Feed Manufacturer Veterinary Feed Directive Checklist

This document is for guidance purposes only and does not constitute legal advice. It is the responsibility of the commercial feed manufacturer/distributor to ensure compliance with the applicable laws and requirements. Following the guidance in this document does not preclude regulatory or compliance action by the Wisconsin Department of Agriculture, Trade, and Consumer Protection when authorized by Federal, state, or local law, nor does it release any commercial feed manufacturer or distributor from legal responsibility or liability of any kind. This document discusses the Federal requirements in Title 21 of the Code of Federal Regulations (CFR) Part 558 (21 CFR §558.6). (Revised May 2018)

1. If you distribute an animal feed containing a VFD drug or a combination VFD drug, you must:
    - ✓ File a Distributor Notification. Send to: FDA, Center for Veterinary Medicine, Division of Animal Feeds (HFV-220), 7519 Standish Pl., Rockville, MD 20855.
    - ✓ Notify FDA within 30 days of any change in ownership, business name, or business address.
    - ✓ Fill a VFD order only if the VFD contains all required information.
    - ✓ Ensure that the distributed animal feed containing the VFD drug or combination VFD drug complies with the terms of the VFD and is manufactured and labeled in conformity with the approval for such drug.
    - ✓ Ensure all labeling and advertising prominently and conspicuously displays the following cautionary statement: “Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian."
    - ✓ Retain VFD orders for two years from date of issuance.
    - ✓ Retain records of the receipt and distribution of all VFD medicated feed for 2 years.
    - ✓ Provide VFD orders for inspection and copying by FDA upon request.
    - ✓ Retain records of VFD manufacturing for 1 year in accordance with 21 CFR part 225 and make such records available for inspection and copying by FDA upon request.
    - ✓ *If* you distribute a VFD medicated feed to another entity that will further distribute the VFD feed, obtain an acknowledgement letter, and retain the letter for 2 years from the final distribution to that entity.
2. **What should the distributor do if the VFD is not completely filled out?** If a VFD order does not contain all of the required information, the distributor must not fulfill the VFD. The distributor must notify the veterinarian that the VFD order cannot be filled until all the necessary information is provided.
3. **What information must be included on the VFD order?**
    - ✓ **The veterinarian name, address, and phone number**. A fax number and/or email address may also be included; a fax number is only required when the VFD order is transmitted via fax.
    - ✓ **The client name, address, and phone number**. A fax number and/or email address may also be included; a fax number is only required when the VFD order is transmitted 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** – not a Type A medicated article or a Type B medicated feed - that can be fed directly to animals.
- ✓ Some VFD orders have a checkbox for identifying if substitution is or is not 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 shall 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, 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.
- ✓ Indication of the ages or weight range of the animals is optional (not required).
- ✓ **The premises at which the animals specified in the VFD are located**.
- ✓ **Special instructions, if any**. This area of the VFD order is for:
    - ☐ Identifying the VFD is for a minor species, in accordance with the Federal Food and Drug Administration'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), or
    - ☐ Writing any other type of special instructions.
- ✓ **An affirmation of intent 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]; or
- ☐ 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. Recall from the "Special Instructions" bullet above, 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**.

For more information, please reference 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.