

PolicyPennings by Daryll E. Ray & Harwood D. Schaffer

FDA's final rule on the use of antibiotics in livestock production

The publication of the Veterinary Feed Directive (VFD) final Rule by the US Food and Drug Administration (FDA) on Wednesday, June 3, 2015 puts in place the final step toward prohibiting the use of medically important antimicrobial drugs in food-producing animal for production purposes (<http://tinyurl.com/oz98y2w>). Once the final rule is fully in effect these drugs “can only be used for therapeutic purposes with the supervision of a licensed veterinarian.”

The VFD has two purposes: 1) to improve the efficiency of the VFD program which was instituted in 1996 and 2) “reducing the unnecessary use of [medically important antimicrobial drugs] in animals and ...slowing or preventing the potential for the development of bacterial resistance to antimicrobial drugs administered through medicated feed.”

“The VFD is the third of three core documents that FDA is using to announce and implement its policy framework for the judicious use of medically important antimicrobial drugs in food-producing animals.” In April 2012, the FDA issued Guidance for Industry (GFI) #209, “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals,” (<http://tinyurl.com/352ks4e>) which called for measures “eliminating the food and water use of [these drugs] for production purposes...and bringing all remaining therapeutic uses under the oversight of licensed veterinarians.”

“The second document, GFI #213, entitled ‘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,’ (<http://tinyurl.com/7cx4q72>) published December 2013, outlined a detailed process and timeline for implementing the measures identified in GFI #209.

“Once GFI #312 is fully implemented, affected feed-use antimicrobial drugs are expected to transition from over-the-counter (OTC) to VFD marketing status. Given that most of the products affected by this effort are feed-use antimicrobial drugs this VFD regulation [the third document] plays an important role since it outlines the requirements associated with veterinary authorization, distribution, and use of VFD drugs in animal feed.

“The VFD drug process as outlined in [the] final rule includes important controls regarding the distribution and use of VFD drugs. In addition to providing

accountability, [the] final rule also updates the VFD requirements to improve the efficiency of the process. These regulatory enhancements are important for facilitating the transition of a large number of OTC feed-use antimicrobial drugs to their new VFD status.”

The implementation of the VFD final rule is one of the most significant changes the FDA has made with regard to the on-farm use of antimicrobial drugs. As a result, “FDA intends to use a phased enforcement strategy for implementation of [the] final rule as OTC drugs become VFD drugs under GFI #213.

“FDA first intends to provide education and training for stakeholders subject to [the] final rule such as veterinarians, clients (animal producers), feed mill distributors and other distributors. Such education and training efforts are important for supporting effective implementation and compliance with the final rule.”

“FDA will then engage in risk-based general surveillance, as well as for-cause inspection assignments. FDA intends to use information such as history of VFD use and the volume of VFD feed being produced to focus inspectional resources within the industry based on risk.”

When the FDA issued the proposed rule in December 2013, it provided members of the public with the opportunity to submit comments. Over 2,000 comments were submitted to the FDA. The FDA uses 17 of the 27-page VFD final rule to address a total of 51 comment areas relating to “specific points related to this rulemaking.”

While some of the comment discussion is tedious, we believe that it would be useful and informative for veterinarians, livestock operators, feed mill operators, and other interested members of the public to take time to read the comments and FDA's responses.

The comment responses provide significant insight into the thinking of FDA and what they will be looking for when the rule becomes effective on October 1, 2015.

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