Veterinary Feed Directive (VFD) Regulation Update

The U.S. Food and Drug Administration (FDA) published three reports in December 2013 outlining upcoming changes for the use of antibiotic products in production animals. The goals of these changes are to:

- Promote judicious use of antibiotics
- Protect public health
- Help limit the development of antimicrobial resistance

Changes in the VFD process will help support a more streamlined approach to the judicious use of antibiotics. The final rule — published June 2015 — provides clarification on the requirements for veterinarians, feed distributors and producers.

Unaffected

Non-Medically Important

Products used exclusively in animals or deemed "non-medically important" if used by both animals and humans:

- Ionophores
- Polypeptides
- Carbadox
- Bambermycin
- Pleuromutilin

Affected

Medically Important

Products deemed "important for human medicine" and used by both animals and humans, such as:

- Penicillins
- Cephalosporins
- Quinolones
- Fluoroquinolones
- Tetracyclines
- Macrolides
- Sulfas
- Glycopeptides
- Others

Production uses

- Still allowed
- Enhance growth or improve feed efficiency

Production uses

- No longer allowed
- Enhance growth or improve feed efficiency

Therapeutic uses

Still allowed under veterinary supervision to:

- Treat animals diagnosed with an illness
- Control the spread of illness in a herd
- Prevent illness in healthy animals when exposure is likely

Veterinarian requirements

- Must be licensed to practice veterinary medicine and operate in compliance with appropriate State-defined veterinarian-client-patient relationship (VCPR) requirements
  - In states where the practice requirements do not require that a VFD be issued within the context of a VCPR, FDA is requiring that the VFD be issued within the context of a Federally defined valid VCPR, which requires that the veterinarian:
    - Engage with the client to assume responsibility for making medical judgments about animal health and the need for medical treatment
    - Have sufficient knowledge of the animal by virtue of examination and/or visits to the facility where animal is managed to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s)
    - Provide for any necessary follow-up evaluation or care
- Prepare a written VFD (paper or electronic) including all required information
- Issue VFD in compliance with the conditions for use approved, conditionally approved or indexed
- Write the name of the VFD drug on the VFD
  - May choose to write the name of a pioneer or generic drug name
  - May choose to specify that a substitution of a drug is not allowed; if not specified, the feed distributor may choose to substitute if the generic VFD drug is part of an approved combination VFD drug
- Include information about the location (e.g., address) of the animals that would allow someone to locate the animals and may include specific additional information (e.g., pen)
  - If a VFD is intended to authorize the use of a VFD feed in a group of animals that are located at more than one physical location, it is acceptable to include multiple specified locations for that group on the VFD, provided 1) they can do so in compliance with professional licensing, and 2) the feed is supplied by a single feed distributor
- Provide a copy of the VFD to the producer (client) and feed distributor, and maintain all original VFD records for 2 years

Producer requirements

- Feed animal feed containing a VFD drug only to animals based on a VFD issued by a licensed veterinarian
- Do not feed a VFD feed after the expiration date on the VFD
- Maintain all VFD records for 2 years

Feed distributor requirements

- May only provide a VFD feed if the VFD contains all required information, complies with terms of the VFD and conforms to product approval
- Provide one-time notifications
  - **Notice To FDA of Distribution of VFD Feeds** — that they intend to handle/distribute VFD drug-containing medicated feeds
  - **Acknowledgement of Distribution Limitations for VFD Feeds** — that the purchasers will sell the VFD feeds only to producers with valid VFD orders or to other distributors for whom they have acknowledgement notices
- Maintain all VFD records for 2 years

Other clarifications

- Defining distributors
  - On-farm mixers that only manufacture medicated feeds for use in their own animals are not distributors
  - On-farm mixers must only be manufacturing VFD feed for their use in their own animals on their own farm, meaning that the ownership of the feed mill, the animals and the animal production facility must be the same and the on-farm mixer must be the person using the VFD feed
  - If an on-farm mixer distributes to another producer, that mixer will be considered a distributor
  - If a producer wishes to receive a VFD feed without a VFD in hand, they must follow the notifications required for a distributor and they may not feed the VFD feed without a valid VFD in hand
- Expiration vs. duration
  - The **expiration** defines the period of time for which the authorization to provide an animal feed containing a VFD drug is lawful
    - Expiration date specifies the last day the VFD feed can be fed to a group of animals
    - The vet should use the valid length of time that is specified on the label; where such date is not specified, the vet can write a date up to 6 months from the date the VFD is initiated
  - The **duration** determines the length of time the VFD feed is allowed to be fed to the animals, as specified on the product label
- VFD drug classification — eliminates current automatic classification of VFD drugs to Category II status, which would have required mills making VFD feeds to have a federal medicated feed mill license
- FDA enforcement strategy
  - Provide education and training for stakeholders subject to this final rule such as veterinarians, clients (animal producers), feed mill distributors and other distributors
  - Engage in risk-based general surveillance, as well as for-cause inspection assignments

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