

Overview

- Why the Changes?
- VFD Form required components
- •Issues in the marketplace answering common questions

Why the Changes?

- FDA's decision to move these drugs to VFD status is to ensure veterinary oversight to promote judicious use of antibiotics.
- The rule affects antibiotics considered medically-important (for humans).
- In feed... moved from OTC to VFD. In water... moved from OTC to Rx.
- $\bullet \ \, \mbox{Injectable/Bolus... remains OTC}.$
- These medications were being used for weight gain and feed efficiency.
- Now approved only for prevention or treatment of disease.

Drugs Transitioned from OTC to VFD

<u>Category I</u> Avilamycin (new VFD)

Chlortetracycline Florfenicol (already VFD) Lincomycin
Oleandomycin (not marke

Oxytetracycline Penicillin Tylosin Virginiamycin

Apramycin (not markete Nygromycin B
Neomycin
Sulfadimethoxine:Ormetoprim
Sulfamerazine

Tilmicosin (already VFD) List of affected products: http://www.fda.gov/AnimalVeterin ealth/AntimicrobialResistance/Ju fAntimicrobials/ucm390429.htm

Obtaining a VFD

- · To lawfully feed certain antibiotics, producers must possess a valid VFD order.
 - Note: Keep documents on file for two years.
- Contact your veterinarian!
- VFD orders can be written only for approved uses (major species) and extralabel use is permitted only for minor species.

Note: CTC has never been legal for foot rot or pink eye.

Required Components of a VFD (1 of 2)

- Vet's name, address and phone number
- · Client's name, address and phone number
- . Premises at which the animals are located
- Date of VFD issuance
- Expiration date of the VFD (six months maximum)
- Name of the VFD drug (pioneer or generic, if available)
- Species and production class of animals to be fed the VFD feed
- · Approximate number of animals

Page 1 of 3 Mills | Southern States

Required Components of a VFD (2 of 2)

- · Indication for which the VFD is issued
- VFD drug level in the feed and duration of use
- Withdrawal time, special instructions, cautionary statements
- Number of reorders (refills) authorized, if permitted by the drug approval. If not listed, refills are not permitted.
- The statement: "Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use) is not permitted."
- An affirmation of intent for combination VFD drugs (three choices)
- Vet's electronic or written signature

Common Question # 1

- Do I have to possess a VFD order to purchase CTC 100 (the raw drug)? [Note: CTC is a Category I drug that does not have a withdrawal period for the lowest use level.]
 - NO. A raw drug is considered a Type A drug. A producer can legally purchase the raw drug (CTC) to be mixed on farm. BUT... the producer must have a VFD to FEED IT to animals.
- What about AS-700? Can a producer purchase the raw drug? NO. This is a *Category II* drug that requires a FML to convert a Type A into a Type B or C.

Common Question # 2

- How does a distributor estimate an "appropriate amount" of feed to sell the producer?
- This depends on the indications for use, drug concentration, and feeding rate as described on the label. A calculation can be done and distributors should keep track of sales to ensure they don't exceed the amount established.
 - ** Let's discuss this... is there any flexibility here?

Common Question # 3

- Which of three choices is the best option for checking Affirmation of Intent?
- This VFD authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs.
- This VFD authorizes the use of the VFD drug(s) cited in this order with the following FDA-approved drug... (enter drug name).
- This VFD authorizes the use of the VFD drug(s) cited in this order and any FDA-approved... combination(s) in medicated feed that contains the VFD drug(s) as a component.

Common Question # 4

- The VFD expiration date is 6 months after date of issuance. Do I have to purchase all the feed at once?
- NO. A producer can purchase small quantities over the time period allowed on the VFD form. The expiration date represents the last day the feed can legally be fed to animals (not the last day a distributor can sell it).

Summary

- The regulatory environment changed January 1, 2017 for producers who wish to continue to use certain antibiotics in feed & water for animals.
- Education is key to understanding the rules and how to maintain compliance.
- Southern States Cooperative has a VFD Booklet available for customers, dealers and veterinarians.

Mills | Southern States Page 2 of 3



Mills | Southern States Page 3 of 3