July 11, 2012

U.S. Food and Drug Administration
Division of Dockets Management (HFA–305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Submitted electronically to: http://www.regulations.gov


Dear Sir/Madam:

The Infectious Disease Society of America (IDSA) appreciates the opportunity to comment on the Food and Drug Administration’s (FDA) Guidance for Industry (GFI) 209, draft GFI 213, and the Veterinary Feed Directive (VFD) proposed rule (Proposed Rule). IDSA represents nearly 10,000 infectious diseases physicians and scientists devoted to patient care, prevention, public health, education, and research in the area of infectious diseases. The Society's members focus on the epidemiology, diagnosis, investigation, prevention and treatment of infectious diseases in the United States and abroad. Our members care for patients of all ages with serious and often life-threatening infections, including those caused by drug-resistant microorganisms.

A large body of evidence has found that the use of antimicrobials in food animals impacts antimicrobial resistance in human pathogens. IDSA is alarmed at the increasing proportion of highly-resistant pathogens that are causing human disease today. We are certain that careful antimicrobial stewardship in agriculture will have a significant impact on human health. Unless we are able to radically change the way we use antimicrobials we face an imminent entry into a “post-antibiotic” era.

We recognize that there have been challenges in the United States regarding elimination of antimicrobials for production purposes in food animals and in ensuring the judicious use of antimicrobials for other purposes in food animals, such as prevention of infection. For that reason, IDSA commends FDA for moving forward with measures to encourage judicious use in animals of antimicrobials important to human health. The FDA GFIs and Proposed Rule represent critical steps toward more appropriate antimicrobial use in food animals.
In particular, IDSA strongly supports the two main objectives of Guidance 209, i.e., elimination of antimicrobial use in food animals for production purposes (i.e., for growth promotion and feed efficiency), and the placement of all food animal antimicrobial use under the control of a licensed veterinarian. IDSA strongly supports the standard that a veterinarian who authorizes food animal antimicrobial use (whether by prescription or VFD) should have specific knowledge of the circumstances of use, to allow the veterinarian to make a valid professional judgment regarding the appropriateness of the use. This is addressed in draft GFI 213 and the accompanying VFD document by the requirement that the approving veterinarian meet applicable licensing requirements, which include holding a license in the state of use and therefore, by implication, practicing within the state's veterinarian client-patient relationship (VCPR) requirements. We regard these provisions as being very important to maximize the likelihood of judicious use under professional veterinary supervision.

Regarding GFI 213, IDSA recognizes there are advantages of using a voluntary approach in seeking companies to remove non-judicious uses from drug labeling, etc., but we also know there is a definite risk that companies may choose not to follow the guidance. Therefore, we urge FDA to assess whether there is timely compliance with GFI 213. Further, we implore FDA to be prepared to move forward, even before the 3-year deadline for compliance is reached, with regulations, if it appears that each and every company will not fully comply with the guidance. Over-the-counter and production use of antimicrobials must be eliminated, and eliminated as soon as possible.

To ensure full transparency, a goal shared by both President Obama and FDA Commissioner Margaret Hamburg, IDSA urges FDA to publish, immediately after issuing the final GFI 213 (and subsequent 90 day comment period wherein industry must respond), a list of manufacturers that have or have not agreed to remove production claims from food animal antimicrobial drugs. This level of transparency would be valuable to all stakeholders and will allow the public to gauge the progress of antimicrobial elimination in food animal production.

If the voluntary approach FDA proposes is, in fact, fully supported by industry in the end, there still remains a palpable risk that overall antimicrobial use in food animals will not significantly decrease. IDSA shares the concern expressed by many other stakeholders that non-judicious production uses will simply be “repackaged” under the ruse of “prevention”. We urge FDA to monitor for this possibility and to take prompt and appropriate action if this is observed. Further, to address this, we urge FDA to invest substantially now in the collection of data on the amount and types of antimicrobials used for prevention purposes versus treatment purposes and work towards continuing a decrease in the overall amount of antimicrobials/kilogram/food animal post-adoption of GFI 213’s requirements by industry. Our goal must be to raise healthy food animals with minimal or no use of antimicrobials.

Finally, regarding the VFD Proposed Rule, IDSA supports FDA’s decision to establish an expiration date for VFD orders for food animal antimicrobial use, but we are concerned with the selection of 6 months as the proposed expiration term. We encourage FDA to shorten this term to 90 days, which is sufficient for many VFD orders and would serve to further encourage appropriate antimicrobial use by requiring a reassessment of need after 90 days. Further, IDSA encourages FDA to stipulate that VFD records should be retained for at least 2 years. Monitoring
of antimicrobial use is an important component of antimicrobial stewardship whether in the human or veterinary setting. Because the FDA may be unable within a one-year time-frame to visit feed mills to review VFD records, the records should be kept for a longer period of time.

Again, IDSA appreciates the opportunity to comment and for FDA’s on-going efforts to eliminate non-judicious uses of antimicrobials in food animals.

Sincerely,

Thomas G. Slama, MD, FIDSA
President

cc: Margaret Hamburg, MD, FDA Commissioner
    Bernadette Dunham, DVM, PhD, Director, CVM