

Veterinary Feed Directives: FDA Final Rule and Draft Guidance

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Food & Drug

Earlier this month, the Food and Drug Administration (FDA) issued a final rule amending its veterinary feed directive (VFD) regulation, 21 C.F.R. § 558.6¹, to make the rule's requirements easier to understand and less burdensome. FDA also revised certain definitions in 21 C.F.R. § 558.3. These amended rules were accompanied by Draft Guidance 120, which explains the amendments in a question and answer format.²

The amended regulations provide that:

- VFD drugs are no longer presumptively Category II drugs, meaning they no longer are required to be produced in a licensed feedmill if they do not independently meet the requirements of Category II.
- Distributors must notify FDA before they first distribute medicated feeds containing VFD drugs.
- Combination animal drugs that contain at least one VFD drug can be sold or distributed only upon the issuance of a VFD order.
- Veterinarians have the option to issue electronic or written VFDs, but VFDs cannot be oral.

The amended rule will become effective on October 1, 2015, but will be implemented with a phase-in period. The Draft Guidance that accompanied the final rule is open for public comment until August 3, 2015.

Background

In 1996, Congress enacted the Animal Drug Availability Act (ADAA), which established veterinary feed directive drugs, a class of animal drugs dosed in or on animal feeds which required the professional oversight of a licensed veterinarian. Section 558.6 of 21 C.F.R., finalized in 2000, provided the regulatory requirements for dispensing and use of veterinary feed directive drugs.

¹ 80 Fed. Reg. 31708 (2015), available at <http://www.gpo.gov/fdsys/pkg/FR-2015-06-03/pdf/2015-13393.pdf>.

² Available at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052660.pdf>.

In recent years, FDA has focused increasingly on the production use in food animals of antibiotics the agency deemed to be important in human medicine. Accordingly, FDA promulgated Guidance for Industry 213 in 2013, seeking the agreement of sponsors of medically-important antibiotics to phase out the drugs' approved production uses in food animals.³ If those antibiotics had approved therapeutic claims for food animal use in addition to the production uses, the Guidance sought the sponsors' agreement to convert the drugs from over-the-counter to VFD status for those drugs dosed in feed and to Rx status for those dosed in drinking water. In June 2014, FDA announced that it had reached agreements with all 26 drug manufacturers affected by Guidance 213 to phase out the production uses of such drugs and phase in veterinary oversight for the remaining therapeutic uses.⁴ This final rule amending 21 C.F.R § 558.6 is part of that process.

Major Concepts of the Amended VFD Regulation

Combination Products

The final rule requires combination animal drugs (*i.e.*, animal drugs containing more than one active ingredient) in which any one of the drugs in the combination is a VFD drug to be used and distributed only under a VFD. Therefore, if any drug in the combination is a VFD drug, the combination can only be distributed if authorized by a valid VFD.

VFD Issue and Recordkeeping Requirements

A VFD can be issued by any licensed veterinarian having a veterinarian-client-patient-relationship (VCPR) with the client and patient(s). The existing rule requires that the VCPR meet the federal VCPR definition. To leverage the accountability that comes with state veterinary licensing board oversight to ensure compliance with the VCPR requirement, however, the amended rule allows for VCPRs to be defined by state definition where that definition meets the key elements of the federal definition, *i.e.*, that the veterinarian must:

- engage with the client to assume responsibility for making clinical judgments about patient health;
- have sufficient knowledge of the patient(s) by virtue of patient examination and/or visits to the facility where the patient(s) is(are) managed; and
- provide for any necessary follow-up evaluation or care.

The Draft Guidance issued concurrently with the final rule clarifies that extra-label uses of VFD drugs are not permitted. Accordingly, the VFD can only authorize use of a drug permitted by the approved labeling or index listing.

The final rule also amended the medium through which a VFD may be issued. The existing VFD regulation allows for hardcopy VFDs only. Because FDA recognized that this requirement was not consistent with the capabilities of modern technology, the amended rule allows a VFD to be issued in either hardcopy or electronic form. Veterinarians may send hardcopy VFD orders to distributors or transmit them via facsimile or electronically, but VFDs still cannot be relayed

³ Available at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf>.

⁴ <http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm403285.htm>.

orally. The veterinarian, the distributor, and the client must all retain a copy of the VFD for two years. The records can be kept as either electronic or hardcopy versions, but the veterinarian must maintain the original VFD in the form in which it was issued. Although VFD drug sponsors are free to provide veterinarians with VFD forms, there is no required form, and veterinarians may make up their own as long as the forms contain the required information.

Required VFD Contents

A VFD must include, *inter alia*, the following:

Species and indications - A VFD must specify the species of animal to be fed medicated feed containing the VFD drug and the approved indication for which the VFD is issued.

Expiration date - A VFD can only authorize a distributor to sell and a client to use a VFD drug until the VFD's expiration date. The VFD drug's approval or index listing will sometimes specify an expiration date. Otherwise, the issuing veterinarian may set the expiration date, which can be no later than six months after the VFD issue date. Once the expiration date has passed, the client may not use a VFD drug.

Duration of use - The duration of use is the time period during which a VFD drug may be fed to the target animals. That period must be completed before the VFD's expiration date. The maximum duration of use for a particular VFD drug will always be specified in its approval or index listing, and a veterinarian may authorize a duration of use up to this maximum period.

Refills - Refills are only allowed if permitted by the VFD drug's approval or index listing. In that case, the VFD must specify the number of refills. FDA explained that it envisions antimicrobial refills will have "limited applicability."

Approximate animal number - The veterinarian must list the approximate number of animals to be fed under the VFD, but the veterinarian is not required to calculate the amount of feed needed to treat this number of animals. Rather, the distributor and the client must consult each other and determine the amount of feed needed for the specified number of animals.

Animal location - A VFD must specify the premises at which the animals to be treated are located. This information can be conveyed by any means that would allow a person to locate the animals, including an address or GPS coordinates. Where the animals to be treated are kept at multiple locations, the veterinarian may include those multiple locations on a single VFD, provided this complies with the veterinarian's professional license and the medicated feed is supplied by a single manufacturer.

Combination drug affirmation - The VFD must include one of three affirmations regarding the veterinarian's intent for combination drug use, *i.e.*, the VFD 1) does not authorize VFD drug use in combination with any other animal drugs, 2) authorizes specific approved or indexed combinations, or 3) authorizes any FDA-approved or indexed combinations.

Registration Requirements for Feed Distributors

Under the existing regulation, all VFD drugs are automatically Category II drugs. FDA realized this restriction was not necessary to protect public health, and the amended rule allows VFD drugs to be categorized under either Category I or Category II based on whether or not they meet the applicable definition. Accordingly, FDA removed the phrase "or are a veterinary feed directive drug" from the definition of "Category II" in 21 C.F.R. § 558.3(b)(1)(ii). VFD drugs will

be designated under Category I if they do not require a withdrawal period at the lowest use level in each species for which they are approved. They will be designated Category II if they “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 there is a required withdrawal period.”

Distributors must file a one-time notification with FDA prior to first distributing animal feed containing a VFD drug. These distributors must also notify FDA within thirty days of any change in ownership, business name, or business address. In addition, any “consignor distributor” selling VFD drugs or medicated feed containing such a drug to a “consignee distributor” must first obtain from the consignee distributor a written acknowledgement letter before shipping the drugs or feed. The acknowledgement letter must affirm that the consignee distributor: 1) will not ship feed containing a VFD drug to an animal production facility that does not have a valid VFD; 2) will not ship such feed to another distributor without receiving a similar acknowledgement letter; and 3) has complied with the FDA notification requirement.

VFD Drug Labeling and Advertising

All labeling and advertising for VFD drugs and medicated feeds containing VFD drugs must “prominently and conspicuously display” the 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.”

Phase-in

The amended rule becomes effective October 1, 2015, but FDA intends to use a phased enforcement strategy for implementation. Initially, FDA will provide education and training to veterinarians, clients, and distributors. Once antibiotics begin to change from OTC to VFD status under the 2013 guidance, FDA will engage in both general surveillance and for-cause inspections as assessment and enforcement tools. The agency’s use of these tools will be risk-based, in response to adverse event reports.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food & Drug practice group:

Jeannie Perron	+1 202 662 5687	jperron@cov.com
MaryJoy Ballantyne	+1 202 662 5933	mballantyne@cov.com

Grant Dixon, a summer associate and student at Georgetown University Law Center, contributed to this alert.

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