March 6, 2012

Bernadette Dunham, DVM, PhD
Director
Center for Veterinary Medicine
U.S. Food and Drug Administration
7519 Standish Place
Rockville, MD 20855

SUBJ: New Animal Drugs; Cephalosporin Drugs; Extralabel Animal Drug Use; Order of Prohibition; Final Rule (FDA-2008-N-0326)

Dear Dr. Dunham:

The Infectious Diseases Society of America (IDSA) strongly supports the Food and Drug Administration’s (FDA) action to publish its order (FDA-2008-N-0326) prohibiting certain extralabel uses of cephalosporin antimicrobial drugs in certain food-producing animals and the agency’s finding that certain extralabel uses of these drugs in animals will likely cause an adverse event in humans and, therefore, present a risk to the public health. As a medical society representing nearly 10,000 infectious diseases physicians and scientists, one of our priority goals is to ensure patient access to effective anti-infective therapies. Antimicrobial agents’ effectiveness in treating infections is becoming increasingly compromised by the growing problem of antimicrobial resistance, which occurs due in great part to nonjudicious use of these precious drugs in human and animal medicine and in agriculture.

Cephalosporins are critically important in the treatment of pneumonia, meningitis, serious infections in cancer patients, complicated skin and soft tissue infections, urogenital infections, infective endocarditis, serious bone and joint infections and Salmonella infections in children. Antimicrobial resistance can complicate the treatment of patients suffering from these infections, sometimes leading to serious disability or death.

Since 2008, there have been several outbreaks of cephalosporin-resistant Salmonella linked to animal products, with the most recent being Salmonella Hadar associated with the consumption of frozen turkey patties. In addition, data from the Centers for Disease Control and Prevention show that approximately three percent of the estimated one million human Salmonella cases occurring in the United States annually are resistant to cephalosporin antibiotics. Treatment failures, including deaths, have already been reported among persons with cephalosporin-resistant Salmonella infections who were treated with cephalosporins. Therefore, reducing the current prevalence of antibiotic-resistant Salmonella infections would have a significant positive impact on the health of U.S. children and adults. There also is
evidence that the nature of cephalosporin resistance in the U.S. is changing for the worse. Researchers at the Ohio State University recently reported detecting in cattle *Escherichia coli* (*E. coli*) that produced cefotaximases, a class of enzymes capable of breaking down most cephalosporins, previously not found in food-producing animals in the U.S.

To prevent and control antimicrobial resistance, IDSA urges the discontinuation of all non-judicious antimicrobial uses, whether in humans or animals. The order of prohibition on cephalosporin drugs is an important step forward, but overall antibiotic overuse in food-producing animals continues to threaten human health. For that reason, we strongly urge FDA to go beyond the immediate order and withdraw approval, by regulation and not voluntary action, of all growth promotion and feed efficiency indications for all antimicrobials in food animals (major and minor species), and to further require that all other uses of antimicrobials be carried out under the supervision of a veterinarian and within the boundaries of a valid veterinarian-client-patient relationship. Adoption of such policies will help to end the over-the-counter sale and non-judicious use of tons of antimicrobial drugs annually. IDSA also supports efforts to clearly define the limited instances where antimicrobials may be used judiciously in food animals for purposes of disease prevention and control. Development and implementation of these policies will clearly demonstrate a commitment to sound and science-based decision-making that is backed up by scores of scientific and medical publications and will protect the health of every American.

IDSA appreciates the opportunity to comment on this important rule limiting cephalosporin use in food-producing animals. Should you have any questions, please do not hesitate to contact Irene Stephens, MPH, IDSA’s program officer for health policy, at istephes@idsociety.org or 703-299-0015.

Sincerely,

Thomas G. Slama, MD, FIDSA
IDSA President

*PAGE TWO—IDSA Response to FDA on Cephalosporin Order*