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March 2, 2012

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

Re: FDA-2008-N-0326: New Animal Drugs; Cephalosporin Drugs; Extralabel Animal Drug Use; Order of Prohibition; Final rule

Dear Dr. Dunham:

The Association for Professionals in Infection Control and Epidemiology (APIC), an international association comprising greater than 14,000 infection preventionists (IPs), wishes to thank the Food and Drug Administration (FDA) for the opportunity to provide input into the Agency's final rule prohibiting certain extralabel uses of cephalosporin antimicrobial drugs in certain food-producing animals. APIC congratulates the FDA for supporting antibiotic stewardship in the U.S. animal husbandry industry through the prohibition of certain extralabel uses of cephalosporins in cattle, swine, chickens, and turkeys. Our comments primarily reflect the views of our members who engage in infection prevention in healthcare facilities, and rely on the integrity of antibiotics to ensure patient safety and wellness. We will provide our thoughts on the prohibition, our general concerns on this issue, as well as our recommendations for future actions to be taken by the FDA.

APIC's goal is the prevention of infections in humans. We believe that antibiotics need to be preserved for medically appropriate uses, including the treatment of infections and surgical prophylaxis, and not to enhance growth in food-producing animals. We encourage the review of all antibiotics that are being used to promote growth and compensate for the effects of unsanitary and overcrowded conditions in the food animal production industry. With regard to the specific prohibition on extralabel cephalosporin use, we support the FDA's efforts.

Currently, too many antibiotics are available without a prescription and are being administered without any veterinary oversight. Studies conducted around the world show that the use of cephalosporins in food animal production has been linked to the emergence of cephalosporin-resistant bacteria that can infect people.¹⁻⁵ Cephalosporins are among the most widely used classes of antibiotics for humans, and their effectiveness is endangered by inappropriate uses in food animal production. This increased resistance of bacteria to cephalosporins will lead to higher healthcare costs, more suffering, and needless human deaths.⁶

The emergence of multi-drug resistant bacteria is already a reality, as can be seen in a recent FDA study which found that cephalosporin-resistant strains of salmonella had increased in retail meat from 2008 to 2009.⁷ This is an example of how resistant microorganisms carried by food-



producing animals can spread to humans through consumption of contaminated food. They can also be transmitted from direct contact with animals or by environmental spread through avenues such as contaminated water.⁸

Due to these concerns, we are thankful that the FDA is taking this step to reduce the inappropriate use of cephalosporins. To ensure that the judicious use of antibiotics remains a primary goal for all interested entities, we encourage several additional steps.

Recommendation #1: APIC recommends that the FDA review extralabel administration of antibiotics to animals so that they are not administered in ways that are unapproved by the FDA.

Recommendation #2: To ensure appropriate dose, frequency, duration, and route of antibiotic administration, APIC believes that veterinarians should be consulted on all uses of antimicrobials in animals.

Recommendation #3: APIC encourages improving sanitation and animal husbandry processes, so that the health of both humans and animals are not compromised. Alternative production techniques should be adopted so that artificial growth in animals is discouraged.

Recommendation #4: APIC recommends that the FDA continue to monitor the impact of antibiotic use in food-producing animals through:

- reviews of the scientific literature;
- antimicrobial resistance surveillance data collected as part of the U.S. National Antimicrobial Resistance Monitoring System (NARMS);
- antimicrobial resistance surveillance data collected in other countries; and,
- unpublished data that has been used previously, collected as part of FDA inspection activities.

Ongoing surveillance of antibiotic resistant trends in animals and humans is important both to assess the precise impact of the cephalosporin prohibition, and to determine what future actions need to be taken for the protection of human health. We are optimistic that this prohibition will be part of a process that produces meaningful changes, and APIC greatly appreciates the FDA's leadership on this matter.

Sincerely,

A handwritten signature in black ink that reads "Michelle Farber". The signature is written in a cursive, flowing style.

Michelle R. Farber, RN, CIC
2012 APIC President

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7. National Antimicrobial Resistance Monitoring System Retail Meat Report. 2009;8. (Available at: <http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/UCM257587.pdf>).
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