FEATURE

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Changes in Progress for Producers, Veterinarians and Feed Mills

Big adjustments are in the works for livestock operators due to the U.S. Food and Drug Administration's (FDA) June 2015 announced Veterinary Feed Directive (VFD) changes, set to be fully implemented by Jan. 1, 2017. While January is still months away, experts are recommending that all parties affected now wait until then to make the needed transitions.and maternal heterosis is advantageous to your breeding program.

The regulations, initially established in 1999, were revised in 2015 to better facilitate the VFD's expanded use under FDA's antimicrobial resistance policies, according National Grain and Feed Association Senior Vice President of Feed Services David Fairfield.

"The revised VFD requirements already are in place. The Jan. 1, 2017 date is when drug sponsors are to have transitioned the marketing status of their affected products from over-the-counter to VFD status," Fairfield says.

The rule now requires producers to administer antibiotics with a VFD marketing status through animal feed under the supervision of a licensed veterinarian to ensure the drugs are only being used when necessary to treat an infection in an animal.

"The VFD regulation only applies to drugs with a VFD marketing status that are used in animal feed. Medically important antimicrobials that are approved for use in water consumed by animals will be transitioned to prescription status effective Jan. 1, 2017," Fairfield says.

Antimicrobial resistance policies being implemented by FDA include eliminating the growth promotion use of medically important antibiotics and expanding the list of feed-grade antibiotics classified as VFD drugs. Historically, a majority of feed-grade antibiotics used in or on animal feeds have been available to producers over-the-counter, without approval from a veterinarian.

The strategy of a VFD is to promote the judicious use of antimicrobials in food-producing animals. To some, that simply boils down to "more regulations." According to the FDA, they put the rule together in the hope of minimizing oversight, taking into consideration the variety of antibiotic needs producers have.

"The actions the FDA has taken to date represent important steps toward a fundamental change in how antimicrobials can be legally used in food-producing animals," said Michael R. Taylor, FDA deputy commissioner for foods, in a news release. "The VFD final rule takes another important step by facilitating veterinary oversight in a way that allows for the flexibility needed to

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accommodate the diversity of circumstances that veterinarians encounter, while ensuring such oversight is conducted in accordance with nationally consistent principles."

The rule requires veterinarians to issue, in writing, all VFDs within the context of a veterinarian-client-patient relationship (VCPR) and specifies the key elements that define a VCPR. These key elements include that the veterinarian engage with the client (i.e., animal producer or caretaker) to assume responsibility for making clinical judgements about patient (i.e., animal) health, have sufficient knowledge of the animal by conducting examinations and/or visits to the facility where the animal is managed, and provide for any necessary follow-up evaluation or care. The final rule requires veterinarians to follow state-defined VCPR requirements; in states where the FDA determines that no applicable or appropriate state VCPR requirements exist, veterinarians will need to issue VFDs in compliance with federally defined VCPR requirements.

"The point is two-fold. First, because the VFD is written and signed by your veterinarian, use of the medicated feed cannot be approved by a phone call. You had better give your veterinarian time to get the documents submitted prior to your need for the medicated feed. Secondly, the VFD is submitted to the feed supplier, with a copy going to the producer, and a third copy remaining with the veterinarian. This is certainly an additional layer of management which hasn't been required before, but for all parties to demonstrate that the sale and the use of the product was legal, the paper trail must be in place throughout the system," Chris Reinhardt, extension feedlot specialist at Kansas State University, says.

For the most part, the label-approved uses of medications won't change. The VFD is designed to curtail unapproved uses of some products, because a veterinarian must sign off on the intended purposes of medicated feed, Reinhardt points out.

"The VFD won't change the ranching world a great deal," Reinhardt says, "but it will require some additional planning and subsequent recordkeeping. If you don't have a veterinarian involved in your operation now, or lose the ability to buy certain medicated feeds in the future."

While it is hoped that the transition will be relatively simple, the American Veterinary Medical Association (AVMA) has been looking at what exactly the VFD means for veterinarians.

"Shifting away from over-the-counter status to one requiring veterinary oversight doesn't come without its challenges," Christine Hoang, DVM, MPH, CPH, assistant director of the Division of Animal and Public Health at AVMA, says.

"Now that nearly all antimicrobial feed additives will transition to VFD drugs, we want to help ensure that the VFD program is as efficient as possible, while keeping in mind the program's primary goal of protecting human health as well as animal health and welfare."

According to Fairfield, under

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FDA's antimicrobial resistance policies, the agency established that use of medically important drugs should limited to that: 1) are considered necessary for assuring animal health (i.e., medically important antibiotics should not be used to promote animal growth or to improve feed efficiency); and 2) include veterinary oversight or consultation (i.e., medically important antibiotics should not be used in the feed or drinking water of food-producing animals without veterinary oversight or consultation).

A listing of those animal drugs and drug combinations that will become subject to FDA's antibiotic-use policies and the VFD regulation is available on FDA's website (http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm390429.htm). Among the animal drugs currently not classified as being important to human medicine are wormers, ionophores, carbadox, bacitracin, bambermycin and tiamulin.

With the implementation planned by the end of the year, Fairfield points out the responsibilities for feed mills.

"That means sponsors of affected drugs are to have eliminated any growth-promotion claims associated with their products by that time. In addition, sponsors are to have transitioned the marketing status of their products so they may be distributed to animal producers only under the requirements established by the VFD regulation. Once the policy implementation is complete, the affected antibiotics no longer will be available to be distributed to animal producers on an over-the-counter basis," Fairfield says.

The added paperwork and costs have industry players working together to develop software for an easier transition.

For example, Purina Animal Nutrition is using New Planet Technologies RxExpress software to help meet feed documentation requirements for VFD. The technology is designed to streamline the VFD and non-VFD prescription processes. Simple electronic protocols prompt veterinarians to quickly and accurately produce an e-transmittable VFD or script; protocols contain unique, intelligent technology to streamline data entry and guide compliance, using a smartphone or tablet.

The FDA has put together several VFD brochures to help with the transition:

- Veterinary Feed Directive Producer Requirements
- Veterinary Feed Directive Requirements for Distributors (Who Manufacture VFD Feed)
- Veterinary Feed Directive Requirements for Distributors (Who Do Not Manufacture VFD Feed)
- Veterinary Feed Directive Requirements for Veterinarians
- Veterinary Feed Directive Requirements for Veterinarians – For Veterinary Students

These resources may be found online, at http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess.

According to the FDA, the rule will cost the industry as much as $1.41 million in one-time compliance fees. FDA expects the annual benefits of veterinarians offering more efficient feed directives to be $13,000 over 10 years, and the reduction in veterinarian labor costs due to this rule is expected to result in a cost savings of about $7.87 annually.

VFD KEY COMPONENTS

- **Producers can fill a VFD order at any mill, retailer or other establishment listed as a distributor with the FDA**
- **In order for feed mills to fill requests for feed with VFD drugs, a current VFD must be on file.**
- **A veterinarian can write a VFD order that may only apply for up to six months. The FDA will publish a list of specific products that are allowed VFD renewal.**
- **The expiration date on the VFD order is the last date the VFD feed can be fed.**
- **A copy of the VFD order must be kept by the producer for two years from the date of writing. If the farm is inspected by the FDA, producers must be able to provide VFD orders, when requested.**
- **Labels of VFD drus must have the following statement: "Caution: Federal law restricts medicated feed containing the VFD drug to use by or on the order of a licensed veterinarian.**
- **VFD feeds made at the mill will need to carry a VFD cautionary statement on their label.**