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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Re: FDA-2011-D-0889: Draft Guidance for Industry on New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209;

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 new animal drugs and new animal drug combination products administered to 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.

APIC is pleased that the veterinary community is being recognized for its expertise, and we support the recommendation that veterinarians provide oversight to determine whether the use of medically important antimicrobials for prevention purposes is appropriate. We encourage the FDA to work with veterinary schools to include the content of these recommendations into coursework, and determine how to increase access to veterinary services for U.S. animal husbandry programs.

APIC supports the FDA's goal to work with affected drug sponsors whose intent is to voluntarily withdraw approved products, or change the prescribing requirements for the use of antimicrobial drugs in animals. APIC encourages rapid review of all medically important antimicrobial animal drugs and combination animal drug products that are currently available



on an over-the-counter (OTC) basis. Ideally, though, we recommend the withdrawal of all medically important OTC antibiotics from the market.

APIC agrees with the FDA's recommendation that the status of OTC medically important antimicrobial new animal drugs and combination new animal drug products intended for use in food-producing animals be changed to veterinary feed directive (VFD). This would put decisions about these important drugs in the hands of trained professionals who understand the risks and benefits to the animals and to the public.

Though we appreciate that the timeline for implementation of these measures is meant to minimize impact and provide for an orderly transition, APIC encourages a timeline shorter than three years for the initial review so that necessary adjustments can begin as soon as possible. Additionally, the seriousness of the issue of antibiotic preservation necessitates a mandatory, rather than voluntary, approach for shifting the status of these drugs from OTC to VFD.

APIC believes that adoption of these recommendations will further the Agency's goals on judicious use principles. We appreciate the FDA's concern about this very important matter.

Sincerely,

A handwritten signature in black ink that reads "Michelle Farber". The script is fluid and cursive.

Michelle Farber, RN, CIC
2012 APIC President