Veterinary Feed Directive
Frequently Asked Questions for Veterinarians

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Q 1: What is a veterinary feed directive drug?
A 1: A veterinary feed directive drug, or VFD drug, is a drug intended for use in or on animal feed under the professional supervision of a licensed veterinarian and authorized by a lawful VFD order. [1]

Q 2: Who determines whether a drug is a VFD drug?
A 2: When a new animal drug application is submitted to the federal Food and Drug Administration's Center for Veterinary Medicine for approval, CVM evaluates the drug for safety and effectiveness as part of the review process. CVM determines whether the drug will be an over-the-counter drug, a prescription drug, or for drugs limited to use in animal feed, a VFD drug.

Q 3: What is a combination veterinary feed directive drug?
A 3: A combination veterinary feed directive drug is a combination new animal drug intended for use in animal feed under the professional supervision of a licensed veterinarian, where at least one of the new animal drugs in the combination is a VFD drug.

Q 4: What are Category I and Category II drugs and what is their relevance to VFD?
A 4: All new animal drugs, including VFD drugs, approved for use in or on animal feed are placed in one of two drug categories: Category I or Category II. Category I drugs require no withdrawal period at the lowest use level in each species for which they are approved. Category II drugs either 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.

See more detail for questions 1 – 4, and other related questions, in FDA's Guidance for Industry #120: Small Entity Compliance Guide, Veterinary Feed Directive Regulation Questions and Answers (https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052660.pdf).

[1] All feed-through animal drugs (VFD and non-VFD) are limited to use according to an approved new animal drug application, a conditionally approved application, or an index listing according to the federal Food, Drug & Cosmetic Act.

Q 5: What information must be included on the VFD order?

A 5: All of the bulleted items below are required (not listed in a specific order).

- ✓ The **veterinarian name, address, and phone number**. A fax number and/or email address may also be included; a fax number is required only when the VFD order transmitted from your office via fax.
- ✓ The **client name, address, and phone number**. A fax number and/or email address may also be included; a fax number is required only when the VFD order transmitted from your office via fax.
- ✓ The **VFD drug name**. Certain drug indications and/or drug levels pertain to specific proprietary drugs; if the selected indication is one of those, be sure to identify the proprietary drug name, and indicate that no drug substitutions are allowed.
- ✓ The **drug level for a Type C medicated feed** that can be fed directly to animals. It is not acceptable to indicate a Type A medicated article or a Type B medicated feed drug level on a VFD order.
- ✓ Some VFD orders have a checkbox to indicate if substitution is allowed. Prior to checking the box, consider the indication on the VFD order, and if that indication is tied to a specific proprietary drug, in which case substitution would not be allowed. For example: tilmicosin is the "established name" of the drug, whereas "Pulmotil®" or "Tilmovet®" are proprietary names.
- ✓ **The duration of use** as it relates to the federal drug approval, conditional approval, or index listing.
- ✓ **The species and production class of animals** to which the VFD order applies, in accordance with the federal drug approval, conditional approval, or index listing.
- ✓ The **number of refills authorized under the VFD order**. Through June 1, 2018, no feed-through drugs are approved for refills. The absence of refill information will be interpreted as a quantity of zero refills.
- ✓ **The indication for use**, a verbatim reflection of the indication as it appears in the federal drug approval, conditional approval, or index listing. For example: "For the treatment of swine disease associated with *Bacterium pathologicum*."
- ✓ **The caution and warning statements** applicable to the drug and indication. This must be a verbatim reflection of the statements as they appear in the federal drug approval, conditional approval, or index listing.
- ✓ 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**," verbatim.
- ✓ The **approximate quantity of animals** to which the VFD order applies.
- ✓ The **premises at which the animals specified in the VFD are located**.
- ✓ **An affirmation of intent (select one of the three statements) for combination VFD drugs**, per 21 CFR §558.6(b)(6). CAUTION: if the intent is for the animal producer to acquire a feed with a specific drug combination, select the correct option:
    - ☐ This VFD only 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 in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component: [Drug(s)]& [Drug level(s) and any special instructions].
- ☐ This VFD authorizes the use of the VFD drug cited in this order, in ANY FDA-approved, conditionally approved, or indexed combination in medicated feed that contains the VFD drug as a component.

- ✓ **The withdrawal time required for the VFD drug** as identified in the drug approval, conditional approval, or index listing. See "Special Instructions" bullet below; an extended withdrawal period shall be acknowledged in the "Special Instructions" of the VFD order.
- ✓ **The date the VFD order is issued**.
- ✓ **The date the VFD order expires**. The VFD medicated feed cannot be fed to the animals after the date of the VFD order expiration.
- ✓ **Licensed veterinarian's electronic or written signature**.
- ✓ **Special instructions, if any**. This area of the VFD order is for any of the following:
  - ☐ Identifying the VFD is for a minor species, in accordance with the FDA's Compliance Policy Guide 615.115.
  - ☐ Further explanation of a duration – for example: "Feeding may be discontinued after 21 days, but prior to 42 days when no symptoms have been observed for [X] days."
  - ☐ Instruction to the feed mill for addition of a feed-through pesticide to the VFD medicated feed.
  - ☐ Stipulation of an extended withdrawal period for the animal producer to follow.
  - ☐ Requiring a longer withdrawal period (e.g. a non-VFD drug used in combination with the VFD drug has a 24 hour withdrawal whereas the VFD drug has zero withdrawal).
  - ☐ Writing any other type of special instructions.
- ✓ Indication of the ages or weight range of the animals is optional, not required.

Q 6: Where can I get VFD forms?

A 6: VFD forms are available through the following:

- ✓ Drug sponsors have forms available online for their specific drug sources
- ✓ Veterinary associations
- ✓ Electronic software – Global Vet Link or Rx Express

Q 7: Where can I find more information?

A 7:

- ✓ Food Animal Residue Avoidance Databank: http://www.farad.org/regulatory/vfd_links.asp
- ✓ FDA: https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm