Veterinary Feed Directive

Introduction

In 2012, the U.S. Food and Drug Administration (FDA) began issuing Compliance Policy Guides (CPG) regarding antibiotic usage in animal agriculture. Compliance Policy Guide 209 established FDA's position that medically important antibiotics should not be used for production enhancement (rate of gain or feed efficiency) and that veterinary oversight should be required when using medically important antibiotics for treatment, prevention or control. Subsequently, the FDA released CPG 213 outlining the process that FDA was implementing to remove production claims from the approved label and requiring veterinary oversight via Veterinary Feed Directive (VFD). The deadline for full implementation of these label changes is January 1, 2017.

The FDA implemented these guides in response to growing concern about antimicrobial resistance. There is no direct evidence that antimicrobial usage in animal agriculture leads to antibiotic resistance in human medicine. Impending changes to FDA drug approvals will insure more veterinary oversight to optimize therapeutic efficacy and minimize resistance to antimicrobials to protect public and animal health. The new restrictions on antibiotic usage only apply to antibiotics that are considered medically important antibiotics in human medicine (Appendix A in CPG 152 and Table 1 below). Antibiotics that are NOT considered important such as ionophores, bambermycins, bacitracin, carbadox and tiamulin are not affected by CPG 209 and 213 and do not require a VFD prior to usage. The guides state that the use of medically important antibiotics for growth promotion will be eliminated, since it is deemed as non-therapeutic use of antibiotics. Many medically important antibiotics approved as feed medications have label indications for both therapeutic and growth promotion. These antibiotics will still be available with a VFD but only for therapeutic purposes, treatment, control or prevention (Table 2), since the growth promotions claims are being removed from the label.

Table 1. List of Medically Important and Non-Medically Important Antibiotics

Medically Important Classes	Non-Medically Important
Tetracyclines (CTC, OTC, Aureomycin)	Tiamulin (Denagard)
Macrolides (Pulmotil, Tylan)	Ionophores (Avatec, Bovatec, Cattlyst, Coban, Maxiban, Rumensin)
Lincosamides (Lincomycin)	Bacitracin (BMD)
Sulfas (RofenAid)	Bambermycin (Flavomycin, GainPro)
Penicillins	Carbadox (Mecadox)

Table 2. Definitions for Clinical Uses of Antibiotics

Note: Green = approved usage for VFD, Red = not allowed for medically important antimicrobials under CPG 209.

Indication	Definition
Treatment	Use of an antibiotic for the treatment of animals showing clinical signs of disease.
Control	Use of an antibiotic for the treatment of a group of animals where a percentage (usually >10% are sick) and the remainder of the group are not showing clinical signs (yet).
Prevention	Use of an antibiotic in a group of healthy animals that are known to be at risk for, or exposed to, disease agents (before clinical signs).
Growth Promotion	Improves growth or feed efficiency.

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What is a VFD

Although the VFD process is similar to a prescription they are not considered prescription drugs. Prescription drugs are governed by state pharmacy laws and in some instances veterinarians can prescribe them for extra-label usage. VFD drugs will have oversight from state departments of agriculture via feed mill licensee oversight. Additionally, VFD drugs are prohibited by federal regulation from extra-label usage.

In October 2015, the FDA amended the 1996 federal regulations and issued the new rules for the VFD process to accommodate for routine, widespread use of feed-grade antibiotics. Starting January 1, 2017, livestock producers will be required to have a VFD in place in order to buy or use medically important antibiotics in animal feed.

A VFD order is issued by a licensed veterinarian that has knowledge of the health and management of the animals. According to federal regulation, there must be a valid Veterinary-Client-Patient-Relationship (VCPR) prior to issuing a VFD. The requirements of a VCPR are:

1. A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian;
2. There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and
3. The practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept. VCPR requirements may differ per state, and the following link (**https://www.avma.org/Advocacy/StateAndLocal/Documents/VCPR_state_chart.pdf**) provides a summary of the VCPR rules in each state, including those states that incorporate the AVMA Principles of Veterinary Medical Ethics in their practice, acts or regulations. Although regulations do not specify the meaning of "recently seen," it has been suggested that at least every six months would be appropriate.

Parts of the VFD

A valid VFD must contain the following information in the documented order. The order can either be written on a paper copy or transmitted as an electronic document (fax or web based) in triplicate. However, telephone orders are not allowed.

- Veterinarian's name, address and phone number
- Client's name, address and phone number
- Name of VFD drug
- Level of VFD drug in the feed
- Duration of use
- Species and production class of animals to be fed
- Reorders or refills
- Indication for which the VFD is issued
- Cautionary statement, if any
- Approximate number of animals
- Premises at which the animals specified in the VFD are located
- An affirmation of intent for combination VFD drugs
- The withdrawal time
- Date of VFD issuance
- Expiration date
- Veterinarian's signature
- The statement: "Use of feed containing this veterinary feed directive (VFD) in a manner other than directed on the labeling (extra label use) is not permitted."

The level of drug in feed, duration of use, species and indication must be according to label.

The duration of use defines how long the VFD drug can be included in the feed for the animals.

Currently, there are no products available that allow for reorders or refills. Future approvals of new feed antibiotics may allow for reorders but if the current label does not specify availability of reorders then the veterinarian cannot authorize it.

Listing the approximate number of animals is a new change to the VFD rule. Previously, the veterinarian had to write a VFD based on tons of feed allowed. This change gives the producer or nutritionist an opportunity to feed the most appropriate diet to the animals covered

The premises is the location where animals are located that will be treated with a VFD medicated feed. Premises should be a 911 address or a GPS coordinate. It is important that the veterinarian knows all the locations where animals included on the VFD may be located. Feed distributers are only able to deliever to sites listed on the VFD. There are some VFD antibiotics that are currently approved to be fed with other medicated feeds. The veterinarian must specify if this VFD order allows the drug to be fed in combination with other approved products according to label directions.

Some VFD drugs require a withdrawal period that must be observed prior to animals being sold for slaughter or the sale of milk or eggs from the treated individuals. The withdrawal time is established by the approved label and must be included on the VFD form and followed by the producer. The expiration date specifies the last day that the VFD feed can be fed and may be different than the duration of use date. Most drugs that are being moved to VFD status under CPG 213 do not specify an expiration date for the VFD because they were not initially approved as VFD drugs. For drugs that do not have a specified expiration date the veterinarian will assign an expiration date up to six months from the date of issue.

Producer Reponsibilities

Both the veterinarian and the feed manufacturer are required by federal law to abide by VFD regulations and could be fined or have their licenses revoked for violating these regulations. Producers will need to provide a copy of the VFD order to the feed distributer unless the veterinarian electronically transmits the VFD. The producer should only use a feed containing a VFD drug if they have a valid VFD issued by a licensed veterinarian. The producer must not feed the VFD feed after the expiration date. The FDA requires that the producer keep their copy (either electronic or hard copy) of the VFD order for at least two years and provide a copy of all VFD orders to the FDA if requested.

The VFD rule is available for review in the Code of Federal Regulations at **https://www.federalregister.gov/articles/2015/06/03/2015-13393/veterinary-feed-directive**.

References

Guidance for Industry #120: Veterinary Feed Directive Regulation Questions and Answers.

Guidance for Industry #209: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals.

Guidance for Industry #213: New Animal Drugs and New Animal Generic Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations.

Code of Federal Regulations, Title 21, Chapter I, Subchapter E, Part 558.

Code of Federal Regulations, Title 21, Chapter I, Subchapter E, Part 530.

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