PHARMACOLOCY AND TOXICOLOGY/CONTEMPORARY ISSUES SYMPOSIUM
Antibiotic Use in Animal Agriculture: Implications for Human Health

21 Food and Drug Administration perspective on the therapeutic and growth enhancing use of antibiotics by the livestock industry and the fluoroquinolone resistance monitoring program. J. M. Cooper, *CVM/FDA, Rockville, MD.*

The Food and Drug Administration (FDA) is the primary federal agency responsible for ensuring the safety of the food supply. The Center for Veterinary Medicine (CVM) approves animal drugs that are effective and safe for animals and for consumers of edible products from treated animals. FDA has determined that the use of antimicrobial drugs in food producing animals is a food safety concern because of the potential to increase the level of human exposure to antibacterial drug resistance factors or enteric pathogens beyond that already experienced. The FDA has pre-approval and post-approval programs to ensure this does not occur. To fulfill pre-approval requirements, the FDA has been requiring studies on drugs used for growth promotion since the 1970s following an FDA taskforce recommendation. As a condition of approval, manufacturers of antibiotics must demonstrate that their product will not promote bacterial drug resistance if their product is intended to be administered in feed for non-therapeutic use in animals. Following our retrospective analysis of these studies, the FDA has identified areas for improvements in the design of the studies. Our challenge for the future will be to improve our current studies and to develop quantitative risk assessment models that predict adverse events associated with antibiotic usage in animals. Relative to post-approval studies, FDA, in cooperation with USDA and CDC, has been collecting surveillance information on susceptibility of *Salmonella* species isolated from animals and humans since 1995. The veterinary medical and anti-infective FDA joint advisory committee members recommended such monitoring as a condition of approving fluoroquinolones for use in food producing animals. FDA also requires sponsors of fluoroquinolone products to monitor and report animal pathogen susceptibility results. The data collected to date on FDA approved antimicrobial animal drug products indicate that the use of these products in food producing animals does not expose the public to unacceptable levels of resistant zoonotic pathogens.

22 Past and Present Use of Antibiotics in Animal Food Production. Implications of Bacterial Resistance to Antibiotics for Livestock Producers and the Animal Health Industry. V. W. Hays, *University of Kentucky, Emeritus, Lexington.*

Antibiotics have been used effectively for the past 46 years to prevent and treat diseases and as feed additives to improve growth and feed efficiency and to reduce morbidity and mortality. From the beginning of their extensive use, there has been concern regarding development of bacterial resistance and loss of effectiveness. Resistant organisms do develop through mutation or from transfer of resistance bearing plasmids (transferable drug resistance) from one organism to another. Through the selective pressure of continued use, the resistant organisms can proliferate to become a dominant portion of the complex bacterial populations in the animals and their environment. Resistance develops in bacteria as a result of antibiotic use for therapy or as feed additives to enhance performance. Limiting usage to therapy only appears to have little impact on rate or extent of resistance development. Data will be presented to illustrate extent of usage, resistance development in bacterial populations, factors that contribute to animal responses to antibiotics, and, the continued effectiveness of antibacterial agents after 46 years of usage.