



1275 K Street, NW, Suite 1000
Washington, DC 20005-4006
Phone: 202/789-1890
Fax: 202/789-1899
apicinfo@apic.org
www.apic.org

March 6, 2014

Leslie Kux
Assistant Commissioner for Policy
U.S. Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. FDA-2010-N-0155, Veterinary Feed Directive

Dear Ms. Kux:

The Association for Professionals in Infection Control and Epidemiology (APIC) applauds the efforts of the Food and Drug Administration (FDA) to streamline the Veterinary Feed Directive (VFD) program and we appreciate the opportunity to provide input on the draft proposal. APIC is a nonprofit, multi-disciplinary organization representing over 15,000 infection preventionists, whose mission is to create a safer world through prevention of infection. 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.

Revision of Veterinarian-Client-Patient Relationship (VCPR)

APIC supports the proposed definitional change to remove the current explicit VCPR provisions and replace them with more inclusive definitions that will allow greater flexibility in veterinary practice in accordance with current veterinary licensing and practice requirements.

Revision of "Category II" Drug Definition

APIC opposes the proposed revisions to the definition of Category II drugs which would eliminate the automatic classification of VFD drugs, specifically antimicrobials used in animal feed, into Category II. APIC believes that the use of antimicrobials in food-producing animals should only be accessed through licensed feed mills that are better able to handle the drugs in concentrated form. The revisions suggested by FDA would allow antimicrobials to be available through the unlicensed feed mill system, which increases the risk of inappropriate use. Though we appreciate the hypothetical concerns with supply chain obstruction due to limitations in availability of antimicrobials via licensed feed mills, APIC believes that the risks of inappropriate antimicrobial practices outweigh the potential benefit of having fluid access of antimicrobials to operators of food-producing farms.

Second, APIC opposes the proposed change to eliminate the requirement for veterinarians to specify the amount of medicated feed to be dispensed on the VFD. We believe this could lead to over-purchasing of VFD feeds, thus leading to stockpiling and unregulated use by farmers. In addition, this change has the potential to remove veterinarian oversight from the prescription of



antimicrobials. Due to this, we request that the FDA continue the practice of requiring veterinarians to specify the amount of medicated feed to be dispensed on the VFD.

Lastly, APIC supports the clarification that veterinarians may not issue a VFD verbally and appreciates the reminder that the extra-label use of any medicated feed is not permitted under Federal law. We agree that the use of digital or hardcopy prescribing allows for tracking of compliance with the VFD regulations.

Revision of Recordkeeping Requirements

APIC continues to oppose the reduction of recordkeeping to <2 years for the VFD program. This is due to our ongoing concern of the impact of inappropriate antibiotic use in food-producing animals and their effect on society. The fact that the large majority of producers and veterinary practices are moving to electronic recordkeeping suggests that the impact of a 2-year recordkeeping requirement will have minimal impact on farmers, but would allow for longitudinal public health investigations in the future.

In conclusion, though we appreciate that the proposed changes are intended to improve the efficiency of the program, we are concerned that the adjustments may allow more widespread use of antimicrobial drugs with less oversight by licensed veterinarians. APIC looks forward to continuing to work with the FDA as it carries out its mission to protect and promote the public health by encouraging the judicious use of antibiotics in food animals.

Sincerely,

A handwritten signature in black ink that reads "Jennie L. Mayfield". The signature is written in a cursive, flowing style.

Jennie L. Mayfield, BSN, MPH, CIC
2014 APIC President