Preparing for the new FDA Veterinary Feed Directive guidance
Soren Rodning, DVM, MS, Extension Veterinarian and Assistant Professor
Kim Mullenix, MS, PhD, Extension Beef Systems Specialist
Alabama Cooperative Extension System and Auburn University

Background
The use of antibiotics in food animals is heavily scrutinized, in part, because of the concern that such usage may facilitate development of antimicrobial resistance to drugs that are important for treating human disease. In response to such concerns, the U.S. Food and Drug Administration (FDA) is in the process of implementing new guidelines related to the use and availability of antimicrobial drugs administered to food animals through feed. The new guidance is currently being implemented, and by December 2016 all antimicrobials administered to livestock in feed will require a Veterinary Feed Directive (VFD). A VFD is like a prescription written by a veterinarian for antimicrobial drugs administered through feed. The following are some frequently asked changes regarding these guidelines:

What is a “VFD drug”? A “VFD drug” is a drug intended for use in or on animal feed that is limited to use under the professional supervision of a licensed veterinarian.

What is a “combination VFD drug”? A "combination VFD drug" is an approved combination of new animal drugs intended for use in or on animal feed under the professional supervision of a licensed veterinarian, and at least one of the new animal drugs in the combination is a VFD drug.

What are antimicrobial drugs and what is antimicrobial resistance? Antimicrobial drugs treat infections from a variety of microorganisms (bacteria, viruses, fungi, parasites). An antibiotic is a specific type of antimicrobial that is effective against bacteria. All antibiotics are antimicrobials, but not all antimicrobials are antibiotics.

Antimicrobial resistance occurs when bacteria or other microorganisms become resistant to the effects of a drug. This means that the drug, and similar drugs, will no longer be effective against those microorganisms. Antimicrobial resistance is a complex phenomenon with many causes. Antimicrobial usage, whether in humans or animals, can likely facilitate the development of resistance, but resistance can also occur spontaneously.

What is the FDA doing? In December 2013, the FDA began taking action to further promote the judicious use of ‘medically important’ antimicrobial drugs in food animals. ‘Medically important’ antimicrobials are those also used to treat human disease. The new FDA guidance was proposed to improve upon existing guidelines regarding Veterinary Feed Directive drugs. The FDA’s goal is to work with animal agriculture in an effort to protect public health by phasing out the use of medically important antimicrobials in food animals for production purposes (e.g., to enhance growth or improve feed efficiency) and to bring the therapeutic uses of such drugs (to treat, control, or prevent specific diseases) under the oversight of licensed veterinarians.

The FDA is requesting that animal drug companies revise product labeled uses for medications administered via feed and/or water by (a) removing the use of antimicrobial drugs for production purposes (e.g., to enhance growth).
growth or improve feed efficiency); (b) add, where appropriate, scientifically-supported disease treatment, control or prevention uses; and (c) change the marketing status from over-the-counter to Veterinary Feed Directive (prescription) for all medically important antimicrobials administered through feed or water which will then require veterinary oversight or consultation.

The FDA is focusing on antimicrobial drugs that are:
- Medically important (i.e., important for treating human disease);
- Currently FDA-approved to be used for production purposes, such as to enhance growth or improve feed efficiency;
- Currently available over-the-counter; and
- Used in the feed or drinking water of food-producing animals.

How will these changes impact cattle producers?
Prior to the FDA’s new guidance, most antimicrobial drugs approved for administration to livestock through their feed were available over-the-counter. This is currently changing. Once animal drug manufacturers completely revise FDA-approved labels, there will be no more antimicrobials used for production purposes (such as growth enhancement or feed efficiency) and the remaining therapeutic uses will require veterinary oversight. Any other use will be a violation of the Federal Food, Drug, and Cosmetic Act.

What drugs will be affected by the new guidance?
According to the American Feed Industry Association (AFIA), there are numerous drug compounds with more than 120 different uses that will be affected by the FDA’s new guidance. An example of a cattle drug that currently requires a VFD is tilmicosin.

Examples of cattle drugs that will soon change from over-the-counter to use only by a VFD include, but are not limited to:
- Neomycin
- Tylosin
- Virginiamycin
- Chlortetracycline
- Oxytetracycline

What drugs will NOT be affected?
Ionophores such as lasalocid and monensin (e.g. Bovatec®, Rumensin®, Pro-Bac-C), coccidiostats, and bacitracin products will not require a VFD unless used in combination with medically important antimicrobials. Ionophores are feed additives used primarily in beef and dairy cattle rations to increase feed efficiency by altering rumen fermentation patterns. They are often included in dry or liquid manufactured feeds, or in mineral mixtures. Ionophores function by selecting against or negatively affecting the metabolism of certain rumen microbes that decrease digestion efficiency of feedstuffs. However, they are not used therapeutically and have a different mode of action than therapeutic antibiotics. There is also no use of ionophores as antimicrobials for humans.

How do you know if a drug is a VFD drug, rather than an over-the-counter drug?
Read the label. All labeling and advertising for VFD drugs and feeds containing VFD drugs must display the following cautionary statement: "Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian." Over-the-counter (OTC) drugs do not have this statement.
What to expect once these changes are fully implemented:
A VFD must be obtained from a licensed veterinarian before a producer may use feeds containing antimicrobials that are medically important to human health. Two important facts to remember:
1. A veterinarian can write a VFD that may only apply for up to six months. Note that the expiration date of the VFD and the duration of use for the drug or combination may not be the same. The duration of use is the length of time the drug may be fed to animals, and can be shorter or longer than the VFD.
2. Veterinarians, feed suppliers, and producers must keep a copy of each VFD for two years.

How can you prepare for these changes?
1. Either initiate or maintain a working relationship with a veterinarian so that when antimicrobials need to be administered through feed or water you have access to a veterinarian that can prescribe the proper treatment.
2. Make a list of all current medications administered through feed and water on your farm and discuss these with your veterinarian to determine which ones will soon require a VFD.