

# Changing Antibiotic Regulations

*The FDA's Veterinary Feed Directive final rule on antibiotics means changes for cattlemen.*

by Julie White

**B**y this time next year, cattlemen and their veterinarians will be gearing up for some changes in antibiotic use in animal agriculture — specifically antibiotics administered in feed and water.

The U.S. Food and Drug Administration (FDA) announced on June 2 the Veterinary Feed Directive (VFD) final rule. According to the FDA, this strategy will bring the use of these drugs outlined in the VFD under veterinary supervision so that they are used only when necessary for assuring animal health. The VFD final rule outlines the process for authorizing use of VFD drugs (animal drugs intended for use in or on animal feed that require the supervision of a licensed veterinarian) and provides veterinarians in all states with a framework for authorizing the use of medically important antimicrobials in feed when needed for specific animal health purposes.

## Addressing antibiotic concerns

In a recent webinar hosted by the National Cattlemen's Beef Association to prepare cattlemen for upcoming changes, Craig Lewis, DVM, MPH, DAVPM, of the FDA Center for Veterinary Medicine, said that antibiotic use in animal agriculture has been a subject of intense scientific and policy debate for decades — particularly as it relates to antimicrobial resistance concerns.

"Consumers and public health advocates and Congress and many other stakeholders continue to be concerned about the public health impacts," Lewis said. "FDA's guidance for industry (GFI) #152 is a qualitative risk assessment process we use in the pre-approval drug evaluation process that provides assurance that any new antibiotic products are safe. Focus of our recent efforts have been to take steps to assure that the existing antibiotics, those that predate the 2003 assessment process, are used as judiciously as possible."

The VFD final rule continues to require veterinarians to issue 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 judgments 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 will require 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. All veterinarians will need to adhere to a VCPR that includes the key elements in the final rule.

Lewis said that this document essentially has two key principles: 1) limiting the use of medically important antimicrobial drugs to those uses considered necessary for ensuring animal health and 2) limiting such drugs to uses that include veterinary consultation.

GFI #209, finalized in 2012, states the policy, and the subsequent GFI #213 provides more details on implementing the policy including definitions of "medically important" and the process for label updates and the data required to obtain approval of any new therapeutic uses.

The affected drugs in the final rule are medically important antimicrobials that are administered in feed or water and available over the counter. Those drugs that are listed but administered through other routes such as injection are not affected by GFI #213.

"The objective of veterinary oversight is not to require the vet to directly administer these drugs, but to involve them in the decision making process," Lewis explains. "Practically speaking this is changing over-the-counter to prescription or in the case of medicated feeds to VFD."

## VFD and cattlemen

What procedure will need to be taken for a cattleman to purchase and use a feed containing a medically important antibiotic like medicated mineral or medicated milk replacer?

Mike Apley, professor in the Department of Veterinary Clinical Sciences at Kansas State University, said it will start with a relationship with the local veterinarian.

"As of December 2016, all medically important antibiotics used in the feed will require a VFD," Apley said. "Your veterinarian may recommend this medically important antibiotic to be contained in the feed based on a response to a disease challenge identified in your ongoing relationship with your veterinarian."

Apley cautioned that a conversation with a veterinarian

will not mean an automatic authorization. "It will initiate a conversation with your vet that will include things such as consideration of non-antibiotic alternatives and legality — does the use match the label," he said.

The legality of use is determined by whether the application complies with the label including dose, duration, indication of use, etc.

"Your veterinarian will evaluate the need for the use, the efficacy of the antibiotic use to the disease challenge and ability to meet withdrawal time before slaughter," Apley explained.

If the antibiotic is deemed appropriate for treatment, the veterinarian will complete a written or electronic VFD form. Apley said it may be a written form provided by a manufacturer of a VFD drug, a written VFD form created by the vet or one created by electronic format.

Three copies will be created and each of the parties will end up with a copy — the veterinarian, the cattleman administering the medicated feed and the designated provider of the feed.

"There is no legal use of in-feed drugs other than as provided for on the label," Apley said. "All medically important antimicrobials used in the water will require a prescription at this time."

Apley added in the webinar that the take-home lesson at this time should be that administering VFDs all revolves around the label. "Labels will be different for different products and you and your vet will need to become familiar with them," he said.

He noted veterinarians are actively engaged with the FDA Center for Veterinary Medicine in initiating the VFD process.

"They are well aware of what's coming up and are being trained on the VFD process," Apley said. "One of the best things you can do as you think through these and have questions on scenarios, talk with your vets. They are committed to their clients in working through this." **HW**

## Real-world scenarios

Mike Apley, professor in the Department of Veterinary Clinical Sciences at Kansas State University, provided a few real-world scenarios.

Q: Will I need a VFD to use milk replacer with neomycin and oxytetracycline?

A: Yes. Milk replacer is a feed and drugs that are approved to be added to milk replacers are approved as feed additives.

Q: I have a foot rot outbreak in a group of cattle. Can I use chlortetracycline in the feed to treat foot rot?

A: A veterinarian will not be able to provide a VFD for this because foot rot is not on the label use. To write that VFD would be illegal.

Q: Is a VFD required for mineral or feed with chlortetracycline for anaplasmosis prevention?

A: Yes. You will need a VFD authorization to obtain the product to add or have in that mineral or feed for that purpose.

Q: Can I use chlortetracycline or oxytetracycline in feed to treat bovine respiratory disease?

A: Yes. Your veterinarian will need to authorize that use with a VFD and will specify the number of animals, where they are located, the dose to be fed and the regimen surrounding that dose along with an expiration date for the VFD. **HW**