## Tips for Small Ruminant Veterinarians on Veterinary Feed Directives (VFD)

- All medically important antibiotics approved for use in feed or water will be VFD or Rx (water-soluble products) on January 1, 2017.
- Veterinarian must be licensed in the state where the animals are located and being fed the VFD feed.
- A valid veterinarian-client-patient relationship (VCPR) must exist that satisfies the requirements of the federally codified VCPR. To see if your state VCPR satisfies this requirement, visit http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm460406.htm
  - If your state does not have a VCPR or does not meet the federal requirements, you must follow the federal VCPR.
- No extralabel use of VFD drugs is allowed – the Animal Medicinal Drug Clarification Act (AMDUCA) does not apply to VFD feeds even with the oversight of a veterinarian. Must use according to species, production class, dose, indication, and duration. Must only use with other approved combinations.
    - In December 2016, the FDA released CPC 615.115 to address the use of VFD products in minor species which can be found here: http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-ice/documents/webcontent/ucm074659.pdf
- In the final rule, VFD drugs will no longer be automatically designated as Category II drugs:
  - Category I = drugs that do not require a withdrawal in the lowest dose level for the species for which they are approved.
  - Category II = drugs that require a withdrawal period at the lowest use level for at least one species for which they are approved or are regulated on a “no-residue” basis or with a zero tolerance because of a carcinogenic concern regardless of whether a withdrawal period is required.
- The manufacture of medicated feeds with Category II Type A medicated articles is restricted to licensed feed mills.
  - Type A medicated articles are the most concentrated form of the new animal drug and are used in the manufacture of another Type A medicated article or a type B or C medicated feed.
  - Type B medicated feed is intended solely for the manufacture of other Type B or C medicated feeds and contains a substantial quantity of nutrients with the new animal drug.
  - Type C medicated feed is intended as the complete feed for the animal or may be added on top of a usual ration or offered as a supplement with other animal feed.
- VFD drugs are technically not prescription products, therefore pharmacists are not required to dispense them.

- The mechanics of writing VFDs include the following:
  - The veterinarian submits the written VFD order to the feed distributor and the producer/client. All parties must keep copies of the VFD for two years. The veterinarian keeps the original copy in the manner it was generated. If the order was generated electronically (for example using an electronic VFD service) then electronic storage is acceptable. If the VFD was a paper copy that was faxed or scanned/emailed then the paper copy must be kept by the veterinarian for two years.
  - The expiration date of the VFD is defined as the time by/before which the VFD feed must be fed to the animals. This is listed on the label of the VFD product and if no expiration date is listed the maximum expiration date is six months. The veterinarian can choose an expiration date less than six months at his/her discretion. If the feed is not fed before the expiration date arrives, a new VFD must be written.
  - The duration of use is the amount of time the VFD feed can be fed. If another round of treatment is needed, a new VFD should be written if medically indicated by the veterinarian.
  - Refills or re-orders are only authorized if the label says such an authorization is allowed. Currently no VFD feeds allow re-orders/refills and FDA does not envision allowing standing re-orders/refills.
  - The following information is required on the VFD:
    - Veterinarian's name/address/phone number. License number is no longer required.
    - Client's name/address/phone number.
    - Description of the premises where the animals are held (premise ID, address, farm descriptor).
    - Date of VFD issuance.
    - Expiration date of VFD (maximum of 6 months or according to label).
    - Name of the VFD drug(s).
    - Species and production class of animals that are being fed the VFD feed.
    - Approximate number of animals to be fed the VFD feed (this is changed from tons of feed due to input from stakeholders).
    - Indication for which the VFD was issued.
    - Level of VFD drug in the feed (e.g., grams per ton) and duration (remember that this information must exactly follow label of the VFD product).
    - Withdrawal time, special instructions, and cautionary statements, if any.
    - The following statement: "Use of feed containing this veterinary feed directive (VFD) in a manner other than as directed on the labeling (extralabel use) is not permitted".
    - An affirmation of intent for combination VFD drugs:
      - May be used in any approved, conditionally approved, or indexed combination in VFD feed.
      - May be used in only specific approved, conditionally approved, or indexed combinations in VFD feed.
      - May not be used in any approved, conditionally approved, or indexed combination in VFD feed.
    - If you do not want a substitution with a generic drug, you must say so on the VFD. The default option is the distributor may use a generic drug instead of the pioneer

product. Ensure that you are aware if the generic product is approved for combination uses or if only the pioneer product has such approval.
    - Veterinarian's written or electronic signature.
  - Optional information the veterinarian can place on the VFD:
    - More specific description of the animals (e.g., site, pen, barn, lot).
    - Approximate age range of the animals.
    - Approximate weight of the animals.
    - Any other information the veterinarian deems appropriate.
- Additional information that is required for using VFD's in minor species for species or indications not on the approved VFD drug labelling according to CPG 615.115
  - Complete a separate written recommendation to the client for the extralabel use that includes the medical rationale dated within 6 months prior to use. Such a written statement should include the diagnosis, drug selection, dose, duration and the withdrawal period which should likely be extended from the approved drug labelling due to the extralabel use.
  - Keep copies of the written recommendation for a minimum of two years.
  - In the "special instructions" box of the completed VFD include:
    - "This VFD is being issued in accordance with CPG 615.115"
    - The actual species for which the medicated feed is intended.
    - The withdrawal time associated with the extralabel use.

**Additional Resources:**
All Blue Bird Labels for all feed grade products to check species, production class, dose, indication, and duration:
http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/BlueBirdLabels/ucm072534.htm

Veterinarian information brochures:
http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/UCM455480.pdf

Producer information brochures:
http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/UCM455419.pdf

To search the animal drugs database at the FDA-CVM:
http://www.accessdata.fda.gov/scripts/animaldrugsatfda/