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Veterinary Feed Directive Regulation Questions and Answers (Revised)

Draft Guidance for Industry

Small Entity Compliance Guide

This draft revised guidance document is for comment purposes only.

This draft guidance document makes revisions to the final guidance made available in September 2015 to provide additional information regarding the VFD final rule that published in June 2015.

Submit comments on this draft revised guidance by the date provided in the *Federal Register* notice announcing the availability of the guidance. Submit electronic comments to <https://www.regulations.gov/>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the Docket No: FDA-2010-N-0155.

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Additional copies of this guidance document may be requested from the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at either <https://www.fda.gov/AnimalVeterinary/default.htm> or <https://www.regulations.gov/>.

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Veterinary Feed Directive Regulation Questions and Answers (Revised)

Guidance for Industry

Small Entity Compliance Guide

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance using the contact information on the title page.

I. INTRODUCTION

Before 1996, there were only two options for dispensing new animal drugs: (1) over-the-counter (OTC), and (2) prescription. In 1996, Congress enacted the Animal Drug Availability Act (ADAA) to facilitate the approval and marketing of new animal drugs and medicated feeds. As part of the ADAA, Congress recognized that certain new animal drugs intended for use in animal feed should only be administered under a veterinarian's order and professional supervision. For example, veterinarians are needed to control the use of certain antimicrobials. Control is critical to reducing unnecessary use of such drugs in animals and to slowing or preventing any potential for the development of bacterial resistance to antimicrobial drugs. Safety concerns relating to difficulty of diagnosis of disease conditions, high toxicity, or other reasons may also dictate that the use of a medicated feed be limited to use by order and under the supervision of a licensed veterinarian. Therefore, the ADAA created a new category of products called veterinary feed directive (VFD) drugs.

In June 2015, FDA published a final rule that revised the VFD regulations in 21 CFR 558.6 and introduced clarifying changes to the definitions in 21 CFR 558.3 (80 FR 31708, June 3, 2015). This guidance provides information to assist veterinarians, VFD feed distributors (e.g., feed mills), and clients (i.e., owners or other caretakers of the animals) in complying with the requirements in the 2015 VFD final rule. This guidance also serves as a Small Entity Compliance Guide (SECG), to aid industry in complying with the requirements of the VFD final rule. FDA has prepared this SECG in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121). This document is intended to provide guidance to small businesses on the requirements of the final rule.

Generally, FDA guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

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To assist our stakeholders, in this revised draft guidance we have identified those Questions and Answers that contain revised information and those that have been added since the last version of the guidance published in September 2015. We have also made minor edits to improve clarity and accuracy.

II. VETERINARY FEED DIRECTIVE – General Information

A. Veterinary Feed Directive Drugs

1. What is a veterinary feed directive drug?

A “veterinary feed directive (VFD) drug” is a drug intended for use in or on animal feed which is limited by an approved new animal drug application filed pursuant to section 512(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), a conditionally approved application filed pursuant to section 571 of the FD&C Act, or an index listing pursuant to section 572 of the FD&C Act to use under the professional supervision of a licensed veterinarian (21 CFR 558.3(b)(6)). Use of animal feed bearing or containing a VFD drug (VFD feed) must be authorized by a lawful VFD (21 CFR 558.6(a)(1)). See section [II.B. Veterinary Feed Directive \(VFD\)](#) below for a discussion of what constitutes a lawful VFD.

2. Who determines whether a drug is VFD drug?

When a new animal drug application is submitted to FDA’s Center for Veterinary Medicine (CVM) for approval, CVM evaluates the drug for safety and effectiveness, and as part of the review process, determines whether the drug will be an over-the-counter (OTC) drug, a prescription (Rx) drug, or a VFD drug (limited to drugs used in or on animal feed).

3. What is a combination veterinary feed directive drug?

A “combination veterinary feed directive drug” (or “combination VFD drug”) is a combination new animal drug (as defined in § 514.4(c)(1)(i)) intended for use in or on animal feed which is limited by an approved application filed pursuant to section 512(b) of the FD&C Act, a conditionally approved application filed pursuant to section 571 of the FD&C Act, or an index listing pursuant to section 572 of the FD&C Act to use under the professional supervision of a licensed veterinarian, and at least one of the new animal drugs in the combination is a VFD drug. Use of animal feed bearing or containing a combination VFD drug must be authorized by a lawful veterinary feed directive (21 CFR 558.3(b)(12)). If any component drug in an approved, conditionally approved, or indexed combination drug is a VFD drug, the combination drug is a combination VFD drug and its use must comply with the VFD requirements.

4. What are Category I and Category II drugs and what is their relevance to VFD drugs?

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 (21 CFR 558.3(b)(1)). Category I drugs

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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 major species for which they are approved, or are regulated on a “no-residue” basis or with a zero tolerance because of carcinogenic concern regardless of whether a withdrawal period is required in any species.

A medicated feed mill license is required if the VFD drug used to manufacture a Type B or Type C medicated feed is a Category II, Type A medicated article (21 CFR 558.4(a)). A list of Category II drugs is located in [21 CFR 558.4\(d\)](#).¹ A license is not required if the VFD drug used to manufacture a Type B or Type C medicated feed is a Category I Type A medicated article, with the exception of certain liquid and free-choice medicated feeds.

5. [Added 2019] If I am a university researcher and I want to perform research on a drug in medicated feed, do I need a VFD to obtain the medicated feed?

No, you do not need a VFD to obtain medicated feed for the purpose of performing research on a drug for use in or on a medicated feed. The VFD regulations apply to the use of VFD drugs and VFD feed for approved indications. When investigating a new indication during the approval process, or performing tests in vitro or in animals used only for laboratory research purposes, the VFD regulations do not apply. Instead, the requirements in 21 CFR part 511 “New Animal Drugs for Investigational Use” apply. When pursuing a new animal drug approval, the requirements in 511.1(a) or 511.1(b) may apply depending on the purpose for the research trial.

For research that is not related to pursuing a new animal drug approval, the requirements in 21 CFR 511.1(a) apply. 21 CFR part 511 can be viewed at: <http://www.ecfr.gov>.²

B. Veterinary Feed Directive (VFD)

1. What is a Veterinary Feed Directive?

A “veterinary feed directive” is a written (nonverbal) statement issued by a licensed veterinarian in the course of the veterinarian’s professional practice that orders the use of a VFD drug or combination VFD drug in or on an animal feed. This written statement authorizes the client (the owner of the animal or animals or other caretaker) to obtain and use animal feed bearing or containing a VFD drug or combination VFD drug to treat the client’s animals only in accordance with the conditions for use approved, conditionally approved, or indexed by the FDA (21 CFR 558.3(b)(7)). A VFD may also be referred to as a VFD order.

2. What is required for a VFD to be “lawful”?

To be lawful, a VFD must be issued and used in compliance with all applicable requirements in 21 CFR 558.6. These include the requirement that a VFD must be issued by a veterinarian licensed to practice veterinary medicine operating in the course of the veterinarian’s professional

¹ https://www.ecfr.gov/cgi-bin/text-idx?SID=b8e74620d2b65cd5c35fb00efa6dbcd9&mc=true&node=pt21.6.558&rgn=div5%20-%20se21.6.558_14

² <https://www.ecfr.gov/cgi-bin/ECFR?page=browse>

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practice and in compliance with all applicable veterinary licensing and practice requirements, including issuing the VFD in the context of a veterinarian-client-patient relationship (VCPR) as defined by the state (21 CFR 558.6(b)(1)). If applicable VCPR requirements as defined by such state do not include the key elements of a valid VCPR as defined in FDA's regulations at 21 CFR 530.3(i), the veterinarian must issue the VFD in the context of a valid VCPR as defined in 21 CFR 530.3(i).

3. [Revised 2019] Does the State or Federal definition of a veterinarian-client-patient relationship (VPCR) apply?

In those States that require a VCPR that includes the key elements of the Federally-defined VCPR in order for a veterinarian to issue a VFD, the veterinarian issuing the VFD must be operating within the context of a VCPR as that term is defined by the State. In all other cases, the veterinarian must be operating within the context of a valid VCPR as defined by FDA in 21 CFR 530.3(i). (21 CFR 558.6(b)(1)(ii)). FDA considers States with VCPR definitions that at least address the concepts that the veterinarian (1) engage with the client to assume responsibility for making clinical judgments about patient health, (2) have sufficient knowledge of the patient by virtue of patient examination and/or visits to the facility where patient is managed, and (3) provide for any necessary follow-up evaluation or care to include the key elements of the Federally-defined VCPR as set forth in 21 CFR 530.3(i).

In States where the veterinary practice requirements do not require that a VFD be issued within the context of a State-defined VCPR that includes the key elements of a valid VCPR as defined in Federal regulations at 21 CFR 530.3(i), FDA is requiring that the VFD be issued within the context of a Federally-defined valid VCPR as defined at 21 CFR § 530.3(i). (21 CFR 558.6(b)(1)(ii)).

FDA has worked with State regulatory authorities to verify whether their State has VCPR requirements in place that apply to the issuance of a VFD and include the key elements of the Federally-defined VCPR. FDA has compiled a list of states that require a VCPR that includes the key elements of the Federally-defined VCPR in order for a veterinarian to issue a VFD. This list is available online³ and the list will be updated periodically as FDA receives and verifies information from States if they change their VCPR definition or its applicability.

4. [Added 2019] Are VFDs only required for food producing animals?

No. A VFD is required to authorize the use of a VFD drug in a medicated feed, regardless of whether the approved use is for a food producing or non-food producing animal.

C. Information on the VFD

1. What specific information must the veterinarian include on the VFD and what information is optional?

³ <https://www.fda.gov/animalveterinary/developmentapprovalprocess/ucm071807.htm>

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21 CFR 558.6(b)(3) requires the following information to be fully and accurately included on the VFD order:

- The veterinarian’s name, address, and telephone number;
- the client’s name, business or home address, and telephone number;
- the premises at which the animals specified in the VFD are located;
- the date of VFD issuance;
- the expiration date of the VFD;
- the name of the VFD drug(s);
- the species and production class of animals to be fed the VFD feed;
- the approximate number of animals to be fed the VFD feed by the expiration date of the VFD;
- the indication for which the VFD is issued;
- the level of VFD drug in the feed and duration of use;
- the withdrawal time, special instructions, and cautionary statements necessary for use of the drug in conformance with the approval;
- the number of reorders (refills) authorized, if permitted by the 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”;
- an affirmation of intent for combination VFD drugs as described in 21 CFR 558.6(b)(6); and
- the veterinarian’s electronic or written signature.

In addition to the information described above that must be included on the VFD, the veterinarian also may, at his or her discretion, include on the VFD the following additional information as described in 21 CFR 558.6(b)(4) to more specifically identify the animals he or she is authorizing to be treated using the VFD feed:

- A more specific description of the location of the animals (for example, by site, pen, barn, stall, tank, or other descriptor the veterinarian deems appropriate);
- the approximate age range of the animals;
- the approximate weight range of the animals; and
- any other information the veterinarian deems appropriate to identify the animals at issue.

2. Who is the “client” for the purpose of filling the VFD?

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For purposes of the VFD regulations, the term “client” typically refers to the person responsible for the care and feeding of the animals receiving the VFD feed. As described in the definition of the term “veterinary feed directive,” the client may be the owner of the animals or other caretaker (see 21 CFR 558.3(b)(7)).

3. [Revised 2019] What information should be included on the VFD to describe the “premises” at which the animals are located?

We expect that the veterinarian would enter information about the physical location of the animals referred to in the VFD that would be sufficiently descriptive to allow someone to locate the animals. Typically, the street address for the facility would be an appropriate way to identify the animals’ location; however, other generally recognized geographical indicators, such a global positioning system (GPS) coordinate or Federal grazing land identification information (allotment), may be appropriate if a street address does not exist.

We recognize that an address for a facility may not provide enough information to identify the location of animals in a case where the VFD is meant to authorize the VFD feed to be provided to a very specific group of animals. As a result, the veterinarian may use his or her discretion to enter additional information on the VFD that more specifically describes the location of the animals, such as the site, pen, barn, stall, tank, or other descriptor (21 CFR 558.6(b)(4)(i)). The veterinarian should consult with the client to determine whether the animals will remain at this more specific location until the expiration date of the VFD.

We also understand that some groups of animals that are of similar age, weight range, etc., are managed in a similar manner, but may be housed in different physical locations. For example, a group of weaned pigs may be moved out of a nursery facility and transferred to multiple grow-out facilities for finishing. If a VFD is intended to authorize the use of a VFD feed in an identified group (approximate number) of animals that are located at more than one physical location, it is acceptable for a veterinarian to include multiple specified locations for that group of animals on the VFD. In the preamble of the VFD final rule, we stated that “the veterinarian may write a VFD that covers animals in multiple locations (animal production facilities) to be fed the VFD feed by the expiration date on the VFD, provided he or she can do so in compliance with professional licensing and practice standards and provided the VFD feed is supplied to such multiple locations by a single feed manufacturer (distributor).” (80 FR 31708 at 31720, June 3, 2015, see response to Comment 27).

4. [Added 2019] Is the listing of multiple premises on the VFD allowed? If so, is it mandatory or optional?

Yes, it is allowed. It is optional to group two or more premises on one VFD or on separate VFDs, and depends on whether one VFD can be written to cover the animals on multiple premises. In the preamble to the final rule, we discussed how VFDs may be written for groups of animals with a similar age, weight range, etc., that are managed in a similar manner but housed at multiple premises. In the preamble of the VFD final rule, we stated, “the veterinarian may write a VFD that covers animals in multiple locations (animal production facilities) to be fed the VFD feed by the expiration date on the VFD, provided he or she can do so in compliance with

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professional licensing and practice standards and provided the VFD feed is supplied to such multiple locations by a single feed manufacturer (distributor).” (80 FR 31708 at 31720, June 3, 2015, see response to Comment 27). Alternatively, the veterinarian may choose to write separate VFDs for each premise.

5. What is an “expiration date” on the VFD?

The expiration date on the VFD specifies the last day the VFD feed can be fed. In other words, a VFD feed or combination VFD feed must not be fed to animals after the expiration date on the VFD (21 CFR 558.6(a)(2)).

6. How is the “expiration date” determined by the veterinarian for a VFD?

In certain cases, FDA determines the expiration date of a VFD (the number of days the VFD feed can be fed to the animal before the VFD expires) as part of the approval, conditional approval, or index listing of that drug. The VFD expiration date defines the period of time for which the authorization to feed an animal feed containing a VFD drug is lawful. The expiration date for the VFD must not extend beyond the expiration date specified in that drug’s approval, conditional approval, or index listing (21 CFR 558.6(b)(3)(v)).

In cases where the expiration date is not specified in the approval, conditional approval, or index listing, the expiration date of the VFD must not exceed 6 months after the date of issuance (21 CFR 558.6(b)(3)(v)). This provision allows veterinarians, based on their medical judgment and knowledge of the animal production operation, to determine on a case-by-case basis whether the maximum 6-month period is an appropriate expiration date for the VFD, or whether a more limited period is warranted. The veterinarian will use his or her medical judgment to determine what expiration date is appropriate for the VFD, based on many factors including, but not limited to, the type of animal production facility and operation, the VFD drug or combination VFD drug at issue, the intended use of the VFD drug, and the health status, treatment history, and lifecycle of the animals.

The date of expiration should be calculated by the calendar date, not the number of days. For example, using a 6-month expiration date for a VFD, if the VFD is written on July 10, then the expiration date would be January 10 of the following year. Using the same 6-month expiration date example, but having the VFD written on the last day of the month, the VFD expiration date would be the last day of the sixth month even if that month has fewer days. Thus, in this example, if the VFD is written on August 31, the expiration date would be the following February 28 during a regular calendar year, or February 29 during a leap year.

7. What is the “duration of use” and how does it relate to the “expiration date”?

The VFD expiration date defines the period of time for which the authorization to feed an animal feed containing a VFD drug is lawful. This period of time may be specified in the approved labeling of a given VFD drug or, if not specified in the labeling, the veterinarian must specify an expiration date for the VFD that does not exceed 6 months (21 CFR 558.6(b)(3)(v)). The duration of use is a separate concept from the expiration date, and determines the length of time,

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established as part of the approval, conditional approval, or index listing process, that the animal feed containing the VFD drug is allowed to be fed to the animals. This period of time is specified in the labeling of the VFD drug. For example, for swine, the currently approved VFD drug tilmicosin has an expiration date of 90 days and a duration of use of 21 days. This means that when the VFD is issued, the client has 90 days to obtain the VFD feed and complete the 21-day course of therapy. It is unlawful to feed the VFD feed to animals after the VFD expiration date (21 CFR 558.6(a)(2)).

8. What is the “approximate number of animals” on the VFD?

The approximate number of animals is the potential number of animals of the species and production class identified on the VFD that will be fed the VFD feed or combination VFD feed at the specified premises by the expiration date of the VFD (21 CFR 558.6(b)(3)(viii)).

9. [Revised 2019] Can a VFD authorize either the approved pioneer or approved generic VFD drug(s)?

The veterinarian is required to write the name of the VFD drug on the VFD (21 CFR 558.6(b)(3)(vi)). To complete this requirement, the veterinarian may choose to write the established name of the VFD drug (i.e., active drug ingredient), or the proprietary name (i.e., trade name) of the approved pioneer or an approved generic (if available) VFD drug.

Established Name on VFD

When the veterinarian uses a VFD with the established name of a VFD drug on it, the distributor may fill the VFD order using VFD feed manufactured from any VFD drug containing the same active pharmaceutical ingredient (API) approved for the use, i.e., from either an approved pioneer or an approved generic.

Proprietary Name on VFD

When the veterinarian uses a VFD with the proprietary name of a VFD drug on it, he/she may choose to specify that a substitution by the distributor of the VFD feed of either the pioneer or generic VFD drug identified under a proprietary name on the VFD is not allowed; or, the veterinarian may choose to remain silent, i.e., not specify that a substitution is not allowed.

When the veterinarian specifies that a substitution of a proprietary name of the VFD drug is not allowed, the distributor must fill the VFD using VFD feed manufactured from the VFD drug identified by the proprietary name.

When the VFD is silent about whether substitution is allowed, then substitution is allowed, and the distributor may fill the VFD using VFD feed manufactured from any VFD drug containing the same API approved for the use, i.e., from either an approved pioneer or an approved generic. In other words, any pioneer or generic VFD drug may be used to substitute for any other pioneer or generic drug containing the same API, provided that the substituting drug is approved for the same uses as the drug written on the VFD, either alone or in a combination with other drugs, as the drug identified on the VFD. The use of a VFD drug must be consistent with the Blue Bird label for the VFD drug (pioneer or generic) the distributor uses, and the labeling of the VFD feed

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must be consistent with the Blue Bird label for the VFD drug (pioneer or generic) the distributor actually uses in the VFD feed.

10. [Revised 2019] In cases where a VFD drug is approved for use at multiple drug levels, or for use in a range of drug levels, would one or multiple VFD orders have to be issued to cover such drug uses?

In cases where a VFD drug is approved for use at multiple drug concentrations, or levels, for a single indication, the veterinarian may issue a single VFD order covering all those approved drug levels intended to be used, and the approved duration(s) of feeding the VFD feed at the approved drug level(s) for the indication.

If a VFD drug is approved for use within a range of drug levels, then the veterinarian may specify a particular drug level within that range or authorize use at any drug level within the range by putting the entire authorized range on the VFD.

The veterinarian may also use the “special instructions” area of the VFD to provide more specific instructions about the use of a drug that is approved for use within a range of drug levels. For example, if a VFD drug can be used within a certain drug level within the approved range and the veterinarian would like the client to use a higher drug concentration within that range for a certain part of the treatment duration and a lower drug concentration within that range for another part of the treatment duration, the special instructions area could be used for that purpose. The distributor would then need to provide the client batches of VFD feed that include the different drug levels specified in the special instructions area of the VFD.

11. [Added 2019] Some VFD drugs are approved at a set dose (e.g., mg/head/day), but different drug levels in the feed may be necessary to accomplish that dose over the course of treatment. How should I reflect this on the VFD?

In cases where the veterinarian issuing a VFD has to determine the drug concentration in g/ton in feed because the concentration was not determined at the time of approval, conditional approval, or index listing, the veterinarian may need to authorize use of more than one drug level in the VFD feed on a VFD to achieve the approved dose. This may be necessary for reasons such as variations in animal weights or feed intake over the course of therapy.

In situations where g/ton is not provided by approval, conditional approval, or index listing, the veterinarian could determine that more than one drug level in the VFD feed is needed to address a particular feeding situation. For example, the veterinarian could determine that the drug level in the VFD feed should be 20 g/ton at feed intake of 2% body weight, 40 g/ton at feed intake of 1% body weight, or 15 g/ton at feed intake of 2.5% body weight to ensure consumption at the approved dosage in mg/head/day or mg/unit body weight/day). The veterinarian should include this information in the drug level area on the VFD and explain in the special instructions area that the observed feed intake will dictate which of the drug levels on the VFD is to be used. This will ensure that the instructions on the VFD are consistent with the approved representative labeling for use in the Type B and Type C medicated feeds containing the new animal drug (Blue

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Bird label). The Blue Bird labels often provide examples, which may be useful to the veterinarian in determining what level of VFD drug in the feed may be appropriate.

It would not be appropriate for the veterinarian to lump those discrete drug levels into a range and then provide a drug range on the VFD. Such an action would be of a limited use to the distributor and producer and could conflict with the approval and the approved Blue Bird label.

12. [Added 2019] Some approvals for use of VFD drugs in feed specify a body weight as part of the indication. When the approval includes body weight as part of the indication, does the VFD need to include estimated body weight of the animals?

The estimated body weight of the animals does not generally need to be included in order for the VFD to be valid. However, there may be instances when information related to the body weight of the animals may need to be included on the VFD as part of the information from the approval. For example, the approved conditions of use for some applications stipulate the body weight of treated animals (e.g., feed to animals >700 lbs. body weight). In this situation, this information would need to be identified on the VFD as part of the description of species and production class.

The VFD regulation does not preclude the veterinarian from including information about the weight of the animals on the VFD. If the issuing veterinarian chooses to include the approximate weight range of the animals on the VFD, he or she can do so under 21 CFR 558.6(b)(4), which permits the veterinarian to include “(iv) Any other information the veterinarian deems appropriate to identify the animals specified in the VFD.”

When information about the animals’ body weight is necessary to determine the appropriate amount of feed, we encourage distributors, veterinarians, and clients to work together to share the necessary information about the animals to determine the appropriate amount of feed for the approximate number of animals authorized by the VFD.

13. [Revised 2019] What additional information is required on a VFD authorizing the use of a combination VFD drug?

A VFD authorizing the use of a combination VFD drug that contains two or more VFD drugs is required to include the name of the drugs in the combination, the indication(s) of use, the levels of the drugs in the VFD feed and duration of use, the withdrawal time, special instructions, and cautionary statements necessary for use of the combination VFD drug required by the approval (21 CFR 558.6(b)(5)) (i.e., the drug-specific information specified in 21 CFR 558.6(b)(3)(vi), (ix), (x), and (xi) for each VFD drug in the combination).

The veterinarian may expand or limit the use of a VFD drug along with one or more OTC animal drugs in an approved, conditionally approved, or indexed combination VFD drug by completing the drug-specific information specified in 21 CFR 558.6(b)(3)(vi), (ix), (x), and (xi) for the use of the VFD drug(s) and by including one of the following affirmation of intent statements (21 CFR 558.6(b)(6)):

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- “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.” [List specific approved, conditionally approved, or indexed combination medicated feeds following this statement.]
- “This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.”

14. [Added 2019] If a VFD is written to allow VFD drugs to be used in feed in combination with OTC drugs using the affirmation statements, do the withdrawal time, special instructions, and cautionary statements need to include both drugs, or just the VFD drug?

If a veterinarian is authorizing a VFD drug in combination with an OTC drug(s) through the use of affirmation statements on the VFD, it is not required to list the withdrawal time, special instructions, and warning statements for the OTC drugs authorized in the combination. The VFD is required to include information for the VFD drug, i.e., the cautionary statements for the VFD drug and indication the VFD is authorizing. However, we do not object to the veterinarian including the cautionary statements for the OTC drugs on the VFD if he or she chooses to do so. In contrast, the requirements for labeling the resulting VFD feed are different than for the VFD order. If a combination is used, we would expect the labeling for the VFD combination feed to include all relevant cautions including those for the OTC drugs included in the combination VFD feed.

A VFD authorizing the use of a combination VFD drug that contains two or more VFD drug(s) is required to include the name of the drugs in the combination, the indication(s) of use, the levels of the drugs in the VFD feed and duration of use, the withdrawal time, special instructions, and cautionary statements necessary for use of the combination VFD drug required by the approval (21 CFR 558.6(b)(5)) (i.e., the drug-specific information specified in 21 CFR 558.6(b)(3)(vi), (ix), (x), and (xi) for each VFD drug in the combination).

15. Do these regulations allow reorders and refills?

The regulation allows the issuing veterinarian to authorize reorders (refills) of the VFD only if reorders (refills) are explicitly permitted by the drug approval, conditional approval, or index listing. In cases where reorders (refills) are not specified on the labeling for an approved, conditionally approved, or index listed VFD drug, reorders (refills) are not permitted (21 CFR 558.6(b)(3)(xii)).

16. What is an “extralabel use” of a VFD drug and is it allowed?

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“Extralabel use” is defined in FDA’s regulations as actual or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling (21 CFR 530.3(a)). For example, feeding the animals VFD feed for a duration of time that is different from the duration specified on the label, feeding VFD feed formulated with a drug level that is different from what is specified on the label, or feeding VFD feed to an animal species different than what is specified on the label would all be considered extralabel uses.

Extralabel use of medicated feed, including medicated feed containing a VFD drug or a combination VFD drug, is not permitted (21 U.S.C. 360b(a); 21 CFR 530.11(b) and 558.6(a)(3)). Use of medicated feeds, including those containing a VFD drug or a combination VFD drug, is limited to the approved, conditionally approved, or indexed conditions of use (21 U.S.C. 360b(a); 21 CFR 558.6(a)(3)).

The VFD must include 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.” (21 CFR 558.6(b)(3)(xiii)).

For a discussion of extralabel use of VFD feed for minor species, please see Question [III.A.22. \[Added 2019\] My client has a minor species. I would like to write a VFD for a therapeutic use of a medicated feed, but there is not an approval for this species. What should I do?](#)

D. VFD Transmission and Recordkeeping

1. How can a VFD be transmitted to the distributor?

A veterinarian must send a copy of the VFD to the distributor in hardcopy, by facsimile (fax), or by electronic means. If the veterinarian sends the VFD in hardcopy, he or she must send the copy of the VFD to the distributor either directly or through the client (21 CFR 558.6(b)(8)).

2. Is the veterinarian required to send the original VFD to the distributor?

No, the veterinarian is not required to send the original hardcopy to the distributor. The veterinarian must retain the original VFD in its original form (electronic or hardcopy). The distributor and client copies may be kept either as an electronic copy or hardcopy (21 CFR 558.6(a)(4)).

3. Can a VFD be transmitted by telephone?

The veterinarian is required to issue a written (nonverbal) VFD (21 CFR 558.6(b)(7)). Therefore, a VFD may not be issued verbally, including verbal transmission by telephone. A VFD may be sent by facsimile (fax).

4. Can a VFD be transmitted to the distributor by the Internet?

Yes. According to 21 CFR 558.6(b)(8), a VFD must be sent to the distributor “via hardcopy, facsimile (fax), or electronically.” The term “electronically” includes sending via the Internet.

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For example, transmitting the VFD “electronically” includes using the Internet to transmit the image of a paper VFD (e.g., emailing a scanned VFD document) or using the Internet to transmit an electronic VFD generated in a system that is shown to be in compliance with FDA’s regulations at 21 CFR part 11. For additional information about how part 11 applies to the VFD process, see discussion at Question [II.D.8. What is 21 CFR part 11 and how does it apply to the issuance of electronic VFDs?](#)

5. Who is responsible for distributing the VFD?

The veterinarian must retain the original VFD in its original form (electronic or hardcopy) (21 CFR 558.6(a)(4)). In addition, the veterinarian is required to send a copy to the distributor directly or, if sending the VFD in hardcopy, either directly or through the client (21 CFR 558.6(b)(8)), and the veterinarian is also required to give a copy of the VFD to the client (21 CFR 558.6(b)(9)). Thus, it is the veterinarian’s obligation to ensure that the VFD is distributed to the client and the distributor.

6. How long must a VFD be kept and who must keep them?

All involved parties (veterinarian, client, and distributor) must retain a copy of the VFD for 2 years. The veterinarian is required to keep the VFD in its original format. The distributor and client copies may be kept as an electronic copy or hardcopy (21 CFR 558.6(a)(4)).

7. In what format can the “original VFD” be kept by the veterinarian?

The veterinarian must retain the original VFD in its original form (electronic or hardcopy) (21 CFR 558.6(a)(4)).

8. What is 21 CFR part 11 and how does it apply to the issuance of electronic VFDs?

21 CFR part 11 sets out the criteria under which the Agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be generally equivalent to paper records and handwritten signatures executed on paper.

21 CFR part 11 applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any FDA records requirements. Therefore, electronic VFDs issued by veterinarians must be compliant with 21 CFR part 11, and electronic VFDs received and electronically stored by distributors and clients must also be compliant with 21 CFR part 11. 21 CFR part 11 does not apply to paper records that are, or have been, transmitted by electronic means such as facsimile, email attachments, etc.

9. [Added 2019] I am a distributor/client who receives electronic VFDs and paper VFDs from veterinarians or clients. I would like to store these VFDs as electronic PDFs to meet the VFD regulation for retention. Can I archive required records in a standard electronic file format such as PDF, XML, or SGML?

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Yes, distributors or clients can retain VFDs and related records (e.g., acknowledgment letters) received in hardcopy or by electronic means in a standard electronic file format (such as PDF, XML, or SGML), irrespective of whether the computer system on which these records are stored is compliant with 21 CFR part 11. We anticipate that storage as a PDF file will be a common method for the maintenance of these records by distributors and clients.

10. Can a third-party server company require testing of its clients' computers before starting to transmit VFDs?

Whether or not third-party server companies require testing of their clients' computers for compatibility with their systems before starting to provide the clients with their service is a business decision between third-party server companies and their clients and not an FDA requirement.

11. [Added 2019] If a staff veterinarian writes a VFD for a company-owned feedmill, for company animals, does the company need to retain one or three copies of the VFD?

The VFD regulation identifies three parties – veterinarian, producer, and the VFD feed distributor – as the parties that are required to keep the record of a VFD. If one entity represents the veterinarian, the distributor, and the client, it is acceptable for the VFD to be stored in one location provided that everyone required to have a copy has access and can provide a copy to the FDA investigator upon request.

12. [Added 2019] I am a client that has multiple premises. Do I need to keep a copy of the VFD at each of those premises?

No, a client who keeps animals at multiple premises is not required to keep a copy of the VFD at each location where animals reside. It is acceptable for the VFD to be stored in one location; however, if the client is not directly feeding the animals at each location (e.g., an employee is feeding the animals), then the VFD should be made available to those responsible for the direct care of the animals so that they can feed the VFD feed in accordance with the VFD as required by the VFD rule. This may be done by having a physical copy of the VFD at each location, or it may be done by providing electronic access to the VFD that is stored in a central location. Either way, the client is required to have a copy of the VFD. If an inspector requests a copy during an inspection at one location, the client (or their employee) must be in possession of the VFD or must have a way to readily access the VFD.

III. QUESTIONS AND ANSWERS SPECIFIC TO INVOLVED PARTIES

A. Veterinarian

1. What are my responsibilities as a veterinarian?

In order for a VFD to be lawful, the veterinarian issuing the VFD:

- Must be licensed to practice veterinary medicine (21 CFR 558.6(b)(1)(i));

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- must be operating in the course of the veterinarian’s professional practice and in compliance with all applicable veterinary licensing and practice requirements (21 CFR 558.6(b)(1)(ii));
- must only write a VFD in the context of a veterinarian-client-patient relationship (VCPR) (21 CFR 558.6(b)(1)(ii));
- must only issue a VFD that is in compliance with the conditions for use approved, conditionally approved, or indexed for the VFD drug or combination VFD drug (21 CFR 558.6(b)(2));
- must prepare a written (nonverbal) VFD (21 CFR 558.6(b)(7)) that includes the veterinarian’s electronic or written signature (21 CFR 558.6(b)(3)(xv));
- must ensure the VFD includes all required information specified in the VFD regulation (21 CFR 558.6(b)(3));
- may enter additional discretionary information to more specifically identify the animals to be treated/fed the VFD feed (21 CFR 558.6(b)(4));
- must include certain drug-specific information for each VFD drug when the veterinarian is authorizing the use of a drug combination that includes more than one VFD drug (21 CFR 558.6(b)(5));
- for VFD drugs approved for use alone or in combination with one or more OTC drugs, must include on the VFD an affirmation of intent either to restrict authorized use only to the VFD drug cited on the VFD or to allow the use of the cited VFD drug in an approved combination with one or more OTC drug(s) (21 CFR 558.6(b)(6));
- must provide the distributor with a copy of the VFD (21 CFR 558.6(b)(8));
- must provide the client with a copy of the VFD (21 CFR 558.6(b)(9));
- must retain the original VFD for 2 years (21 CFR 558.6(a)(4)); and
- must provide VFDs for inspection and copying by FDA upon request (21 CFR 558.6(a)(5)).

2. [Revised 2019] Can I write a VFD for an OTC drug?

No, a veterinarian may only write a VFD for drugs that have been approved, conditionally approved, or indexed as VFD drugs by the FDA (21 U.S.C. 354). However, where the veterinarian is authorizing the use of a VFD drug approved for use in combination with one or more OTC drugs, the veterinarian may include certain information about the OTC drug(s) on the VFD. For further discussion about the information to be included on the VFD when the veterinarian authorizes VFD drug combinations that include both VFD and OTC drugs, please see Question [II.C.14. \[Added 2019\] If a VFD is written to allow VFD drugs to be used in feed in combination with OTC drugs using the affirmation statements, do the withdrawal time, special instructions, and cautionary statements need to include both drugs, or just the VFD drug?](#)

3. [Revised 2019] How do I authorize or limit the use of a VFD drug that is approved to be used in combination with OTC drugs?

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Some VFD drugs are approved for use alone or in a combination with one or more OTC drug(s). In those circumstances, the issuing veterinarian would specify on the VFD whether he or she authorizes the VFD drug to be used alone or in an approved drug combination with one or more OTC drug(s). In accordance with 21 CFR 558.6(b)(6), the veterinarian is required to affirm his or her intent by including one of the following three statements on the VFD:

- “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 statement is used if the veterinarian does **not** authorize the VFD drug to be used in combination with any other animal drug in the medicated feed. For those VFD drugs that are only approved as a single ingredient Type A medicated article, i.e., there are no approved combinations that contain the VFD drug as a component, this statement is the only one of the three statements that can be selected and it must be included in the VFD.
 - “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.” [List specific approved, conditionally approved, or indexed combination medicated feeds following this statement.]
 - This statement is used if the veterinarian chooses to authorize the use of the VFD drug(s) only in **specific** combination(s); the veterinarian may only list approved, conditionally approved, or indexed combination(s) that contain the VFD drug. The client is authorized to use the VFD drug(s) in medicated feed either alone or in those specific combinations that the veterinarian has specified on the VFD.
 - “This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.”
 - This statement is used if the veterinarian authorizes the use of the VFD drug(s) in **any** approved combination that contains the VFD drug. The client is authorized to use the VFD drug(s) either alone or in any approved, conditionally approved, or indexed combination with the OTC drug(s) in the medicated feed.
4. [Added 2019] Can I authorize a feed through pesticide to be used in a VFD feed? If so, how do I do that?

An EPA-registered feed through pesticide may be added to most medicated feeds, including VFD feed. However, adding a feed through pesticide to a liquid medicated feed or free-choice dry/liquid medicated feed would require a specific FDA approval. Addition of a feed through pesticide to these types of feeds would affect the approved formula/specifications, which could affect the safety profile of the medicated feed by altering the drug intake and drug stability.

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It would not be appropriate to add an EPA registered feed through pesticide to a VFD feed if there is information suggesting that the addition of the EPA registered feed through pesticide would interfere with the safety and/or efficacy of the VFD feed. In addition, feed through pesticides must be used according to their labeling and in compliance with EPA regulations, including the “Tolerances and Exemptions for Pesticide Chemical Residues in Food” requirements in 40 CFR part 180.

You do not need to specify the inclusion of any feed through pesticide on the VFD. However, there is a location for the veterinarian to write any “special instructions” on the VFD (21 CFR 558.6(b)(3)(xi)). If the issuing veterinarian wants to recommend the inclusion of a feed through pesticide when authorizing the use of a VFD feed, this may be included in the special instructions area of the VFD.

5. Other than the required information, what other information may I include in the VFD?

As also noted in Question [II.C.1 What specific information must the veterinarian include on the VFD and what information is optional?](#) above, the veterinarian may, at his or her discretion, more specifically identify the animals authorized to be treated/fed the VFD feed (21 CFR 558.6(b)(4)). Specifically, the veterinarian can further specify the location of the animals (e.g., site, pen, barn, stall, or tank), the approximate age or weight range of the animals, or any other information the veterinarian deems appropriate to identify the animals subject to the VFD.

6. How can I transmit an electronic VFD to the distributor immediately if my third-party computer server holds all VFDs and only transmits them once per day (e.g., midnight)?

For an immediate delivery of an electronic VFD in this situation, we recommend that the veterinarian print a copy of the VFD and have it hand delivered, transmitted by facsimile, or scanned and transmitted electronically to the distributor.

7. [Revised 2019] How do I cancel my VFD?

To cancel a paper VFD we recommend that the veterinarian promptly contact the client and distributor in possession of a copy of the VFD and notify them of the cancellation.

To cancel an electronic VFD that involves a third-party server, we recommend that the veterinarian contact the server and request that the VFD not be transmitted. If the veterinarian wants to cancel the VFD after the order has been electronically transmitted, we recommend that he or she contact the distributor and client who received a copy of the VFD and notify them of the cancellation.

We recommend that all involved parties document the cancellation and be prepared to make all records available at the time of an inspection. We also recommend that all involved parties document the final outcome of the cancellation (e.g., state that the VFD feed was neither prepared nor distributed to the client, or the client did not receive or did not use any VFD feed).

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If the veterinarian wishes to cancel a VFD, but some animals have already started consuming the VFD feed, the veterinarian should work with the client to ensure those animals complete consumption of the VFD feed in accordance with the VFD unless the veterinarian determines under their medical judgment that continuation of treatment would not be in the best interest of the animals' health.

8. In the past, I issued paper VFDs. Must all VFDs be issued electronically now?

No, issuing VFDs electronically is optional. Paper VFDs remain an acceptable means of authorizing the use of a VFD drug.

9. How do I obtain a VFD form for a VFD drug?

Although it is not mandatory for VFD drug sponsors to provide copies of VFD forms specific to their products for use by veterinarians, sponsors may make the VFD forms available to veterinarians in triplicate or on a website to enhance efficiency and completeness of VFD transmissions. Regardless of whether or not a drug sponsor makes VFD forms available to veterinarians, a veterinarian may create a VFD form for a VFD drug. Any VFD form, whether provided by the drug sponsor or created by a veterinarian, must include the information specified in 21 CFR 558.6(b)(3).

10. [Revised 2019] Can I make my own VFD form to authorize the use of a VFD drug?

Although many companies distribute for use by veterinarians a VFD form that is specific to their products, a veterinarian may also create or use a different VFD form provided it contains all of the required information specified in 21 CFR 558.6(b)(3). We have issued guidance on a common format for VFDs which may be useful if you choose to make your own VFD form. See [Guidance for Industry #233, "Veterinary Feed Directive Common Format Questions and Answers."](#)⁴

11. [Added 2019] If the VFD has expired for a batch of feed, can I reissue a VFD to use the remaining feed?

Yes, VFD feed that was distributed under a VFD that has since expired can be used under a new VFD so long as that use is in conformance with the VFD drug's approval and the VFD regulations. For example, the VFD feed may be used for another group of animals under a new VFD, so long as the VFD feed is consistent with the authorization on the new VFD (e.g., correct drug level).

12. [Added 2019] I'm a veterinarian and I also want to sell VFD feed. What do I have to do?

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<https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM474640.pdf>

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If you are a veterinarian and a distributor, to distribute medicated feed you would need to follow the distributor requirements, including sending a one-time notification to FDA that you are a distributor. As a distributor, you would need to have on file either a VFD from a client or an acknowledgment letter, if the client is also a distributor. In addition, you would need to meet all of the requirements related to being a distributor and distributing VFD feed in 21 CFR 558.6.

13. [Added 2019] If I'm licensed in one State, can I write a VFD for animals located in another State? What if I have a temporary license in the State where the animals are located?

In order for a veterinarian to write a lawful VFD, the veterinarian issuing the VFD must: 1) be licensed to practice veterinary medicine; and 2) be operating within the course of the veterinarian's professional practice and in compliance with all applicable veterinary licensing and practice requirements, including issuing the VFD in the context of a veterinarian-client-patient relationship (VCPR) as defined by the State. If applicable VCPR requirements as defined by such State do not include the key elements of a valid VCPR as defined in 21 CFR 530.3(i), the veterinarian must issue the VFD in the context of a valid VCPR as defined in 21 CFR 530.3(i) (21 CFR 558.6(b)(1)).

Refer to this link to determine if the State or Federal VCPR definition applies to a lawful VFD in your State:

<https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm460406.htm>

A veterinarian would need to meet these requirements for the State the animals are located in, in order to issue a lawful VFD. This requirement is typically met by the veterinarian having a license to practice veterinary medicine in the State. However, in some States a veterinarian may be able to practice veterinary medicine within that State even if the veterinarian is licensed in another State, through reciprocity or a similar type of program.

Because under both Federal and State VCPR requirements, veterinarians must be available to provide any necessary follow-up evaluation or care, veterinarians cannot write a lawful VFD under a valid VCPR if they do not have permission to practice veterinary medicine for those animals during the entire duration of the VFD. Therefore, the expiration date of the VFD should not exceed the length of time during which the veterinarian is temporarily authorized to practice veterinary medicine in the state where the animals are located.

14. [Added 2019] If a VFD label has a duration range in which a VFD can be fed (e.g., 21-42 days), and I authorize the use of the VFD for the full 42 days, can the client decide when to stop feeding the VFD feed after the minimum provided in the range?

No, the client cannot decide when to stop feeding a VFD feed when you authorize the VFD for the full 42 days. The VFD authorizes the use of the VFD feed as required by 21 CFR 558.6(a)(1). Therefore, the use of the VFD feed must conform to the information the veterinarian authorizes on the VFD.

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In situations where there is a range for the VFD, the veterinarian should use his or her medical judgment to determine an appropriate duration. It is acceptable for the veterinarian to indicate the approved range for the duration and then provide additional information in the special instructions, including when it is appropriate to discontinue treatment. Using the example provided, the veterinarian could write 21-42 days in the duration and write in the special instructions “Feeding may be discontinued after 21 days but prior to 42 days when no symptoms have been observed for [X] days.”

15. [Added 2019] What if the label for the VFD drug uses the dosage (e.g., mg/head/day) instead of the level of the drug (e.g., g/ton) in the feed? Can I just include the dosage on the VFD?

Because the final rule requires the veterinarian to write “the level of VFD drug in the VFD feed and duration of use” on the VFD (§ 558.6(b)(3)(x)), the VFD must specify the drug(s) in terms of “g/ton” in feed. The allowable level of drug in the VFD feed is part of the VFD drug approval and is located on the VFD drug label. Many non-FDA resources are available to assist veterinarians in making any needed calculations. The veterinarian may work with the distributor and/or client to determine an appropriate level of VFD drug in the VFD feed. The distributor and client often have additional information such as the nutritional formulation and consumption rate that may be necessary to determine an appropriate drug level that is consistent with the approval.

16. [Added 2019] Can I assign an extended withdrawal to a VFD medication even though the producer will be using the VFD feed as labeled (i.e., no extralabel use)?

Yes, a veterinarian may instruct a client (producer) to hold animals beyond the labeled withdrawal period for VFD drugs used in those animals. The labeled withdrawal period is a minimum that needs to be met. Therefore, it would be acceptable for a veterinarian to recommend an extended withdrawal period beyond the minimum required by the label if they deem it necessary.

For purposes of writing a lawful VFD, the VFD rule requires the withdrawal time, special instructions, and cautionary statements necessary for use of the drug in conformance with the approval be written on the VFD (21 CFR 558.6(b)(3)(xi)). Therefore, the withdrawal period that the veterinarian writes on the VFD must be the withdrawal period that appears on the approved labeling for the use being authorized. However, the veterinarian may use the special instructions area of the VFD to provide the client (producer) with instructions for holding the animals for a longer time than the minimum required by the label to help ensure that any food from these animals is not adulterated.

17. [Added 2019] Can I work with a feed distributor, nutritionist, or other animal health professional in order to write a VFD?

Yes, a veterinarian may consult with others when preparing the VFD. As stated in the VFD final rule, the veterinarian is responsible for ensuring the VFD is complete and in accordance with the conditions for use in the relevant approval, conditional approval, or index listing (558.6(b)(2)

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and (3)). While we encourage veterinarians to work together with the client, feed distributor, nutritionist, or other animal health professionals to gather the information necessary to write a complete and accurate VFD, it is ultimately the veterinarian's responsibility to issue the VFD and ensure that it is complete and in accordance with the approval, conditional approval, or index listing.

18. [Added 2019] My client will have multiple groups of animals moving through their farm during the time period the VFD covers. Can I write the VFD to include the successive groups of animals that will be on the farm during the time period?

Yes. The approximate number of animals is the potential number of animals of the species and production class identified on the VFD that will be fed the VFD feed or combination VFD feed manufactured according to the VFD at the specified premises by the expiration date of the VFD.

The approximate number of animals should include all animals that are being authorized for treatment from the current and successive groups of animals on the premises prior to the expiration date. The treatment of any animals with VFD feed after the expiration date would need to be authorized under a new VFD.

19. [Added 2019] Some drug labels have different wording for the duration of use. For example, some say feed for X days and some say feed up to X days. How should I fill out the duration of use on the VFD?

Durations of use may be reflected in different ways in the approval, conditional approval, or index listing and on the corresponding labeling. Some labels do not allow the veterinarian any discretion in selecting a duration of use. For example, a label that states “feed for X days” indicates that the VFD feed must be fed for the exact number of days specified on the label and does not provide discretion for the veterinarian to authorize use for a different number of days.

In contrast, some labels do allow the veterinarian some discretion in selecting a duration of use. For example, a label that states “feed up to X days” indicates that the veterinarian has some discretion in selecting any number of days up to day X when writing the duration of use on the VFD. The client (producer) is authorized to use (feed) the medicated feed in compliance with the terms of a lawful VFD that is issued by a licensed veterinarian, so when discretion is allowed, it is important that the veterinarian writes the VFD to reflect how long the client should feed the animals the VFD feed.

20. [Added 2019] Our veterinary clinic has multiple veterinarians. Can any of our veterinarians write a VFD for any of our clients?

The Federal VCPR may apply to multiple veterinarians involved in a group practice so it is permissible for any of the veterinarians providing for the veterinary needs of an individual client or patient to write the VFD, so long as the Federal VCPR definition is met. (See Comment 26, 61 Fed. Reg. 57732 at 57738 (Nov. 7, 1996)). If you are operating in a State in which the State VCPR requirement applies to the issuance of a VFD, you should consult your State.

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21. [Added 2019] My client wants to use the VFD to receive a Type B medicated feed. Do I fill out the VFD with the Type B information?

The veterinarian is required to issue the VFD that is in compliance with the approved, conditionally approved, or indexed conditions for use (21 CFR 558.6(b)(2)). Therefore, the VFD must contain the information in the approval, which is the information for the Type C medicated feed that will be fed to the authorized animals.

However, this does not mean that the VFD must be filled with a Type C medicated feed. A VFD authorizes a client to receive a Type B or Type C medicated feed. If a client receives a Type B medicated feed, the client needs to follow the appropriate mixing directions so that the resulting Type C medicated feed conforms to the VFD drug approval and the VFD authorizing the use of the VFD feed. FDA's "Blue Bird Labels" website has representative labeling with mixing instructions for Type B medicated feeds.

<https://www.fda.gov/animalveterinary/products/animalfoodfeeds/medicatedfeed/bluebirdlabels/default.htm>

22. [Added 2019] My client has minor species. I would like to write a VFD for a therapeutic use of a medicated feed, but there is not an approval for this species. What should I do?

Extralabel use of drugs, including VFD drugs, in or on animal feed is prohibited (21 U.S.C. 360b(a)(4); 21 CFR 530.11(b)). However, we recognize that there are limited approved, conditionally approved, or indexed drugs for use in or on animal feed available for minor species. In addition, some minor species cannot be practically medicated in any other way than through the use of medicated feed. We have recently revised Compliance Policy Guide (CPG) Sec. 615.115 Extralabel Use of Medicated Feeds for Minor Species, which provides direction to field investigators to exercise enforcement discretion for the extralabel use of medicated feeds in minor species when certain conditions have been met. The revised CPG provides guidance to FDA field personnel on when to exercise enforcement discretion for the extralabel use of both OTC and VFD drugs in medicated feed for minor species.

See the link below for information on the revised CPG Sec. 615.115 Extralabel Use of Medicated Feeds for Minor Species:

<https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm529164.htm>.

23. [Added 2019] Do I need to have a laboratory confirmation of disease prior to writing a VFD?

No, there is not a requirement in the VFD regulations for laboratory analysis to confirm a diagnosis. It is up to the veterinarian authorizing the VFD to determine the level of clinical and diagnostic evidence necessary to authorize the VFD.

24. [Added 2019] If a veterinarian makes a mistake on a VFD and wants to go back and make corrections to the VFD rather than fill out a new VFD, can the veterinarian do that?

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Yes, under certain circumstances. For paper VFDs, the veterinarian can make changes to the original VFD at the time it is created by initialing and dating the corrections in ink or another indelible (i.e., permanent) method provided that the original information is not obscured. Please note that we expect only minor edits (e.g., correcting the address, the expiration date, etc.) could be made without needing reissue a new VFD. For electronic VFDs, simply correct the error electronically prior to issuing the VFD. A new VFD would be necessary if these conditions cannot be met.

If the VFD has already been issued (i.e., the copies have already been sent to the client and/or distributor), we recommend you cancel the original incorrect paper or electronic VFD and issue a new corrected VFD. If you plan to cancel the incorrect VFD, you should promptly contact the client and distributor in possession of a copy of the VFD and notify them of the cancellation. See Question [III.A.7. \[Revised 2019\] How do I cancel my VFD?](#)

25. [Added 2019] My client has requested a new VFD to replace the former VFD that will soon expire. Can I fill out the new VFD ahead of time and date it to begin when the previous VFD expires?

No. If a client requires a new VFD before the first VFD expires, the client must be issued a new VFD in accordance with the VFD regulation in 21 CFR 558.6. This requires that the new VFD include, among other things, the veterinarian's signature, the date of VFD issuance, and the VFD's expiration date. The date the veterinarian signs the VFD is the date of VFD issuance, and the date of issuance is the basis for determining the expiration date as it signifies the date the VFD came to effect.

B. Distributor

1. [Added 2019] Who is a distributor?

The term "distributor" means any person who distributes a medicated feed containing a VFD drug to another person. Such other person may be another distributor or the client-recipient of a VFD (21 CFR 558.3(b)(9)). As defined in the FD&C Act, the term "person" includes an individual, partnership, corporation, or association (section 201(e) of the FD&C Act (21 USC 321(e)).

If you are a feed mill or another person who meets the definition of "distributor" in 21 CFR 558.3(b)(9), you will be responsible for complying with the requirements applicable to distributors of VFD feed found in sections 558.6(a) and (c) of FDA's VFD regulations (21 CFR 558.6(a) and (c)), which are discussed below.

2. What are my responsibilities as a distributor?

If you distribute an animal feed containing a VFD drug or a combination VFD drug, you must:

- file a one-time notice with FDA of intent to distribute animal feed containing a VFD drug (21 CFR 558.6(c)(5)). The notice should be sent to FDA, Center for Veterinary

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Medicine, Division of Animal Feeds (HFV-220), 7519 Standish Pl., Rockville, MD 20855 (21 CFR 558.6(c)(7));

- notify FDA within 30 days of any change in ownership, business name, or business address (558.6(c)(6));
- fill a VFD only if the VFD contains all required information (21 CFR 558.6(c)(1));
- 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 approved, conditionally approved, or indexed conditions of use for such drug (21 CFR 558.6(c)(2));
- 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.” (21 CFR 558.6(a)(6));
- retain VFDs for 2 years from date of issuance (21 CFR 558.6(a)(4));
- retain records of the receipt and distribution of all medicated animal feed containing a VFD drug for 2 years (21 CFR 558.6(c)(3));
- provide VFDs for inspection and copying by FDA upon request (21CFR 558.6(a)(5));
- 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 (21 CFR 558.6(c)(4)); and
- if you are the originating distributor (consignor), you must obtain an acknowledgement letter from the receiving distributor (consignee) before the feed is shipped (21 CFR 558.6(c)(8)); and
- if you are a consignor distributor, you are required to retain a copy of each consignee distributor’s acknowledgement letter for 2 years (21 CFR 558.6(c)(8)).

3. [Revised 2019] What is the Distributor Notification Process?

A distributor must submit a one-time notification to FDA of intent to distribute medicated feed containing a VFD drug (21 CFR 558.6(c)(5)). The distributor notification must include the distributor’s complete name and business address, the distributor’s signature or the signature of the distributor’s authorized agent, and the date the notification was signed (21 CFR 558.6(c)(5)).

In some cases, an animal producer (client) may also be a distributor. When a manufacturer of a Type B VFD feed distributes the Type B VFD feed to an animal producer, the animal producer may manufacture a Type C VFD feed to either feed the VFD feed to his or her own animals and/or further distribute the Type C VFD feed to another distributor or client-recipient.

If the VFD feed is being shipped to an animal producer who is a distributor that has sent a one-time notification to FDA, the animal producer must supply either an acknowledgement letter (see below [Question III.B.6. \[Revised 2019\] What is an acknowledgement letter?](#)) or a VFD for the

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receipt of the Type B VFD feed from the distributor (21 CFR 558.6(c)(2) and (8)). (Note: In order for the animal producer to receive a Type B or Type C VFD feed without a VFD in hand, he or she must have previously notified FDA that he or she is a distributor in accordance with 21 CFR 558.6(c)(5). If the animal producer provides an acknowledgment letter to the distributor from whom the animal producer receives the VFD feed, the animal producer must either receive an acknowledgment letter or a VFD prior to further distributing the VFD feed to another person, or have a VFD on hand prior to feeding the Type C VFD feed to his or her own animals (21 CFR 558.6(c)(2) and (8)).

4. When is a distributor required to submit an updated notification to the FDA?

An updated notification is required to be sent within 30 days of any change in ownership, business name, or business address (21 CFR 558.6(c)(6)).

5. Is there a publicly available VFD distributor notification list?

Yes, there is a publicly available VFD distributor notifications list. The list is available at: <https://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/default.htm>.

6. [Revised 2019] What is an acknowledgment letter?

An “acknowledgement letter” is defined in FDA’s regulations as “a written (nonverbal) communication provided to a distributor (consignor) from another distributor (consignee). An acknowledgement letter must be provided either in hardcopy or through electronic media and must affirm: (i) that the distributor will not ship such VFD feed to an animal production facility that does not have a VFD, (ii) that the distributor will not ship such VFD feed to another distributor without receiving a similar written acknowledgment letter, and (iii) that the distributor has complied with the distributor notification requirements of § 558.6(c)(5).” (21 CFR 558.3(b)(11)).

7. [Revised 2019] How is an acknowledgment letter different from a distributor notification?

A distributor notification is the one-time notice by a distributor to the FDA of its intent to distribute a medicated feed containing a VFD drug (21 CFR 558.6(c)(5)).

The acknowledgment letter is a tool used when a distributor is distributing VFD feed to another distributor, instead of to a client (the owner of the animals or other caretaker). The distributor that is sending the VFD feed, also known as the consignor, gets the acknowledgment letter from the distributor receiving the VFD feed, also known as the consignee. The acknowledgment letter allows a distributor to have VFD feed on hand so that when a client provides a valid VFD, the distributor can fill the VFD promptly.

8. When is a medicated feed mill license required?

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A medicated feed mill license is required to manufacture a Type B or Type C medicated feed from a Category II, Type A medicated article (21 CFR 558.4(a)). A list of Category II drugs is located in [21 CFR 558.4\(d\)](#).⁵ A medicated feed mill license is also required to manufacture certain free-choice medicated feeds (21 CFR 510.455(f)) and liquid medicated feeds (21 CFR 558.5(g)). The licensing requirements are the same whether manufacturing medicated feed from OTC or VFD drugs.

9. Is a medicated feed mill license required when a medicated feed containing a VFD drug is manufactured from a Type A medicated article?

It depends. A medicated feed mill license is required if the VFD drug used to manufacture a Type B or Type C medicated feed is a Category II, Type A medicated article (21 CFR 558.4(a)). A license is not required if the VFD drug is Category I with the exception of certain liquid and free-choice medicated feeds. A list of Category II drugs is located in [21 CFR 558.4\(d\)](#).

10. What should the distributor do if the VFD is not completely filled out?

The veterinarian must ensure that all required information is fully and accurately included on the VFD (21 CFR 558.6(b)(3)). The distributor is permitted to fill a VFD only if the VFD contains all required information (21 CFR 558.6(c)(1)). If it does not contain all the required information, the distributor must not fill the VFD and we recommend that the distributor notify the veterinarian that the order cannot be filled until all the necessary information is provided on the VFD.

11. [Revised 2019] If a VFD authorizes the use of a drug(s) that is not approved as a VFD drug or combination VFD drug, can a distributor fill the VFD?

No, a lawful VFD can only be used to authorize the use of a VFD drug, either alone, or in an approved combination VFD drug(s) that may in some cases include one or more OTC animal drugs in addition to the VFD drug(s). See Question [II.C.13. \[Revised 2019\] *What additional information is required on a VFD authorizing the use of a combination VFD drug?*](#) If a distributor receives a VFD that specifies a drug other than an approved, conditionally approved, or indexed VFD drug(s) or combination VFD drug(s), the distributor may not fill that VFD.

12. [Added 2019] Am I considered a distributor if I manufacture feed in my feed mill and deliver it to animals that I own, but are kept in a barn that is not mine and raised by a contract grower?

A distributor is defined in the VFD regulations at 21 CFR 558.3(b)(9) as a person who distributes medicated feed containing a VFD drug to another person who is either the client or another distributor. Therefore, in the situation described, whether you are considered a distributor or not depends on whether the same person (individual or business entity) distributing the VFD feed is also acting as the client in the context of the VCPR that the VFD has been authorized under. If the same person is doing both of these activities, then the person is not

⁵ https://www.ecfr.gov/cgi-bin/text-idx?SID=b8e74620d2b65cd5c35fb00efa6dbcd9&mc=true&node=pt21.6.558&rgn=div5%20-%20se21.6.558_14

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distributing VFD feed to “another person” and is not a distributor. If different people are doing these activities, then the person distributing the VFD feed is distributing VFD feed to “another person” and is, therefore, a distributor within the meaning of 21 CFR 558.3(b)(9).

The question states that the animals are raised by the contract grower. So, it appears that the contract grower is the person who is responsible for feeding the animals the VFD feed and therefore would likely be considered the “client” for the purposes of the VCPR requirements for a valid VFD.

If the contract grower is the “client” as reflected on the VFD, the feed mill would then be distributing VFD feed to another person, and, therefore, would be considered a “distributor.” In such cases, the person providing the feed to the contract grower would need to meet the distributor requirements as described in 21 CFR 558.6 (e.g., provide one-time notification to FDA).

If the contract grower is not considered the client and instead the feed mill/animal owner is the “client” for the purposes of the VCPR requirements, the feed mill/animal owner would not be distributing a VFD feed to “another person” and thus would not be considered a distributor under 21 CFR 558.3. However, it is important to note that the client would need to have a lawful VFD in hand prior to feeding the VFD feed to the client’s animals.

13. [Added 2019] Can a distributor distribute a VFD feed to a representative of the client (e.g., a family member, or employee)?

Yes, the distributor may distribute a VFD feed to a representative of the client. We recommend that if a distributor has questions about whether a person is a representative of a client, they should contact the client directly to verify the relationship.

14. [Added 2019] Can an acknowledgment letter be written to cover multiple shipments of VFD feed?

Yes, an acknowledgment letter can be written to cover multiple shipments and there are several ways to do so. One way is to write an acknowledgment letter to cover specific shipments of VFD feed within a specified time period. Another way is to write an acknowledgment letter to cover multiple shipments of VFD feed with an open-ended time period.

The acknowledgment letter must be kept for 2 years. If the acknowledgment letter has a specified time period, the acknowledgment letter must be kept for 2 years from the specified end date. If the acknowledgment letter is open-ended, the acknowledgment letter must be kept for 2 years from the date the last shipment was distributed under the acknowledgment letter.

15. [Added 2019] I manufacture a VFD feed and ship a VFD feed to a farmer, but the sales transaction is handled through a dealer who does not physically take possession of or distribute the VFD feed. What are my responsibilities and what are the dealer's responsibilities?

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In the described scenario, the person manufacturing the VFD feed and shipping it to a farmer is considered a distributor because he/she is distributing VFD feed to another person. Any distributor must send a distributor notification to FDA and comply with the distributor requirements in 21 CFR 558.6, including maintaining a copy of the VFD.

In the described scenario, the dealer would not be a distributor as defined in 21 CFR 558.3 because the dealer is not distributing the VFD feed to another person, even though the dealer has a business relationship with the distributor and the farmer. As a result, there would not need to be an acknowledgment letter between the distributor and the dealer. A dealer does not have to submit a distributor notification to FDA unless the dealer physically distributes VFD feed.

However, the dealer must retain a copy of the VFD, because the dealer is also involved in the distribution and use of the VFD feed. The statute requires that any person involved in the distribution or use of a VFD feed maintain a copy of the VFD for that feed. The only exception in the statute is when the distributor is distributing the VFD feed to another person for further distribution (another distributor) (section 504(a)(3) of the FD&C Act (21 U.S.C. 354(a)(3))).

16. [Added 2019] What is needed in a distributor notification and can a distributor notification cover multiple locations?

The VFD distributor notification letter can be done in a number of ways, so long as it contains the following required information:

- The distributor's complete name and business address;
- The distributor's signature or the signature of the distributor's authorized agent; and
- The date the notification was signed.

We suggest using a letter format for the notification, with the subject line "VFD Distributor Notification." The distributor notification must be submitted to the Food and Drug Administration, Center for Veterinary Medicine, Division of Animal Feeds (HFV-220), 7519 Standish Place, Rockville, MD 20855, FAX: 240-453-6882. (21 CFR 558.6(c)(7)).

A single notification may include multiple locations. For multiple locations, each address must be included in the notification. A company with multiple locations may also send separate VFD distributor notifications for each location. Both methods are acceptable as long as they contain the required information described above. A notification from a company that states their intent to distribute at all of their locations but fails to provide the address of each location would not be acceptable.

17. [Added 2019] What is needed in an acknowledgment letter and can an acknowledgment letter cover multiple locations between the distributors?

There are specific items that must be included in the acknowledgment letter. As specified in 21 CFR 558.3(b)(11), an "acknowledgment letter" is a written (nonverbal) communication provided to a distributor (consignor) from another distributor (consignee) which must affirm:

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- That the distributor will not ship such VFD feed to an animal production facility that does not have a VFD,
- That the distributor will not ship such VFD feed to another distributor without receiving a similar written acknowledgment letter, and
- That the distributor has complied with the distributor notification requirements of 21 CFR 558.6(c)(5).

In addition to the affirmation above, we would expect to see the name of the distributor who is sending the acknowledgment letter and the name of the distributor who is receiving the acknowledgment letter.

An acknowledgment letter may cover multiple locations between two distributors. For example, the acknowledgement letter could be written as described above with an appendix that includes all of the locations covered by that acknowledgement letter for each distributor. Each location should have a current copy of the acknowledgment letter and appendices. The appendices could then be updated when the locations operating under the acknowledgment letter change. We recommend that the appendices be dated to easily identify the most current version.

18. [Added 2019] Do I need to hold VFD drugs or feed in a secure or locked area?

No, there is no requirement in the VFD regulations at 21 CFR 558.6 for distributors to lock up or secure Type A medicated articles, or Type B or C VFD feed. However, some distributors may choose to secure or lock up VFD drugs or feed as one way to meet the requirement that VFD feed can only be distributed after receipt of a valid VFD (or an acknowledgment letter in the case of distribution to another distributor). Other distributors may implement other business practices that would ensure a valid VFD or an acknowledgment letter has been received prior to distribution of the VFD feed and that the distribution of the VFD feed is in compliance with the terms of the VFD. In some instances, a distributor may make a business decision to secure drugs as a method to meet other drug handling requirements (e.g., to maintain control of drug inventory under medicated feed CGMP requirements).

19. [Added 2019] Do I have to repackage VFD feed into smaller amounts if the client does not need all of the VFD feed in a bag? If I don't repackage, will I be responsible for keeping track of the extra amount the client has on hand?

Generally, distributors will package VFD feed in the amount ordinarily used by each client. However, there may be situations wherein a client may be authorized to feed a VFD feed to a smaller than normal group of animals. In those situations, distributors may, but are not required to, repackage the feed into smaller bags.

If you are considering repackaging a Type B or C VFD feed, you may want to contact the VFD feed distributor regarding assistance with the labeling requirements and should contact your State feed regulatory agency regarding State requirements. If you choose to repackage medicated feeds, you will need to register with FDA as a food facility and follow the medicated feed CGMPs (21 CFR part 225), as well as the CGMPs for animal food (21 CFR part 507). In

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addition, the repackaged product will need to comply with the animal food labeling requirements in 21 CFR part 501, the labeling requirements for medicated feed in 21 CFR part 558 (e.g., following representative labeling), and relevant State requirements (in most cases, your State's requirements are likely to be inclusive of the requirements found in 21 CFR 501).

Also, please note that repackaging medicated feed does not extend the expiration date of that feed. In addition to the VFD expiration date, the medicated feed itself may have an expiration date specified on the label to ensure the effectiveness of the medicated feed. If no expiration date is on the label, this generally means that the feed is good for up to 3 months from the date of manufacture. If you do not want to repackage the medicated feed, you should provide the client with a pre-packaged amount that is most in line with the number of animals authorized on the VFD to be fed the medicated feed.

For example, if 15 lbs. would be appropriate to feed the number of animals indicated on the VFD and the packaged feed is sold in 25 and 50 lb. bags, the distributor should sell the 25-lb. bag. Another example would be if 60 lbs. of VFD feed is appropriate to feed the number of animals indicated on the VFD and the packaged feed is sold in 25 and 50 lb. bags. In this situation, the distributor should sell the client a 25 lb. bag and a 50 lb. bag, not two 50 lb. bags.

It is ultimately the client's responsibility to feed the VFD feed in compliance with the terms of the VFD, which means completing the authorized course of treatment by the expiration date. If a VFD will expire prior to the completion of a course of treatment, the client must either discard the remaining VFD feed once the VFD expires, or obtain a new VFD from the veterinarian to authorize use of the remaining feed for the full course of treatment before the new VFD expires.

20. [Added 2019] I am a distributor with multiple locations. Can I fill a VFD from any of my locations?

One distributor may have multiple locations (all under the same corporate ownership) and, provided the distributor has already sent FDA a letter indicating its intent to distribute VFD feed at each of these locations, it is acceptable for that distributor to fill a VFD from any of its locations. However, it is the distributor's responsibility to comply with the applicable requirements in 21 CFR 558.6(a) and (c), including the requirement to distribute a VFD feed only if it complies with the terms of the VFD and the requirement to keep records of receipt and distribution of all VFD feed for 2 years.

In addition, if the distributor manufactures the VFD feed, the distributor must also keep manufacturing records as required under 21 CFR part 225. During an inspection, we intend to review VFDs and compare them to manufacturing records. We would expect that the amount of medicated feed produced to fill a VFD, whether in one or several batches, would be commensurate with the amount of feed necessary for the approximate number of animals the VFD authorizes to be fed.

21. [Added 2019] I am a distributor with multiple locations. Do I need a VFD or acknowledgment letter to transfer VFD feed between my locations?

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When VFD feed is transferred between different locations within the same corporate entity, we would not consider the corporate entity to be distributing the VFD feed to another person. Therefore, an acknowledgment letter would not be required for transfers within the same corporate entity.

However, when VFD feed is transferred between different locations that are not part of the same corporate entity, then the person at the first location would be distributing VFD feed to another person (the second location). In this situation, the distributor at the first location would need to maintain a written acknowledgment letter from the distributor at the second location receiving the VFD feed.

For more information on who is a distributor and when a distributor is distributing to another “person” please see Question [III.B.1. \[Added 2019\] Who is a distributor?](#)

For more information about what is required in an acknowledgment letter, please see Question [III.B.6. \[Revised 2019\] What is an acknowledgment letter?](#)

22. [Added 2019] Can I provide a client with nutritionally different diets over the duration of use for a VFD?

Yes, you may provide a client with nutritionally different diets over the duration of use for a VFD.

The VFD includes information about the drug as approved for the indication. The VFD does not include information about the nutritional ingredients in the ration of the VFD feed. It is acceptable to feed several nutritionally different rations under a single VFD so long as each of those rations is consistent with the VFD and the drug approval.

23. [Added 2019] The client wants to purchase a Type B medicated feed under the VFD. If I distribute a Type B medicated feed, what are my responsibilities and what are the animal producer's responsibilities?

In order to obtain a Type B medicated feed, the client would need to provide the distributor with a VFD. The distributor is responsible for distributing a Type B medicated feed approved for manufacture of the Type C medicated feed specified in the VFD. The distributor and client (producer) are expected to work together to determine the appropriate amount of the Type B medicated feed that would result in a commensurate amount of Type C medicated feed for the approximate number of animals identified in the VFD.

After obtaining the Type B medicated feed from the distributor, the client would be responsible for using it to manufacture the Type C medicated feed specified in the VFD. Any client who is manufacturing, processing, packing, or holding medicated feed must do so in compliance with the applicable CGMP requirements for medicated feeds, which are found in 21 CFR part 225. The client would also be responsible for feeding the Type C medicated feed in accordance with the VFD.

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24. [Added 2019] I want to distribute a Type A medicated article to a client. Do I need a VFD from the client? Are there additional requirements for distributing Type A medicated articles?

Because Type A medicated articles for VFD drugs are not considered VFD feeds, a client does not need to present a VFD to obtain a Type A medicated article from a distributor. However, the FD&C Act requires a VFD for the distribution and use of any VFD feed resulting from the Type A medicated article (section 504(a)(3) of the FD&C Act (21 U.S.C 354(a)(3))). Additionally, a medicated feed mill license approved by FDA is required when manufacturing feed from a Type A medicated article that falls into Category II. (21 CFR 558.4). Therefore, Type A medicated articles in Category II must not be distributed to a client that does not have a medicated feed mill license. (See statutory text immediately following 21 U.S.C. 360b(a)(1)(D), and 21 CFR 510.7). See Question [III.B.8. When is a medicated feed mill license required?](#)

Also, the CGMP requirements for Type A medicated articles are found in 21 CFR part 226, which includes some requirements that are applicable to the holding and distribution of a Type A medicated article. For example:

Complete records shall be maintained for each shipment of Type A medicated article(s) in a manner that will facilitate the recall, diversion, or destruction of the Type A medicated article(s), if necessary. Such records shall be retained for at least 2 years after the date of the shipment by the manufacturer and shall include the name and address of the consignee, the date and quantity shipped, and the manufacturing dates, control numbers, or marks identifying the Type A medicated article(s) shipped. (21 CFR 226.110).

25. [Added 2019] Now that the VFD has the approximate number of animals instead of the amount of feed, what are my responsibilities as a distributor to make sure that the client is not receiving too much feed under the VFD? Will the FDA take enforcement action against me if a client over-orders or misuses a VFD feed?

As stated in the preamble to the VFD final rule, we expect that feed mills will only distribute VFD feeds in quantities that are commensurate with the approximate number of animals as specified by the veterinarian in the VFD. (80 FR 31708 at 31723, June 3, 2015). Feed mills should retain the necessary records to document the amount of feed that was manufactured and distributed under the VFD and make such records available for inspection and copying by FDA upon request.

Since the VFD specifies the number of animals that will be fed and not the exact amount of feed that can be manufactured, feed mills can work with the client as batches of feed are shipped under the VFD to adjust the amount of feed as feed consumption rates change among the animals. In the preamble to the VFD final rule, we discussed the change from the requirement to include the amount of feed to be manufactured on the VFD to the requirement to instead include the approximate number of animals to be treated. In this discussion, we stated that we expect the feed mill to share expertise and work with the client and veterinarian to determine the appropriate amount of feed to be manufactured for the approximate number of animals

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authorized to be treated under the VFD. (80 FR 31708 at 31722, June 3, 2015). We anticipate that, as part of our inspectional activities, we will consider such factors as whether the amount of feed distributed is reasonable relative to the approximate number of animals specified in the VFD.

If we encounter a situation where there has been a violation in the authorization, distribution, or use of a VFD drug or VFD feed, we intend to hold the party who committed the violation responsible. For example, if a feed mill appropriately fills a lawful VFD for an approximate number of animals based on reasonable consumption information provided by the client, but the client uses the VFD feed in a manner inconsistent with the terms of the VFD as issued by the veterinarian, we would conduct a follow-up investigation. Based on the results of this investigation, we would consider whether to pursue enforcement against the individual or individuals responsible for any improper activity.

26. [Added 2019] Can I manufacture VFD feed to have on hand before a client comes in with a VFD?

Yes. VFD distributors may be aware of VFD medicated feeds that are commonly ordered by their customers. A VFD distributor that has met the VFD distributor requirements (e.g., one-time notification to FDA) and any applicable licensing requirements for manufacturing medicated feed may manufacture a Type B or C VFD medicated feed in accordance with the VFD drug approval, provided they do not distribute the VFD medicated feed until presented with either a lawful VFD from a client or the client's veterinarian, or an acknowledgement letter from another distributor. We anticipate that this may occur in situations where a VFD distributor wants to have retail stock on hand, or distributes retail stock under an acknowledgment letter to another VFD distributor such as a farm store.

C. Client

1. What are my responsibilities as a client?

A client recipient of an animal feed containing a VFD drug or a combination VFD drug must:

- only feed animal feed bearing or containing a VFD drug or a combination VFD drug (a VFD feed or combination VFD feed) to animals based on a VFD issued by a licensed veterinarian (21 CFR 558.6(a)(1));
- not feed a VFD feed or combination VFD feed to animals after the expiration date on the VFD (21 CFR 558.6(a)(2));
- provide a copy of the VFD to the distributor when requested to do so by the issuing veterinarian (21CFR 558.6(b)(8));
- maintain a copy of the VFD for a minimum of 2 years (21 CFR 558.6(a)(4)); and
- make the VFD available for inspection and copying by FDA upon request (21 CFR 558.6(a)(5)).

2. What is my role as a client in the veterinarian-client-patient-relationship (VCPR)?

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In order for a VFD to be lawful, the VFD must be issued and used in compliance with all applicable requirements in 21 CFR 558.6. One such requirement is that the veterinarian must issue the VFD in the context of a State-defined VCPR or, if the VCPR requirements as defined by such State do not include the key elements of the Federally-defined valid VCPR or are not applicable to the issuance of a VFD, then the veterinarian must issue the VFD in the context of a valid VCPR as that term is defined in FDA's regulations at 21 CFR 530.3(i). (21 CFR 558.6(b)(1)(ii)). In cases where the Federally-defined VCPR applies, in order for the VFD to be written in the context of a valid VCPR you, as the client, must agree to follow instructions of the veterinarian (21 CFR 530.3(i)(1)). In cases where a veterinarian is issuing the VFD in the context of a State-defined VCPR, as a client you must follow the client requirements in the State-defined VCPR.

3. [Revised 2019] Can I have my veterinarian write a VFD to authorize the use of a medicated feed that is not approved for the use I'm intending (i.e., extralabel use)?

No, a veterinarian may only write a VFD to authorize use of a VFD drug or combination VFD drug in feed for the approved, conditionally approved, or indexed conditions of use. Use of VFD feed in an extralabel manner is prohibited. 21 CFR 558.6(a)(3). However, if you raise a minor species and there is no approved use for that species, see Question [III.A.22. \[Added 2019\] My client has minor species. I would like to write a VFD for a therapeutic use of a medicated feed, but there is not an approval for this species. What should I do?](#)

4. Can I feed my animals a VFD feed after the VFD expiration date?

No, a VFD feed or combination VFD feed must not be fed to animals after the expiration date on the VFD (21 CFR 558.6(a)(2)). A client may use the VFD to obtain VFD feed any time prior to the VFD's expiration, but the client may not feed that feed to animals after the VFD expires. For some drugs, there are discrete expiration and duration of use time periods specified as part of the drug approval which make it easier to determine in advance whether treatment would be completed by the VFD's expiration date. The client is responsible for feeding the VFD feed in compliance with the terms of the VFD, which means completing the authorized course of treatment by the expiration date. If a VFD will expire prior to the completion of a course of treatment, the client must either discard the remaining VFD feed once the VFD expires, or obtain a new VFD from the veterinarian to authorize use of the remaining feed for the full course of treatment before the new VFD expires.

5. I have a VFD that I would like to use to feed a VFD feed, but the VFD will expire before I can complete the duration of use on the VFD. What should I do?

In cases where a client would like to use a VFD feed but cannot complete the duration of use on the VFD before the VFD expires, the client should contact the veterinarian to request a new VFD. A VFD feed or combination VFD feed must not be fed to animals after the expiration date on the VFD (21 CFR 558.6(a)(2)).

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6. [Added 2019] Do I have to use the same distributor to obtain all of the VFD feed on a VFD?

In general, only one distributor (e.g., feed mill) should receive and fill a VFD.

The VFD regulation requires a veterinarian to send a copy of the VFD to the distributor via hardcopy, facsimile (fax), or electronically. If in hardcopy, the veterinarian must send the copy of the VFD to the distributor either directly or through the client. (558.6(b)(8)). If the veterinarian provides the client with a hardcopy to take to the distributor, the client can choose which distributor to use.

When the veterinarian is issuing the VFD directly to the distributor (i.e., the client will not be taking a hardcopy to the distributor), the client should tell the veterinarian to which distributor the VFD should be sent. If the client is unsure of which distributor should receive the VFD, the client should get a hardcopy from the veterinarian to provide to the client's distributor of choice. If the veterinarian has sent the VFD to a distributor and the client decides to get the VFD feed from a different distributor, the client should ask the veterinarian to revoke the VFD from the original distributor and resend it to the new distributor.

In special circumstances, such as when a mill runs out of a VFD drug and the client needs VFD feed immediately to adhere to the treatment regimen, there may be a need for two distributors to fill the entire order. If that is the case, the client and distributors should all keep records documenting the situation so that it is clear that the animals received only the treatment authorized by the VFD.

7. [Added 2019] What do I do if I need to treat animals for a specific duration (e.g., 30 days) but need to receive the VFD feed from two separate mills? For example, because of the animals' growth stage and needs, one mill will provide the ration for animals during the first 20 days of the VFD's duration and another mill will provide the ration for animals during the last 10 days of the VFD's duration.

In situations where it has been predetermined that the VFD feed will come from two different distributors during the VFD's duration of use, the veterinarian should indicate in the special instructions area of the VFD who the distributor of the VFD feed will be for each portion of the treatment period. Both distributors should receive copies of the VFD. Each distributor should provide only the amount of feed that is commensurate with the approximate number of animals and the portion of the treatment period for which the distributor is responsible for distributing the VFD feed.

8. [Added 2019] I feed my animals several different rations based on their nutritional needs during each growth stage. I have a VFD with a duration of use that will encompass several of these growth stages. Can my feed mill provide me VFD feed with different formulations over the duration of the VFD?

Yes. The VFD does not include information about the nutritional ingredients in the ration of the VFD feed, so it is acceptable to feed several rations under a single VFD provided that each of

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those rations is manufactured in a way that is consistent with the drug approval and used in accordance with terms of the VFD.

9. [Added 2019] I have a VFD that authorizes me to feed my animals for 5 days as indicated on the drug approval. What happens if the animals get sick again? Can I use the same VFD to get additional VFD feed and feed the animals again for 5 days? Can the veterinarian write the VFD to allow me to use the VFD feed for more than one 5-day period prior to the 6-month expiration date?

A veterinarian cannot issue a VFD that authorizes a duration of use that is inconsistent with the directions for use described on the approved product labeling. In the example provided, the approval limits the treatment to 5 days and therefore the VFD can only authorize that approved duration. Issuing a VFD that authorizes a 5-day course to be repeated for the same animals would be considered an illegal extralabel use.

However, if the veterinarian reassesses the animals involved after a single course of therapy (i.e., after the drug was administered according to the labeled dose and duration), the veterinarian may decide that additional therapy is warranted. In such case, a new VFD would be needed.

The veterinarian should report to FDA any treatments that were not clinically effective or any adverse reactions that may have occurred within 10 days of their occurrence. For instructions on reporting such information, visit FDA's webpage entitled "How to Report Animal Drug Side Effects and Product Problems" at:

<https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm>.

10. [Added 2019] I am currently feeding my animals a VFD feed under a valid VFD. I would like to transfer ownership of my animals. May I do that?

Yes, but the new owner may need to get a new VFD to continue treatment. In some situations, ownership of the animals changes but the animals continue to be fed by the same caretaker. Where this is the case, provided the caretaker is the client for the purposes of the VCPR requirements, the VFD would still be valid. However, if the ownership transfer results in a new client for the purposes of the VCPR, the new client would need a new VFD for the transferred animals. Only a veterinarian that has a VCPR with the new owner (i.e., the new client) and the transferred animals could write the new VFD.

In many situations, the transfer of ownership during a certain life stage of the animal may be expected. For example, oftentimes one owner may raise a group of animals to a certain age or weight and then sell that group to another owner who will continue to raise them. It is very important during a transfer of ownership that the veterinarians and clients are communicating and working together to avoid any unlawful use of the VFD feed.

For example, the veterinarian and original client should discuss the implications of a planned transfer of ownership at the time the veterinarian is issuing the VFD to ensure that the authorized course of treatment can be completed prior to the planned transfer of ownership. The original

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client should also make the new client (purchaser) aware of any VFD feed that already has been fed to the animals, including information about the indication, dosage, and duration of use.

To ensure the animals will receive a complete treatment, it is preferable not to transfer ownership during a time when VFD feed is being fed for a specific duration of use. If a transfer of ownership needs to be made while animals are being fed under a VFD, coordination between the original owner and veterinarian, and the new owner and veterinarian is important. The new veterinarian should issue a new VFD according to the approval but may use the special instructions area of the VFD to acknowledge the ownership transfer and record how much time remains to complete the treatment under the duration of use, taking into consideration how long the animals received treatment under the VFD held by the previous owner.

11. [Added 2019] Does the VFD feed authorized by a VFD need to be shipped in one load, or can it be delivered in multiple loads?

A VFD feed may be manufactured and shipped in one load, or multiple loads. This provides flexibility for the VFD feed to be manufactured and distributed in a way that meets the nutritional needs of the animals, the manufacturing capacity of the feed distributor, and the storage capacity of the client. However, the amount of feed manufactured and distributed should be appropriate for the approximate number of animals authorized to be fed under the VFD and can only be used up to the VFD's expiration date unless the client obtains another VFD authorizing the use of the remaining VFD feed.

12. [Added 2019] My animals are in the United States, but I receive my feed from Canada. Can I get a VFD feed from Canada and if so what are the requirements?

Yes, you can get VFD medicated feed from Canada. However, medicated feeds coming into the U.S. must comply with U.S. requirements. If the medicated feed is a VFD feed, it must comply with the requirements in the VFD final rule. This means, for example, that the veterinarian authorizing the use of the VFD feed must have a valid VCPR with the client and the client's animals, and must be licensed in the State where the animals are being raised and fed. In addition, the medicated feeds must be manufactured and labeled in conformance with U.S. requirements – including being labeled for the U.S. market.

13. [Added 2019] The veterinarian used an affirmation statement to indicate that I can feed the VFD feed in combination with an over-the-counter (OTC) drug. Is it okay for me to feed the VFD drug alone?

Yes, when the veterinarian selects an affirmation of intent statement that allows for the use of the VFD drug in combination with OTC drugs, either in a specific approved combination, or in any approved combination, the producer may also use the VFD drug alone. In the preamble to the VFD proposed rule, after describing the three affirmation of intent options, we stated that "In all cases, the VFD may be used to authorize the distribution and use of medicated feed containing the VFD drug alone." (78 FR 75515 at 75521).

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14. [Added 2019] I want to get a Type A medicated article and manufacture my own feed. What are the requirements?

Type A medicated articles for VFD drugs are not considered VFD feeds. Therefore, a VFD is not required to obtain a Type A medicated article from a distributor. However, the FD&C Act requires a VFD for the distribution and use of any VFD feed resulting from the Type A medicated article. (Section 504(a)(3) of the FD&C Act (21 U.S.C 354(a)(3))). Therefore, you must have a VFD prior to distributing or using the VFD feed manufactured with the VFD Type A medicated article.

A medicated feed mill license is required if the VFD drug used to manufacture a Type B or Type C medicated feed is a Category II, Type A medicated article (21 CFR 558.4(a)). A list of Category II drugs is located at [21 CFR 558.4\(d\)](#).⁶ See Question [III.B.8. *When is a medicated feed mill license required?*](#)

In addition, any person who is manufacturing, processing, packing, or holding medicated feed must do so in compliance with the applicable CGMP requirements for medicated feeds, which are found in 21 CFR part 225.

15. [Added 2019] When I purchase a Type A medicated article to create an authorized Type C VFD feed, where does the copy of the VFD intended for the distributor go?

Three parties, the veterinarian, producer (client), and the VFD feed distributor, are required to keep the record of a VFD (21 CFR 558.6(a)(4)). In cases of on-farm milling, where a VFD feed distributor was not involved in the original transaction, only the veterinarian and the client would need to maintain copies of the VFD since there would not be a need for a VFD distributor copy.

16. [Added 2019] I have 4 months remaining on my VFD and I would like to get my VFD feed from a different distributor. Can I ask my veterinarian to cancel the first VFD and issue a new VFD to the second distributor?

Yes. If a client decides to source VFD feed from another distributor prior to the expiration date of the existing VFD, then:

- (1) the existing VFD will need to be cancelled with the current distributor as described in Question [III.A.7. *\[Revised 2019\] How do I cancel my VFD?*](#), and
- (2) a new VFD will need to be issued and sent to the second distributor.

All parties, including the veterinarian, client, and the first distributor, should document the situation to explain why the cancellation occurred. The veterinarian authorizing the new VFD will need to consider any changes in the approximate number of animals left to be fed the VFD feed under the new distributor. Switching from one distributor to another after distribution of VFD feed is expected to be a rare occurrence.

⁶ https://www.ecfr.gov/cgi-bin/text-idx?SID=b8e74620d2b65cd5c35fb00efa6dbcd9&mc=true&node=pt21.6.558&rgn=div5%20-%20se21.6.558_14

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17. [Added 2019] I am a client. Do I need to keep any records describing my use of the VFD feed in addition to keeping the VFD?

Under the VFD final rule, clients are only required to keep a copy of the VFD itself. However, it may be important for clients, particularly those who raise food-producing animals, to keep additional records to help ensure that the VFD feed was used in accordance with the VFD and any food made from the treated animals will be safe. For example, a producer may want to record information such as the date the VFD feed was received, when the VFD feed was used, and which animals received the VFD feed to document that the VFD feed was fed in accordance with the VFD. While this documentation is not required by the VFD regulation, it would be helpful for a producer to have such information available during an inspection to demonstrate whether a particular VFD was actually used and, if so, how the VFD feed was used.

In addition, where a VFD that has been issued to a client is subsequently cancelled, either at the client's request or for other reasons, we recommend that the client keep records documenting the cancellation as described in Questions [III.A.7. \[Revised 2019\] How do I cancel my VFD?](#) and [III.C.16. \[Added 2019\] I have 4 months remaining on my VFD and I would like to get my VFD feed from a different distributor. Can I ask my veterinarian to cancel the first VFD and issue a new VFD to the second distributor?](#), above.