July 10, 2012

David Dorsey, J.D.
Acting Associate Commissioner for Policy and Planning
Food and Drug Administration
7519 Standish Place
Rockville, MD 20855

Re: FDA-2010-D-0094: Guidance for Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals; Availability

Dear Mr. Dorsey:

The Association for Professionals in Infection Control and Epidemiology (APIC), a nonprofit, multi-disciplinary organization representing over 14,000 infection preventionists (IPs), wishes to thank the Food and Drug Administration (FDA) for the opportunity to provide input into the Agency’s guidance document for industry on the judicious use of medically important antimicrobial drugs in food-producing animals. Our comments primarily reflect the views of our members who rely on the integrity of antibiotics to treat and prevent infections in humans and ensure patient safety.

We applaud the work of the FDA in disseminating the science that chronicles the risks to public health caused by the inappropriate use of medically important antimicrobial drugs in food-producing animals. The guidance document clearly stresses the importance and urgency of setting practices that support the conclusions of the 2011 World Health Organization (WHO) report on tackling antibiotic resistance from a food safety perspective in Europe.

APIC is concerned, however, that the FDA guidance document relies on industry to voluntarily limit its use of antimicrobial drugs in animals. Specifically, we are concerned with the lack of clarity on how these voluntary actions are to be implemented, as well as the absence of an enforcement mechanism from either the FDA or the U.S. Department of Agriculture (USDA). For these reasons, APIC recommends that the FDA prohibit the use of medically important antibiotics for growth promotion, and require veterinary approval of their uses in treatment, in order to preserve the efficacy of antimicrobials in the treatment of disease.

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As noted in this guidance document, over three decades of scientific research supports restrictions on the use of medically important antibiotics in food-producing animals to preserve the public health. We appreciate the FDA’s attention to this very important matter.

Sincerely,

Michelle Farber, RN, CIC
2012 APIC President