Veterinary Feed Directives

What beef cattle producers need to know about the upcoming federal regulatory changes for medicated feeds

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Introduction

In order to limit the use of some antimicrobials in livestock production, the U.S. Food and Drug Administration (FDA) has published a final ruling that will affect the way antimicrobials can be used by livestock producers. As of January 1, 2017, all antimicrobials that are considered by the FDA to be important for human medicine 1) will no longer be able to be used for growth promotion and feed efficiency, and 2) will require a veterinary feed directive (VFD) for use for treatment, prevention or control of a disease. Although there are many unknowns in terms of how these changes will affect the availability of some medicated feeds, the following publication outlines the currently available information that livestock producers need to know and is focused primarily toward beef cattle producers.

Background

Medicated feeds are valuable tools that can be utilized by beef cattle producers for various health or production reasons. Such reasons include the treatment, control or prevention of certain diseases, or for growth promotion and feed efficiency. Antimicrobials are only one of many types of drug used in medicated feeds, and include any drug that destroys or inhibits the growth of microorganisms. All antibiotics that are administered to animals are considered antimicrobials. All drugs that are used in medicated feeds (officially referred to as *new animal drugs* by the FDA, regardless of their "age"), including antimicrobials, are evaluated by the FDA prior to their approval for use in the U.S. This approval process is used to determine if the new animal drug meets a number of requirements focused on the health and safety of humans, animals and the environment. If, and only if, the drug meets or exceeds these requirements is the drug approved and legally marketed for use in medicated feeds. Approved drugs are then continuously regulated and monitored by the FDA.

A number of antimicrobials are currently available for purchase over the counter (OTC) for treatment, control or prevention of disease, or for growth promotion and feed efficiency. Antimicrobials that are labeled for OTC use are often available for purchase directly through feed retailers or other venues and do not require a veterinary prescription for purchase. Although antimicrobials administered through feed and water have been used safely and effectively in U.S. livestock production for more than 40 years, some of these antimicrobials are commonly used in human medicine, and are considered to be medically important by the FDA. Due to the inherent biology of microorganisms, any use of antimicrobials — whether it be for humans, pets or

livestock — has the potential to result in some degree of resistance. Antimicrobial resistance also develops naturally in the environment, and its occurrence does not necessarily require human application of an antimicrobial drug. It is important to note, however, that there have been no documented occurrences of direct transfer of antimicrobial resistance from livestock, meat or milk products to humans in the U.S. at the time of this publication.

In order to maintain the efficacy of antimicrobials (in other words, to ensure that they will work when they are called upon for use), to increase veterinary oversight of their use, and to take a proactive approach to the prevention of their contribution to antimicrobial resistance in humans, the FDA is implementing a number of regulatory changes. These changes will affect 1) the way some antimicrobials are used in livestock production, and 2) how these products are obtained by livestock producers. The impact of these changes will be dependent upon the frequency of use of antimicrobials in medicated feeds, and thus will vary widely amongst producers.

Upcoming changes

The two major upcoming federal regulatory changes that will affect beef cattle producers are 1) the removal of production claims (e.g., use for growth promotion and feed efficiency) from the label of antimicrobials that are considered by FDA to be medically important, and 2) the amendment of their previous approvals from OTC to VFD status. Under the newly defined regulations, antimicrobials used in livestock production that belong to a class that are considered medically important will only be approved and labeled for use in the treatment, control or prevention of disease.

Due to the fact that medically important antimicrobials will no longer be labeled for use for growth promotion and feed efficiency, use in such a manner will be **illegal**. Medicated feeds can only be fed to animals for their intended use as specified on the medicated feed label. The same is true for antimicrobials that are applied to drinking water. Any use of a drug in a way other than what is specified on the label is considered "off-label". Although not a new regulation, drugs that are administered to animals through medicated feeds (in contrast to some other methods of administration) can **never** be used off-label. This means that medicated feeds can only be fed for purposes and at levels that have been previously approved by the FDA. These uses are always described on the label. It is **unlawful** for a veterinarian to recommend or prescribe medicated feeds for off-label use. When used for treatment, control or prevention of disease, medically important antimicrobials will no longer be available OTC. Their use will require a VFD, which can only be issued by a licensed veterinarian with whom the producer has a valid veterinarian-client-patient relationship (VCPR).

The VFD process

In order for a VFD to be issued, the producer must have a current, valid and documented VCPR. A VCPR will allow for the veterinarian, when he or she deems appropriate, to issue a VFD without necessarily viewing the animals or making a farm visit, reiterating its importance. If the veterinarian determines that the use of a VFD antimicrobial is necessary, the veterinarian will complete and sign an original VFD form. The veterinarian will then retain the original form, and issue copies to the producer and the feed distributor. Alternatively, a veterinarian may choose to issue both copies to the producer, who will be required to deliver the distributor copy directly to the licensed feed mill or feed retailer. The original VFD form will only be able to be completed and submitted electronically or by hand. Telephone submissions will not be permitted.

The livestock producer will need to retain his or her copy of the completed and signed VFD form, and maintain it in his or her records for a minimum of two years. This reiterates the importance of establishing and maintaining good record-keeping practices. Once received by the distributor, then and only then can a VFD Type C medicated feed (the only type of VFD medicated feed that can be fed directly to animals) be issued to a producer and fed to the animals specified on the VFD form. Each state has the option to develop its own guidelines for VFD forms; however, each state will be required to follow certain guidelines mandated by the FDA. At the time of this publication, Tennessee plans to follow the guidelines mandated by FDA without implementing any additional requirements.

The VFD form will outline a number of specifications to which a producer must adhere. These include, but are not limited to the following:

- Approximate number of animals to which the VFD medicated feed will be fed
- Specific location of the animals to which the VFD medicated feed will be fed
- Required duration of feeding
- Permitted number of refills, if applicable
- Required withdrawal period, if applicable
- Expiration date

Adherence to these specifications will be crucial, as they will be **legally binding**. For example, it will be **unlawful** for a producer to feed a validly issued VFD medicated feed past its expiration date. The FDA has not yet released any information regarding proper methods of disposal for expired VFD medicated feed, which means that guidelines for handling and disposing of expired VFD medicated feeds do not currently exist. However the VFD, if executed appropriately, should result in all VFD medicated feed being fed in advance of its expiration date. Additionally, producers that use VFD medicated feeds should anticipate the potential for inspections and manage their records accordingly.

Timeline

The most recent regulatory changes, as published in the Code of Federal Regulations (CFR), went into effect as of October 1, 2015. This applies only to VFD drugs that were previously approved as VFDs, or future new animal drugs approved as VFD after October 1. These drugs include tilmicosin (Pulmotil; for swine **and cattle**), florfenicol (Nuflor; for swine and fish) and avilamycin (Kavault; for swine), which were initially approved as VFDs rather than OTC. Factors that contributed to their approval as such included label complexities and potential for misuse to result in a violative residue or the development of resistance.

Conversion of all previously approved medically important antimicrobials from OTC to VFD status will occur on or before January 1, 2017. This will include the removal of production claims from these drugs, making their use for growth promotion and feed efficiency **unlawful**. Their use as and only as VFDs for treatment, control or prevention of disease (depending upon how they are labelled) will become effective January 1, 2017. This **will** apply to any VFD drugs that were purchased OTC prior to January 1, 2017, meaning that their use for growth promotion and feed efficiency, and/or without a validly-issued VFD will be **illegal**, even if the medicated feed was legally purchased prior to the deadline.

Affected and unaffected drugs

Medically important antimicrobials that **will** be affected by these changes include all drugs that are classified as cephalosporins, fluoroquinolones, glycopeptides, macrolides, penicillins, quinolones, sulfas and tetracyclines, as well as a few others that have yet to be specified. At the time of publication of this document, a comprehensive list that includes all OTC antimicrobials that will be affected by these regulatory changes is not available. However, some of the specific antimicrobials that are commonly used in medicated feeds for beef cattle that **will** be transitioning from OTC to VFD and will no longer be available for use for growth promotion and feed efficiency as of January 1, 2017 include (but are not limited to) the following:

- Aureomycin (chlortetracycline)
- Neomycin (neomycin sulfate)
- Terramycin (oxytetracycline)
- Tylan (tylosin)
- V-max (virginiamycin)

Antimicrobials that are not considered medically important and that have been previously available OTC **will not** be transitioning to VFD status, and thus will not be affected by the new regulations. These antimicrobials will continue to be available OTC for use for growth promotion and feed efficiency, and include the following ionophores and bambermycins:

- Bovatec (lasalocid)
- Cattlyst (laidlomycin propionate)
- Flavomycin (bambermycin)
- Gainpro (bambermycin)
- Rumensin (monensin)

Use of a VFD in combination with other non-VFD drugs

In order for any drug to be used to medicate animal feed in combination with another drug, the two drugs must be approved for use in such a combination. A veterinarian **cannot** legally prescribe the use of a drug combination in medicated feed or water that has not been previously approved for such use. Although not a new regulation, this is often a misconception. Any use of a previously approved combination of drugs where one or more of the drugs is considered a VFD drug will require a VFD prior to use of the combination. This means that if a VFD drug is going to be used in combination with one or more OTC drugs, 1) their combined use must be approved by the FDA, and 2) a VFD will be required that includes all of the drugs in the combination.

Examples of how these changes may affect your operation

A few examples of how the upcoming changes may affect beef cattle operations are listed below. This is not intended to be an all-inclusive list, but rather to provide examples of some of the most common practices in beef cattle feeding programs that will be affected.

- Chlortetracycline (commonly referred to as CTC) will no longer be labeled for use for increased rate of weight gain and improved feed efficiency. This means that free-choice mineral supplements medicated with CTC (commonly marketed for cattle grazing fescue) will no longer be available for this use. Any use of CTC in feed, regardless of form (free-

choice feed, top-dressed, or in a total-mixed-ration), or in water, will require a VFD. For example, Aureomycin will no longer be available OTC, and its use for the control of bacterial pneumonia in incoming stocker cattle will require a VFD. CTC will continue to be available for use to control anaplasmosis and treat bacterial enteritis; however, this use will require a VFD.

- Oxytetracycline will no longer be labeled for use for increased rate of weight gain and improved feed efficiency. This means that milk replacers medicated with oxytetracycline, alone or in combination with another drug such as neomycin sulfate, will no longer be available for this use. Any use of oxytetracycline in feed or water, regardless of form, will require a VFD. For example, milk replacers medicated with Terramycin, alone or in combination with Neomycin, will no longer be available OTC, and their use will require a VFD.

- Tylosin will no longer be available OTC for use to reduce the incidence of liver abscesses. However it will be available for this use through obtaining a VFD. For example, feedlot rations medicated with Tylan alone or in combination with another drug (even if the other drug is still available OTC (e.g., in combination with Rumensin), will require a VFD.

- Virginiamycin will no longer be available OTC for use to reduce the incidence of liver abscesses. However it will be available for this use through obtaining a VFD. For example, feedlot rations medicated with V-Max alone or in combination with another drug (even if the other drug is still available OTC (e.g., in combination with Rumensin or Bovatec), will require a VFD.

What you can do to prepare

The following are some steps that can be taken **now** to help ensure that this transition is as seamless as possible:

- Establish and maintain a valid VCPR with your veterinarian. A VCPR in Tennessee requires that the veterinarian 1) has assumed the responsibility of making clinical judgments on your farm, 2) has examined your animals within the past 12 months, or made annual visits to the premises where the animals are kept, and 3) is readily available or has arranged for an emergency follow-up evaluation in the event of an adverse reaction to a treatment.

- Consult with your county Extension agent and veterinarian regularly about the VFD process in order to receive the most up-to-date information.

- Contact your current feed retailer or distributor to determine if they will continue to market OTC medicated feeds that will be transitioning to VFDs. Also confirm if they will continue to market specific VFDs that you have used in the past. This can serve as a good opportunity to ask if they intend to stock pre-manufactured VFDs for immediate distribution, or if the VFD medicated feed will only be manufactured upon receipt of a completed and signed VFD form. If your current retailer or distributor does not intend to market VFDs, consult with your veterinarian or county Extension agent to find one that does.

- For affected OTC antimicrobials that you have used in the past for growth promotion and feed efficiency, work with your county Extension agent and veterinarian to determine the reason why they were effective. This will help to identify the management practices that could be changed or improved upon in order to prevent their necessity. If necessary, determine which OTC products could be used as alternatives, but keep in mind that all antimicrobials, regardless of their importance for human health, should be used responsibly. If you don't need them, don't use them, and instead consider using non-antimicrobial alternatives.

- Work with your veterinarian to develop and implement a biosecurity risk management program to reduce the risk of disease transmission to and from your farm. This will ultimately help to reduce the need for antimicrobials.

- Work with your veterinarian to develop and follow standard operating procedures for adverse health events that may require the use of a VFD feed.

- If you have not already done so, establish and maintain an extensive record-keeping protocol, and put it to use.

Conclusions

Although these upcoming federal regulatory changes may affect the way some antimicrobials are used in medicated feeds on your operation, they may also yield a number of benefits. The limitation of use of medically important antimicrobials to the treatment, prevention and control of disease will help to ensure the efficacy of these drugs for both human and animal health. This may also present the opportunity for the refinement of production practices in a way that negates their necessity of use for growth promotion and feed efficiency. Ultimately, this could — and likely will — lead to the development of new and novel non-antimicrobial technologies that enhance your ability to profitably, responsibly and sustainably produce beef.

Additional online resources and information

Federal regulations, as they relate to VFDs can be found in the Code of Federal Regulations, Title 21, Chapter I, Subchapter E, Part 558, Subpart A, available online at:

- www.ecfr.gov/cgi-bin/text-idx?SID=27770310fb74d33622f93dadbbe4a753&mc=true&node=pt21.6.558&rgn=div5#sp21.6.558.a

Specific drug approvals (including approved combinations), as they relate to use in medicated feeds and water, can be found in the Code of Federal Regulations, Title 21, Chapter I, Subchapter E, Part 558, Subpart B, available online at:

- www.ecfr.gov/cgi-bin/text-idx?SID=27770310fb74d33622f93dadbbe4a753&mc=true&node=pt21.6.558&rgn=div5#sp21.6.558.b

Veterinary Feed Directive producer requirements outlined by the FDA can be found online at:

- http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm455413.htm

Guidance for industry #120, which is the most current (as of November 2015) Question & Answer published by FDA about VFDs with a target audience of veterinarians, VFD feed distributors and producers, can be found online at:

- www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052660.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery

A listing of large animal/livestock veterinary practices in Tennessee that is maintained by the Tennessee Department of Agriculture can be found online at:

- www.tn.gov/agriculture/article/ag-businesses-veterinarians

References

Code of Federal Regulations. Title 21. http://www.ecfr.gov/cgi-bin/text-idx?SID=27770310fb74d33622f93dadbbe4a753&mc=true&node=pt21.6.558&rgn=div5.

Final Rule: Veterinary Feed Directive. Federal Register. Published June 3, 2015. 80(106):31708-31735. http://www.gpo.gov/fdsys/pkg/FR-2015-06-03/pdf/2015-13393.pdf.

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