Among the priorities cattlemen and women balance each day, it’s a safe bet that the health and well-being of their animals is close to or at the top of the list. A producer’s animal-health and well-being program likely includes practices related to nutrition, genetics, reproduction, animal handling and more, but central to any comprehensive program is having effective tools available to prevent and control specific diseases. For producers in all segments of the cattle industry changes are coming in the way certain antibiotics are accessed and used, and now is the time to begin preparing for those changes.

FDA guidance
In order to understand the impending changes, a brief refresher on the path taken to get here is important. In April 2012, the U.S. Food and Drug Administration (FDA), the federal agency that for more than 40 years has approved labels for antibiotics, including those used in livestock and poultry, released its final Guidance for Industry 209 (GFI 209) that outlined the agency’s position on phasing out the use of medically important antibiotics in feed and water for growth promotion. Also in that document, FDA indicated that the agency intended to bring the use of medically important antibiotics in feed and water under veterinary control. FDA based its definition of “medically important” on a previous agency guidance document and includes such compounds as aminoglycosides, cephalosporins, lincosamides, macrolides, penicillins, sulfas and tetracyclines, some of which are available over the counter (OTC). Ionophores, which are not used in human medicine, and bacitracin are not included in GFI 209.

Then, in December 2013, FDA issued another guidance document, GFI 213, which spelled out the process for achieving GFI 209. It included the process for antibiotic-producing companies to withdraw growth-promotion claims from the label of products containing medically important antibiotics and how to apply for a prevention claim on the same products, which will require additional data to be sent to the agency. Dr. Gerald Stokka, associate professor of livestock stewardship, North Dakota State University, says this is a process that will take companies some time because labels for proper use need to be changed to reflect the removal of all claims for growth promotion. In addition, changes must accompany official publications in order to guide antibiotic-use manuals in feed stores and veterinary clinics. That is one reason FDA is giving companies until December 2016 with changes coming to the rules governing antibiotic use in cattle, the working relationship between producers and veterinarians has never been more important.
to make the changes. Earlier this year, FDA reported that 294 product labels were affected by the GFI documents and that the companies of all the affected products have indicated they will comply.

Also in December 2013, FDA issued a proposed rule to amend its veterinary feed directive (VFD) regulations to make them more efficient and practical for producers, and to bring them in line with GFI 209. VFD regulations were first established in the late 1990s as a mechanism to require producers to obtain veterinary approval for certain antibiotics used in animal feed. The December 2013 proposed rule would bring all medically important antibiotics from their current OTC status to VFD status. Antibiotics have historically been used in feed to prevent or treat health issues such as scour, coccidiosis, respiratory diseases, anaplasmosis, foot rot and liver abscesses. (Currently, injectable products with an OTC status will remain available as an OTC product.) The final rule is expected to be released from FDA this spring.

**A new field of play**

What does all this mean for cattle producers? Stokka says, for example, the cow-calf producer who in the past has used tetracyclines in the feed to treat respiratory disease in calves or who has used medicated milk replacer to treat calves with *E. coli* scour, or the feedlot operator who has used antibiotics to control liver abscesses will now need a VFD from a veterinarian to purchase the products. “If you don’t use a vet, you better find one you can work with. This is a new field of play,” Stokka says.

It’s a new field of play for many veterinarians too, according to Dr. Gatz Riddell, executive vice president, American Association of Bovine Practitioners (AABP). Riddell says AABP has and continues to be engaged with FDA on this process. He notes all of the association’s comments pointed out that cattle veterinarians have had little experience writing VFDs in the past and that educational materials and training will be crucial in the implementation of the new regulations. Riddell says AABP urged FDA to make VFD forms electronically transmittable and reduce the recordkeeping requirements from two years to one to be consistent with current recordkeeping requirements for feed mills. Riddell also says AABP urged the FDA to remove the requirement that the total amount of feed to be consumed be a necessary part of completing the VFD form.

Dr. Sam Ives, feedlot research group professor, West Texas A&M University, agrees, saying training will be necessary to understand how inclusions are figured. Since the extra-label use of VFD products is strictly prohibited, when completing the VFD order the veterinarian will be required to make sure the VFD is consistent with the approved application of the product. That means understanding how the products can be mixed into specific feed rations.

While the proposed rule will result in reclassification of some products from OTC status to VFD status, Riddell says FDA committed early in the process that the change will not result in a supply chain disruption. “FDA committed that if ‘you can get that feed from an unlicensed feed mill, once the VFD regulations go in place, you will still be able to get that feed from that source; you’ll just have to have a VFD order from a veterinarian,’” he says.

Additionally, the proposed VFD states that a “licensed veterinarian may only issue a VFD for the use of VFD drugs in animals ‘under his or her supervision or oversight in the course of his or her professional practice, and in compliance with all applicable veterinary licensing and practice requirements.’” This is a more objective definition than the current VFD regulation, and the proposal would allow individual states to adjust their own criteria to align with local needs and capabilities.

While the final VFD rule may be published soon, Riddell says part of educating veterinarians requires knowing what the VFD forms look like. That, in itself, presents a challenge because the VFD form is part of the label, and he says most of the labels may not be available until they are approved by FDA, which probably won’t happen until very late in the process — possibly as late as December 2016. Riddell says the AABP’s educational focus would benefit if a generic “strawman” label were created. “Whether it’s a paper copy, a mobile app or another electronic service, hopefully we’ll have that. We’d like to develop slide sets or videos that provide use-specific guidance for correct generation of a VFD by the herd’s veterinarian of record. It doesn’t take away the art of diagnosing and the management skill acquired by the producer, but it just puts into black-and-white terms how you would go about filling out a VFD for a product in this situation,” he says.

**Don’t sit and wait**

While all of the details and new requirements under the VFD regulation are not finalized yet, Riddell says producers and veterinarians can begin preparing today. “The first step for producers is to make a list of all the antibiotics you’ve used over the last couple of years and those you expect to use during the next couple of years. That list should include what may be used and why it would be considered necessary. Plan for a year and a half from now about what you think you will use,” Riddell says.

The next step for producers is finding a veterinarian to talk to about the list. “Find somebody you can work with on that. That may be a big ask because there are probably some producers who do not want to have a veterinarian on their place. Today, that may be OK, but in another year and a half, that’s going to make life a lot harder. The general or consuming public expects things of our industry and profession that they didn’t expect 10 years ago,” Riddell says.

For veterinarians, it goes back to the same list. “Go to producers and review points one and two. That’s a starting place. We can complain about everything we want, but if we’re going to prepare for that date (December 2016), we need to know what we’re using and who we can talk to in order to get the animals under our care the antibiotics needed to maintain health and well-being,” he adds.

For information on the proposed rules, visit fda.gov/Animal-Veterinary/DevelopmentApprovalProcess/ucm071807.htm.

*This is the first in a multi-part series related to upcoming changes to regulations governing antibiotic use in the cattle industry.*