Antibiotics on the Farm

What you need to know about new regulations

By Tony Nye

On January 1, 2017, the new U.S. Food and Drug Administration (or FDA) regulations addressing on-farm antibiotic use in food-animal production will take effect. The agency's effort is aimed at eliminating the use of antibiotics that are "medically important" in treating human illnesses for growth promotion purposes in food-animal production. These upcoming regulations will also cover therapeutic use in feed and water to treat, control, or prevent specific disease under additional veterinary oversight. Producers, veterinarians, feed mills, and suppliers will all face these new requirements.

There is great debate about antibiotic use in farm animals. If you have ever raised animals, you know that there can be situations that may require treatment with antibiotics for the benefit of the animal's health. The use and distribution of antibiotics in animal production is facing changes, and all producers, both big and small, need to begin to adapt to regulations that are already in place as well as those that will change the first of next year.

Who's included

The FDA's new regulations have defined all sectors of animal agriculture—from drug companies and producers to veterinarians and feed mills—that need to collaborate to implement the new FDA antibiotic regulations.

■ **Guidance 209:** In 2010, the FDA outlined its intent and recommendations regarding growth promotion uses of medically important antibiotics in food animal production. The FDA also specified that veterinarian oversight will increase for the remaining therapeutic applications (e.g., prevention, treatment, and control) of medically important antibiotics. This action applies to both feed-grade and water-based antibiotics.

■ **Guidance 213:** On December 11, 2013, the FDA initiated a three year transition process to complete its food-animal antibiotic strategy. This action requests animal-health companies to outline intentions to voluntarily remove any production/growth promotion uses from product labels of medically important antibiotics. The guidance also eliminates over-the-counter status of these medications and increases veterinary oversight for on-farm therapeutic use by requiring a veterinary feed directive (or VFD) for feed applications and a prescription for water treatments. Implementation must be completed by January 1, 2017.

■ **Final VFD Rule:** On June 3, 2015, FDA announced the final VFD rule. The final rule outlines specific requirements of the VFD process for medically important feed-grade antibiotics.

What does this mean for animal agriculture?

Farmers must work with a licensed veterinarian with whom they have an established veterinarian-client-patient relationship (or VCPR, covered in detail in the August 2016 issue of *AcreageLife*)

in order to receive permission to order and use feed containing a VFD drug. The veterinarian's primary role is to advise and guide the producer (or client) in determining which medications are appropriate for their animals (the patients). This relationship must be established and recognized by the veterinarian prior to any VFD order being written. Feed distributors will require a valid VFD, provided by the veterinarian, prior to supplying customers with the regulated feed product. VFDs will need to be renewed every six months according to the renewal guidelines set by FDA.

So far, only a small number of antibiotics (tilmicosin, florfenicol, and Avilamycin) have been restricted in feed-grade use under a VFD. While some industries, like swine, are very familiar with the VFD process because of the common use of Pulmotil (tilmicosin), many producers have never had to use the VFD process to acquire antibiotics. With the expansion of the rule, this will soon change as nearly all sectors of animal agriculture will be affected, including honey bees among other "minor-use" species.

Are all antibiotics affected?

It is important to note not all antibiotics will be considered VFD drugs (see Figure 1 on page 16). The use of injectable antibiotics will not be affected. At this time, FDA has only moved antibiotics essential to human medicine and being fed to animals to VFD status. Also, as a part of the new FDA changes, water soluble antibiotics, which are important to human medicine, will now require a prescription from a veterinarian. This transition of water soluble drugs will include Aureomycin water soluble concentrate (chlortetracycline).

Figure 1. Present listing of in- and on-feed antibiotics outside of VFD directive*

Carbodox
Ractopamine
Bambermycin
Melengestrol
Ionophores (e.g., Lasalocid and monensin)
Decoquinate
Tiamulin
Fenbendazole
Bacitracin
Amprolium

*Unless used in combination with a VFD drug.

(Source: Michigan State University Extension)

The basics of on-farm VFD compliance for producers

The biggest change for producers, veterinarians, and feed mills will be the expanded VFD process. While the current VFD regulation may offer some familiarity with the compliance process, the new FDA rule will require some additional time and effort on the part of both producers and their veterinarians.

What to do

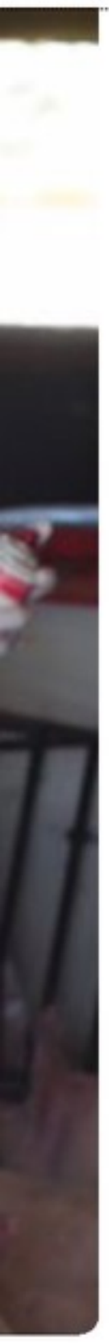
Here are some key steps required to comply:

- The issuing veterinarian is required to keep the original VFD, while the feed mill/distributor and producer (client) must each keep a copy of the VFD. Hardcopy or electronic versions are allowed
- The VFD and records of the related feed distribution must be kept for a period of two years
- Each VFD includes a specific expiration date. Any VFD feed remaining after its related VFD has expired may not be fed to animals without obtaining a new VFD. This would include any remaining feed in a bin or feeder

Where do you begin?

The new FDA antibiotics regulations will require livestock producers to have a valid VCPR. In the simplest terms, this means a livestock producer will need to have a good relationship with their veterinarian and expect to spend more time in developing a plan that satisfies all VFD requirements. As for the veterinarian's role, he or she must be familiar with the operator's production practices and herd health profile.

Talk with your veterinarian about using any antibiotics that fall under the new VFD requirement. Most antibiotics labeled for food animal use will be affected by the VFD rule, while a few, such as those listed in Figure 1, will not be affected.



Remember, there will be **record keeping requirements at all levels**. Producers, veterinarians and feed processors will all need to be especially diligent in keeping records associated with VFDs and prescription water antibiotics once FDA's new policies go into effect.

The types of records FDA will require include things like the number of animals, reason for treatment, product name, and who administered the treatment. The record-keeping commitment will involve keeping hard copies or electronic versions of all VFDs for two years and one year for all prescriptions. The issuing veterinarian will maintain the originals for the same amount of time. Distributors who manufacture VFD feed also will keep VFD copies for two years. Any of the parties must be able to provide the VFD orders (and prescriptions) to FDA upon request.

To help you as a livestock producer be compliant with the new regulations, here is a recap of steps you should take:

- Understand the new feed (VFD) and water (prescription) rules
- Strengthen your VCPR. Schedule periodic herd visits with your veterinarian and review health monitoring and herd health strategies
- Communicate with your feed mill
- Assess your herd health and welfare strategies. Sit down with your veterinarian to outline production and management changes to maximize animal health and minimize antibiotic use
- Renew your commitment to responsible antibiotic use
- Ensure your record-keeping compliance. For producers, this means keeping copies (print or electronic) of VFDs for two years and prescription records for one year.

About the author

Tony Nye is the state coordinator for the Ohio State University Extension Small Farm Program and has been an OSU Extension Educator for agriculture and natural resources for 29 years, currently serving Clinton County and the Miami Valley EERA. Tony and his family also own and operate a small livestock farm in Washington Court House, Ohio, raising purebred swine and meat goats.