very limited. Should this circumstance arise, it may be useful to consider whether animal models of serious bacterial infections can provide useful information to assess the activity and efficacy of the drug. In such a situation, please discuss the following:
 - a. The types of animal models and appropriate endpoints that you think might be useful to assess the efficacy of an investigational agent.

 - b. If there is a situation where efficacy is principally demonstrated in animal models of infection and only limited clinical trial data are available in humans, how might such a product be used clinically?