

FOOD AND DRUG ADMINISTRATION  
Center for Drug Evaluation and Research  
ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE (AIDAC) MEETING

**AGENDA**  
January 9, 2003

Marriott Washingtonian Center, Grand Ballroom, 9751 Washingtonian Blvd., Gaithersburg, MD

Topic: Ranking of Antimicrobial Drugs According to Their Human Importance in Human Medicine  
(Appendix A of “Draft Guidance for Industry: Evaluating the Safety of Antimicrobial New Animal Drugs  
With Regard to Their Microbiological Effects on Bacteria of Human Health Concern”)

9:00 a.m.	Call to Order	James E. Leggett, Jr., M.D. Acting Chair, AIDAC
	Introduction of Committee	
	Conflict of Interest Statement	Tara P. Turner, Pharm.D. Executive Secretary, AIDAC
	Opening Comments	Mark Goldberger, M.D., M.P.H. Director Office of Drug Evaluation IV Food and Drug Administration
9:15 a.m.	Overview	Linda Tollefson, D.V.M., M.P.H. Deputy Director Center for Veterinary Medicine Food and Drug Administration
9:45 a.m.	Explanation of Antimicrobial Risk Assessment	Mary Bartholomew, Ph.D. Mathematical Statistician Biometrics Team Center for Veterinary Medicine Food and Drug Administration
10:15 a.m.	Ranking of Antimicrobial Drugs Relative to Their Use in Animals	Richard Carnevale, V.M.D. Vice President Scientific, Regulatory and International Affairs Animal Health Institute
10:45 a.m.	Questions from Committee	
11:00 a.m.	Break	
11:15 a.m.	Relating Food Animal and Human Antimicrobial Use	Mike Apley, D.V.M., Ph.D. Associate Professor Veterinary Diagnostic and Production Animal Medicine Iowa State University American Veterinary Medical Association

11:45 a.m.	Questions from Committee	
12:00 p.m.	Process of Ranking of Drugs by Importance in Human Medicine	John H. Powers, M.D. Lead Medical Officer for Antimicrobial Drug Development Office of Drug Evaluation IV Food and Drug Administration
12:30 p.m.	Lunch	
1:30 p.m.	Open Public Hearing	
2:30 p.m.	Summary and Charge to Committee	Mark Goldberger, M.D., M.P.H.
2:35 p.m.	Committee Discussion	
2:30 p.m.	Break	
3:55 p.m.	Concluding Comments	Mark Goldberger, M.D., M.P.H.
4:00 p.m.	Adjourn	