Sheep Producers and the Veterinary Feed Directive (VFD)

Brad R. LeaMaster, DVM, MS, PhD
Oregon State Veterinarian

The U.S. Food and Drug Administration's (FDA's) new Veterinary Feed Directive (VFD) rules for managing antibiotic use in livestock will go into full effect Jan. 1, 2017, less than one year away. Now is the time for producers to educate themselves and determine how the regulations will impact their operations so there are no surprises.

History

The driving force behind the VFD concept is the concern for antibiotic resistance that has occurred in many species of bacteria. The antibiotic resistance topic is real, complex, and not completely understood. Research on this subject is ongoing. However, it is recognized that the agricultural use of antibiotics does play a role in the phenomenon. There is a national concern that extended use of antibiotics, such as for growth promotion purposes, allows bacteria to develop resistance.

Over a decade ago the decision was made nationally to move toward removing all antibiotics important in human medicine from being used in livestock that was associated with growth promotion, increased feed efficiency, or other long-term use. The FDA has indicated that all uses of medically important antibiotics (i.e., for humans) in feed for food-animals are to be under veterinary control. Basically, medically important antibiotics include everything we use in food animals except for the ionophores (i.e. monensin, lasalocid), bacitracin, bambermycins, coccidistats (eg. decoquinate) and the pleuromutilins (tiamulin, used in swine). The VFD concept became the option for restricting extended uses of antibiotics but allowing for fundamental feed antibiotic use in livestock for therapeutic reasons. Antibiotics approved for use under the VFD regulations will be for "prevention", "treatment" and/or "control" of specific bacterial diseases.

The current focus is on antimicrobials delivered in feeds that are deemed to be medically important for humans. This does not preclude a broadened approach in the future. The label for the medicated feed item must state whether the additive is a VFD drug or not.

What is a VFD?

A VFD is a written order (paper or electronic) by a licensed veterinarian approving the use of a VFD listed medication. The difference between a VFD and a veterinary prescription is that a VFD is not governed by a state's "Board of Pharmacy." A VFD simplifies the requirements for inventory control, dispensing and required records. A VFD permits feed manufacturers to possess and distribute VFD drugs. VFD regulations do not apply to injectable antibiotics.

The VFD topic can be a bit confusing at first. Antibiotics in feed will require a VFD. Water-soluble drugs will require a prescription (Rx). A VFD and Rx are different documents but both require a licensed veterinarian for issuance. A listing of the prescription water-soluble drugs can be found at the following link: http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm482106.htm

What does the VFD rule do?

The VFD rule and associated FDA Guidance documents accomplish the following: 1) ends the use of medically-important antimicrobials to enhance livestock performance; 2) transitions many of the feed medications that are currently available "over-the-counter" (OTC) into the VFD drug category; 3) places the use of VFD animal drugs in (or on) animal feed under the professional supervision of a licensed veterinarian; and 4) requires producers to obtain written VFD orders from a licensed veterinarian to purchase and utilize the VFD antimicrobials on or in feed.

When does the VFD Regulation Take Effect?

In June 2015, the FDA published final VFD regulations in the Federal Register. The rules were implemented to promote judicious use of antibiotics, protect public health and help limit the development of antimicrobial resistance. The VFD final rule became effective October 1, 2015. Currently, feed manufactures are revising medicated feed labels to remove all feeding performance statements. The revised labels will read for use to treat, control or prevent a disease. Labeling transition will continue to January 1, 2017 when all feed grade antibiotics will require a valid VFD. Most of the drugs will transition in December 2016 to their VFD label.

Drugs Transitioning From OTC to VFD Status

Examples of medicated feed use antibiotics that are expected to be withdrawn or transition from OTC to VFD status include: Apramycin, chlortetracycline (CTC), neomycin, streptomycin, ormetoprim, hybromycin B, lincomycin, erythromycin, oleandomycin, tylosin, penicillin (currently only production uses), virginiamycin, sulfadimethoxine, sulfamerazine, sulfamethazine, sulfaquinoxaline, and oxytetracycline.

Note: Apramycin, erythromycin, neomycin (alone), oleandomycin, sulfamerazine, and sulfaquinoxaline are also approved for use in feed and are expected to transition to VFD status, but are not marketed at this time. If they return to the market after January 1, 2017, they will require a VFD.

A table of the drugs scheduled to transition from OTC to VFD status can be found at the following link:
http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm482107.htm

Current VFD Drugs

As of September 2015 there are three VFD drugs which include: 1) Avilamycin, for reduction of E. coli diarrhea in swine; 2) Florfenicol, for control of various diseases in fish and for control of respiratory disease in swine; and 3) Tilmicosin, for control of respiratory disease in cattle and swine.

This information is up-to-date as of January 19, 2016. As the industry transitions, FDA anticipates additional changes during the coming months to this information. Please check the link below for the most recent updates:
http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm

Your Veterinarian is the key person for the VFD

Veterinarians will become responsible for supervising all use of antibiotics in feed that are considered by the FDA as medically important to humans. In order for a veterinarian to issue a VFD a Veterinary Client Patient Relationship (VCPR) must be established. This relationship is an important part of the process as it will not be possible for a producer to just call any veterinarian and ask for a VFD. The veterinarian you call must know you and have knowledge of your operation.

In Oregon, a VCPR shall exist when the following conditions met: The veterinarian must have sufficient knowledge of the animal to initiate at least a general or preliminary diagnosis of the medical condition of the animal. This means that the veterinarian has seen the animal within the last year and is personally acquainted with the care of the animal by virtue of a physical examination or by medically appropriate and timely visits to the premises where the animal(s) is/are kept. A VCPR must be in place for a veterinarian to be able to legally provide treatment, prescribe medications, or administer vaccines to an animal. The veterinarian must have examined the animal within the last year in order to establish the VCPR.

How to obtain a VFD order

There are six basic steps required to obtain a VFD order: 1) Contact your veterinarian with whom you have a valid VCPR. (If a producer does not have a valid VCPR with an appropriate veterinarian, then the preliminary step is to establish a VCPR); 2) The veterinarian determines whether conditions warrant use of a VFD drug or feed; 3) If warranted, the veterinarian issues a written and signed VFD order containing information specified by regulations. Verbal orders are not allowed but electronic orders are acceptable. Incomplete and unsigned orders are invalid and cannot be filled; 4) The veterinarian retains a copy of the VFD order and gives the completed, signed original and a copy to the client; 5) The client keeps the copy and gives the original signed VFD to the feed mill/feed distributor supplying the VFD feed. (Client must keep copies of records for 2 years). The VFD order allows the feed to be released to the client; and 6) Depending on the specific VFD drug, and the conditions outlined by the veterinarian, separate VFD orders may be required for different groups of livestock.

What does the VFD mean for minor species i.e., sheep and goats?

The VFD requirements apply to all VFD drugs for use in major or minor species. Other medicated feed drugs for minor species are expected to convert from their present OTC status to VFD and at that time a VFD will be required for their use. Extra label use of VFD feed is not permitted. Regulations governing feed medications have never allowed usage other than as labeled. "Off label Use" or "Extra Label" has never been allowed and this legal requirement will continue with the use of VFD medications. For sheep producers that also have cattle and/or goats, the FDA will not allow a VFD written for sheep to be used for cattle and/or goats.

Basic Producer Responsibilities

In preparing for the full implementation of the VFD regulations contact your veterinarian for consultation and guidance. This establishes the very important association that is required to establish a VCPR. By all means, follow your veterinarian's recommendations. The FDA will conduct spot checks and you don't want to be caught with violations. Administer the VFD medicated feed according to the directions on the VFD order and keep copies of your VFD orders for at least two years. (Be prepared to provide your VFD order copies for FDA inspectors to copy and review, if requested). Plan ahead and let your vet know about upcoming management issues that may require a feed use antibiotic. Examples might include weaning related health issues, anticipated purchases (common to have stress induced respiratory disease associated with new purchases) or a seasonal endemic disease such as chlamydial abortions.

Visit with your vet about how a VFD medication will be obtained on a timely basis through your feed distributor. Contact your feed supplier so that you know the order minimums and the time it takes to make a VFD feed. Some stores and vets plan to floor stock some VFD medicated feeds and some will have to be made on demand. Communicate your needs ahead of time with your suppliers. I suggest OSGA to consider assembling a list of mills in Oregon that will be doing VFDs. This information could be posted on OSGA's website and would be very beneficial to the entire membership.

Conclusion

In conclusion, remember that VFD regulations only apply to antibiotics used in feed. They will not affect other feed use medications such as ionophores, non-antibiotic coccidiostats, or other parasite and insect control drugs. VFD regulations will not apply to antibiotics used by injection, tablet, bolus or water. (Remember, the use of antibiotics in water will require a prescription not a VFD).

For sheep producers, chlortetracycline and some sulfa's used as coccidiostats are going to be of concern. They will need a VFD for the chlortetracycline and for the sulfamethazine in feed form. The VFD regulations will require more paperwork, will

increase vet costs, will decrease producer access to antibiotics and will result in significant changes to management practices for producers.

There are many sources of information pertaining to the VFD available online. Spend some time educating yourself on this important topic to avoid last minute misunderstandings and possible delays in acquiring necessary medicated feed.