#233

Guidance for Industry

Veterinary Feed Directive Common Format Questions and Answers

DRAFT GUIDANCE

This draft guidance document is for comment purposes only.

Submit comments on this draft guidance by the date provided in the *Federal Register* notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. You should identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

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Additional copies of this draft guidance document may be requested from the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at either http://www.fda.gov/AnimalVeterinary/default.htm or http://www.regulations.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
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Draft Guidance for Industry

Veterinary Feed Directive Common Format Questions and Answers

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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 as listed on the title page.

I. INTRODUCTION

On December 12, 2013, the Food and Drug Administration (FDA) published a proposed rule to revise the veterinary feed directive (VFD) regulations in Title 21 of the Code of Federal Regulations section 558.6 (21 CFR 558.6), and introduce clarifying changes to the related definitions in 21 CFR 558.3. On June 3, 2015, FDA published the final rule. Concurrently with the final rule, FDA published Draft Guidance for Industry #120 entitled "Veterinary Feed Directive Regulation" to provide guidance on the final rule.

A few of the comments in response to the proposed rule requested FDA require a uniform veterinary feed directive (VFD) form. We declined this request because we thought that requiring a specific VFD form would be too prescriptive. However, we acknowledge that a common VFD format would help clients, veterinarians, and distributors (including feed mills) quickly identify relevant information on the VFD. Therefore, we are issuing this draft guidance to recommend a common VFD format. In this guidance, when we use the term "VFD," we are referring to the form used to convey the VFD order.

FDA regulations require that an animal drug sponsor who is seeking approval of a drug for use in or on feed as a VFD drug must submit copies of a VFD for review by FDA's Center for Veterinary Medicine (CVM) "in a form that accounts for the information described under 21 CFR 558.6(b)(3) and 558.6(b)(4)" as part of the application process. This draft guidance addresses the requirement for sponsor submission of a VFD found in 21 CFR 514.1(b)(9), and recommends a common format for the information to be included on the VFD. Once the sponsor's drug is approved, the VFD form provided by the sponsor will be made available for use by veterinarians when authorizing their client to obtain and use medicated feed containing the VFD drug. (Please note that a veterinarian is not required to use the sponsor's form and may instead create his or her own VFD form.) This document also provides guidance concerning the elements that must be included in the VFD as required by 21 CFR 558.6(b)(3) and the elements that may be included on a VFD as described in 21 CFR 558.6(b)(4). Finally, this draft guidance provides examples that illustrate how a common VFD format might appear and how some information may be pre-populated on the VFD by the sponsor and subsequently completed with all of the remaining relevant information filled out by the issuing veterinarian. This draft guidance only covers the contents and format of the VFD. Guidance for Industry #120, "Veterinary Feed Directive Questions and Answers," contains more comprehensive information

about the VFD process, including information about the requirements for authorizing, manufacturing, distributing, and using VFD drugs in animal feed.

In general, FDA guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe 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.

II. VETERINARY FEED DIRECTIVE

A. Sponsor Submission of a Veterinary Feed Directive

1. What responsibilities does a sponsor have for creating and submitting a VFD to CVM?

As part of the application process for approval of a new animal drug for use in or on animal feed as a VFD drug, the drug sponsor is required to submit for FDA review three copies of a VFD in a format that accounts for the information described under 21 CFR 558.6(b)(3) and 558.6(b)(4). (21 CFR 514.1(b)(9)). Once the sponsor's drug is approved, veterinarians have the option to use the sponsor's VFD form when authorizing his or her client to obtain and use medicated feed containing the VFD drug.

2. Can a sponsor submit a VFD that does not include the VFD drug-specific information to meet the requirements of § 514.1(b)(9)?

No. A sponsor's VFD must account for the VFD drug-specific information described in 21 CFR 558.6(b)(3) and (b)(4) to meet the requirements of 21 CFR 514.1(b)(9).

3. What VFD drug-specific information should be pre-populated on the VFD at the time a sponsor submits a VFD to CVM as part of the new animal drug application?

A VFD pre-populated by the sponsor with as much of the required VFD drug information as possible and with areas designated on the form to account for the rest of the information that can only be provided by the veterinarian at the time the VFD is issued will reduce the risk of a veterinarian making an error or leaving out required information when filling in the form. Sponsors, at a minimum, should pre-populate the following information on the VFD submitted to CVM as part of the new animal drug application to reflect the conditions of approval, conditional approval, or index listing: (1) drug name(s); (2) drug level and duration of use (exact level or ranges as approved); (3) indication(s); (4) species and production class(es); (5) withdrawal time(s); (6) near the space where the veterinarian includes the expiration date, the maximum expiration date specified in the approval, conditional approval, or index listing, or 6 months if a date is not otherwise specified; (7) the maximum number of reorders (refills) permitted by the drug approval, conditional approval, or index listing or, if none are permitted, the statement, "Refills of this VFD are not permitted."; (8) any special instructions specified on the approved

labeling as necessary for use of the drug; (9) 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."; and (10) cautionary statements (including warnings) necessary for use of the drug in conformance with the approval. Special instructions, cautionary statements, and warnings found on the approved representative Type C medicated feed (Blue Bird) labeling should appear on the VFD.

4. What information should not be pre-populated on the VFD at the time a sponsor submits a VFD to CVM as part of the new animal drug application?

There is some information that a sponsor would generally be unable to pre-populate on the VFD because that type of information can only be filled in by the veterinarian once he or she has engaged with a particular client. This includes: (1) the client name, business or home address, and telephone number; (2) veterinarian name, address, and telephone number; (2) the premises at which the animals specified on the VFD are located; (3) the date of VFD issuance; (4) the VFD expiration date (a date not to exceed the date as specified in the approval, conditional approval, or index listing, or if not specified, not to exceed 6 months); (5) the approximate number of animals to be fed the VFD feed by the expiration date of the VFD; (6) the veterinarian's special instructions; (7) the number of reorders (refills) authorized by the veterinarian (not to exceed the number permitted by the drug approval, conditional approval, or index listing, if any); (8) more specific identification of the animals to be treated as allowed by 558.6(b)(4); (9) the veterinarian's affirmation of intent for combination VFD drugs as described in 558.6(b)(6); and (10) the veterinarian's signature.

Several pieces of information required on the VFD result from the veterinarian's professional judgment and discretion but, based on the conditions and indications of use of the drug as set forth in the relevant approval, conditional approval, or index listing, the veterinarian may have limited options from which to choose. At a minimum, the VFD submitted to CVM by the sponsor as part of the new animal drug application should have identified space available for this information. The sponsor may pre-populate all of the optional information available to the veterinarian under the approval, conditional approval, or index listing by using formatting such as checkboxes or blanks for the veterinarian to indicate his or her decision. For example, if a VFD drug is a component of an approved, conditionally approved, or indexed combination VFD drug, the sponsor should include all three affirmation of intent statements on the VFD for the veterinarian to choose from. If a VFD drug is not a component of an approved, conditionally approved, or indexed combination VFD drug, the sponsor should include only the statement, "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."

Furthermore, when the veterinarian's options are limited by the approval, conditional approval, or index listing, the sponsor should provide blank space with information in a parenthetical that indicates the approved options available to the veterinarian. For example, the expiration date should have a blank line with a parenthetical that indicates the maximum expiration date allowed by the approval, conditional approval, or index listing (e.g., Exp. Date: _____ (not to exceed 21 days). Another example is when the approval, conditional approval, or index listing allows the veterinarian to select a drug level from within a range. In that case, the sponsor should include

space for the veterinarian to indicate his or her selection, as well as pre-populated parenthetical information about the range allowed by the approval, conditional approval, or index listing (e.g., Drug level: _____ g/ton (20-40 g/ton).

5. Is a sponsor allowed to further customize the VFD after CVM has approved the VFD?

Because some drugs may be approved for more than one use (e.g., multiple indications), sponsors may wish to create VFDs that contain information relevant to more than one approved use of the drug in order to make them more user friendly for veterinarians. This is an acceptable reason for making further revisions to the VFD after CVM has approved it as long as the sponsor's customization: (1) conforms with the approved or conditionally approved application, or index listing; (2) includes all of the pre-populated information and spaces for the veterinarian-specified information that was included in the VFD(s) submitted to and approved by CVM; (3) includes all of the options available to a veterinarian consistent with the approval, conditional approval, or index listing; and (4) clearly organizes these options (for example, it should be clear which drug level, duration, withdrawal period, and cautionary statements, etc., correspond to a particular species, class, and/or indication). We think that this customization may, in some instances, reduce the possibility that veterinarians may accidentally include information not allowed by the approval, conditional approval, or index listing.

6. Can a sponsor pre-populate information into the special instructions area of the VFD?

Generally, the special instructions area should be reserved for special instructions that appear on the approved representative Type C medicated feed (Blue Bird) labeling. A sponsor should pre-populate information in this area only if this information is always necessary for use of the VFD drug in conformance with the approval, conditional approval, or index listing, and is not already included elsewhere on the VFD as part of the information required by 558.6(b)(3) or permitted by 558.6(b)(4).

The special instructions area also provides space for the veterinarian to communicate information necessary for the appropriate treatment of the animals and/or the use of the VFD feed, relevant to the specific clients and patients for whom they are authorizing the VFD. Examples of this type of information include:

- Specific treatment instructions the veterinarian wants the client to follow that are allowable under the approval, conditional approval, or index listing, but may be impractical to include elsewhere on the VFD. For example, if a VFD drug can be used within a certain drug level 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.
- Specific response monitoring instructions the veterinarian wants the client to follow. For example, the veterinarian may want the client to monitor the animals daily and call if the symptoms do not improve after a certain number of days.

- Specific husbandry practices the veterinarian wants the client to follow to achieve maximum treatment results (e.g., weather or housing considerations);
- A reminder to the client to follow all labeling instructions. The veterinarian may want to specifically remind the client that if they choose to use the VFD drug in a combination feed the veterinarian has authorized with the affirmation statements, that labeling information such as withdrawal times and caution statements may differ and the client should comply with the information on the labeling for the combination feed.

7. Can the sponsor include other information on the VFD?

Because non-required information that is placed on the VFD can create confusion and make it more difficult to locate required information, we recommend limiting the information on the VFD to the required and discretionary information listed in § 558.6(b)(3) and (b)(4). We also recommend that any non-required information the veterinarian or sponsor may choose to include on a VFD be in a place and manner that does not interfere with the required and discretionary information listed in § 558.6(b).

8. Should the VFD have the proprietary name (trade name) or established name of the VFD drug(s)?

The name of the VFD drug is required to be included on the VFD. (21 CFR § 558.6(b)(3)(vi)). The veterinarian may choose to write either the established name (e.g., florfenicol, tilmicosin) or the proprietary (trade name) of a specific VFD drug.

If the VFD lists a VFD drug by the proprietary name (trade name), the veterinarian may choose to specify that a substitution by the feed manufacturer is not allowed. If the veterinarian does not specify that a substitution is not allowed, the feed manufacturer may substitute the approved pioneer or any approved generic VFD drug to manufacture the VFD feed provided that the approval for the drug being used is consistent with the information on the VFD order (e.g., approved for that indication, in that species and production class, and at the drug level specified on the order). However, the feed manufacturer may not substitute a generic VFD drug for a pioneer VFD drug in a combination VFD feed if the generic VFD drug is not a component of an approved combination VFD drug (21 U.S.C. 360b(a)). For a sponsor-generated VFD that has the drug name pre-populated with the trade name, the sponsor may include a checkbox with the statement "[ ] Drug product substitution is not allowed if checked."

If the VFD lists a VFD drug by an established name, the feed manufacturer may use the approved pioneer or any approved generic VFD drug to manufacture the VFD feed provided that the approval for the drug being used is consistent with the information on the VFD order (e.g., approved for that indication, in that species and production class, and at the drug level specified on the order). However, the feed manufacturer may not use a pioneer VFD drug or a generic VFD drug in a combination VFD feed if the VFD drug is not a component of an approved combination VFD drug (21 U.S.C. 360b(a)).

B. Veterinary Feed Directive Information and Recommended Common Format

1. What information is required to be on the VFD and what information is discretionary? (21 CFR 558.6(b)(3) and (4))

The regulation at 21 CFR 558.6(b)(3) requires that the following information be fully and accurately included on the VFD:

- 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.

21 CFR 558.6(b)(4) permits the veterinarian to include on the VFD, at his or her discretion, the following additional information to identify more specifically the animals authorized to be fed 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 specified in the VFD.

2. In what order should the information be included on the VFD?

The order the information is presented is important to ensure that the VFD can be understood and the correct medicated VFD feed manufactured and distributed. A common VFD format that a sponsor may use in order to meet the requirements of the regulations at § 514.1(b)(9) and

558.6(b) is shown in APPENDIX A. FDA believes that using this common format will help clients, veterinarians, and distributors (including feed mills) quickly identify relevant information on the VFD, reduce the potential for typographical or other errors on the VFD, and reduce errors in using the VFD to manufacture feed or feed the VFD feed to animals.

The common format in APPENDIX A contains the following features in the order listed below:

1. The contact information for the veterinarian and client. Including this information first allows the veterinarian, distributor, and client to easily see who authorized the VFD and who will be using the VFD;

2. Information about the VFD drug and the required statement about extralabel use. This information should be pre-populated by the sponsor on the VFD submitted to FDA as part of the new animal drug application. In cases where a veterinarian uses a VFD that has not been pre-populated with the VFD drug-specific information, grouping this information together helps the veterinarian identify and copy the appropriate information from the label and completely fill in all of the relevant drug information;

3. Information about the animals for which the VFD is being authorized, including the required and discretionary information;

4. The affirmation of intent statements for VFD drugs that are approved, conditionally approved, or indexed to be used in combination with other drugs, and also provides, if applicable, a checkbox for the veterinarian to affirm whether the use of the VFD drug is authorized with all combination VFD drugs, only certain combination VFD drugs, or no combination VFD drugs;

5. A section demarcated by compressed arrows that indicates the required drug withdrawal time. Separating and demarcating this information from the other drug approval information makes it easy for the client to locate on the VFD; and

6. Information on the issuance and expiration date, as well as the veterinarian's signature. Including this required element last will help the veterinarian ensure that they have completed all of the required information on the VFD before applying his or her signature to the VFD.

APPENDIX B provides hypothetical examples of pre-populated VFDs using the features of this recommended common format, while APPENDIX C shows these same examples with all of the remaining relevant information subsequently filled out by the issuing veterinarian.

3. Do all three affirmation of intent statements need to be included for a VFD drug with no approved, conditionally approved, or indexed combination with other animal drug(s)?

No. If there is no approved, conditionally approved, or indexed combination of a VFD drug with other animal drug(s), only the first of the three affirmation of intent statements (the one specified

in 21 CFR 558.6(b)(6)(i)) should be included. When a VFD drug is a component of one or more approved, conditionally approved, or indexed combinations, all three affirmation of intent statements will need to be included, with checkboxes for the veterinarians to select their choice.

4. How does the recommended common format apply to an electronic VFD?

Any VFD, whether paper or electronic, is required to include the information specified by regulation. VFDs that are issued electronically may also follow this recommended common format.

5. The examples in the appendices do not include space for additional information a sponsor may want to include, such as a logo. Can this information be included on the VFD?

The examples provided in the appendices only include the required and discretionary information that is specified in the regulation. You may use these templates as the starting point to develop a VFD that may contain additional information (e.g., logo, sequential VFD number). However, keep in mind that additional information on the VFD can create confusion and make it more difficult to locate required information. We recommend that additional information on a VFD be included in a place and manner that does not interfere with the information listed in § 558.6(b).

APPENDIX A: BLANK VFD IN THE RECOMMENDED COMMON FORMAT

Veterinary Feed Directive

Veterinarian: _____ Client: _____

Address: _____ Address: _____

_____ (business or home) _____

Phone: _____ Phone: _____

Fax or email (optional): _____ Fax or email (optional): _____

Drug(s) Name: _____ Drug(s) Level: _____ g/ton Duration of use: _____

Species and Production class: _____ Number of reorders (refills) authorized (if permitted by the drug approval): ___

Indications for use (as approved): _____

Caution (related to this medicated feed, if any): _____

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

Approximate Number of Animals: _____

Premises: _____

Other Identification (e.g., age, weight) (optional): _____

Special Instructions (if any): _____

Affirmation of intent (for combination VFD Drugs) (check one box)*:
(*For VFD drugs for which there are no approved VFD combinations, only the first affirmation statement should be included 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 VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component:

Drug(s)	Drug Level(s) and any Special Instructions

☐ This VFD authorizes the use of the VFD drug(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.

Withdrawal Time (if any): This VFD Feed must be withdrawn ____ days prior to slaughter

VFD Date of Issuance: _____ (Month/Day/Year) VFD Expiration Date: _____ (Month/Day/Year) (As specified in the approval; cannot exceed 6 months after issuance)

Veterinarian's Signature: _____

All parties must retain a copy of this VFD for 2 years after the date of issuance

APPENDIX B: EXAMPLES OF VFDS IN THE RECOMMENDED COMMON FORMAT PRE-POPULATED BY THE SPONSOR FOR SUBMISSION TO CVM

EXAMPLE 1: A PRE-POPULATED VFD FOR A VFD DRUG THAT IS NOT APPROVED, CONDITIONALLY APPROVED, OR INDEXED FOR USE WITH OTHER ANIMAL DRUG(S)

Veterinary Feed Directive
For Mydrug

Veterinarian: _____ Client: _____
Address: _____ Address: _____
_____ (business or home) _____
Phone: _____ Phone: _____
Fax or email (optional): _____ Fax or email (optional): _____

Drug(s) Name: Mydrug Drug(s) Level: 100 g/ton Duration of use: 14 days

Species and Production class: Swine Number of reorders (refills) authorized (if permitted by the drug approval): 0

Indications for use (as approved): For the treatment of Swine Disease associated with *Bacterium pathologicum*

Caution (related to this medicated feed, if any): Not for use in pregnant sows

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

Approximate Number of Animals: _____

Premises: _____

Other Identification (e.g., age, weight) (optional): _____

Special Instructions (if any): _____

Affirmation of intent (for combination VFD Drugs):

☐ 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.

Withdrawal Time (if any): This VFD Feed must be withdrawn 5 days prior to slaughter

VFD Date of Issuance: _____ (Month/Day/Year) VFD Expiration Date: _____ (Month/Day/Year) (As specified in the approval; cannot exceed 6 months after issuance)

Veterinarian's Signature: _____

All parties must retain a copy of this VFD for 2 years after the date of issuance

EXAMPLE 2: A PRE-POPULATED VFD FOR A VFD DRUG THAT IS APPROVED, CONDITIONALLY APPROVED, OR INDEXED FOR USE WITH OTHER ANIMAL DRUG(S)

Veterinary Feed Directive
For Mydrug

Veterinarian: _____ Client: _____
Address: _____ Address: _____
_____ (business or home) _____
Phone: _____ Phone: _____
Fax or email (optional): _____ Fax or email (optional): _____

Drug(s) Name: Mydrug Drug(s) Level: 100 g/ton Duration of use: 14 days

Species and Production class: Swine Number of reorders (refills) authorized (if permitted by the drug approval): 0

Indications for use (as approved): For the treatment of Swine Disease associated with *Bacterium pathologicum*

Caution (related to this medicated feed, if any): Not for use in pregnant sows

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

Approximate Number of Animals: _____

Premises: _____

Other Identification (e.g., age, weight) (optional): _____

Special Instructions (if any): _____

Affirmation of intent (for combination VFD Drugs) (check one box)*:
(*For VFD drugs for which there are no approved VFD combinations, only the first affirmation statement should be included 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 VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component:

Drug(s)	Drug Level(s) and any Special Instructions

☐ This VFD authorizes the use of the VFD drug(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.

Withdrawal Time (if any): This VFD Feed must be withdrawn 5 days prior to slaughter

VFD Date of Issuance: _____ (Month/Day/Year) VFD Expiration Date: _____ (Month/Day/Year) (As specified in the approval; cannot exceed 6 months after issuance)

Veterinarian's Signature: _____

All parties must retain a copy of this VFD for 2 years after the date of issuance

APPENDIX C: EXAMPLES OF PRE-POPULATED VFDS IN THE RECOMMENDED COMMON FORMAT THAT HAVE SUBSEQUENTLY BEEN COMPLETED BY THE ISSUING VETERINARIAN

EXAMPLE 1: A VFD DRUG THAT IS NOT APPROVED, CONDITIONALLY APPROVED, OR INDEXED FOR USE WITH OTHER ANIMAL DRUG(S)

Veterinary Feed Directive
For Mydrug

Veterinarian: John Doe, DVM or VMD
Address: 123 Anystreet
Anytown, Anystate 00000
Phone: 111-111-1111
Fax or email (optional):

Client: John Smith
Address: 456 Anystreet
(business or home) Anytown, Anystate 00000
Phone: 111-111-1111
Fax or email (optional):

Drug(s) Name: Mydrug Drug(s) Level: 100 gm/ton Duration of use: 14 days

Species and Production class: Swine Number of reorders (refills) authorized (if permitted by the drug approval): 0

Indications for use (as approved): For the treatment of Swine Disease associated with *Bacterium pathologicum*

Caution (related to this medicated feed, if any): Not for use in pregnant sows

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

Approximate Number of Animals: 200

Premises: 777 Country Road, Anytown, Anystate 00000

Other Identification (e.g., age, weight) (optional): All animals are between 4 and 4.5 months of age

Special Instructions (if any): OK to move the swine to Barn 5 after treatment

Affirmation of intent (for combination VFD Drugs):

☒ 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.

Withdrawal Time (if any): This VFD Feed must be withdrawn 5 days prior to slaughter

VFD Date of Issuance: 05/15/17 (Month/Day/Year) VFD Expiration Date: 08/01/17 (Month/Day/Year) (As specified in the approval; cannot exceed 6 months after issuance)

Veterinarian's Signature: My signature, DVM or VMD

All parties must retain a copy of this VFD for 2 years after the date of issuance

EXAMPLE 2: A VFD DRUG THAT IS APPROVED, CONDITIONALLY APPROVED, OR INDEXED FOR USE WITH OTHER ANIMAL DRUG(S)

Veterinary Feed Directive
For Mydrug

Veterinarian: John Doe, DVM or VMD
Address: 123 Anystreet
Anytown, Anystate 00000
Phone: 111-111-1111
Fax or email (optional):

Client: John Smith
Address: 456 Anystreet
(business or home) Anytown, Anystate 00000
Phone: 111-111-1111
Fax or email (optional):

Drug(s) Name: Mydrug Drug(s) Level: 100 g/ton Duration of use: 14 days

Species and Production class: Swine Number of reorders (refills) authorized (if permitted by the drug approval): 0

Indications for use (as approved): For the treatment of Swine Disease associated with *Bacterium pathologicum*

Caution (related to this medicated feed, if any): Not for use in pregnant sows

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

Approximate Number of Animals: 200

Premises: 777 Country Road, Anytown, Anystate 00000

Other Identification (e.g., age, weight) (optional): All animals are between 4 and 4.5 months of age

Special Instructions (if any): OK to move the swine to Barn 5 after treatment

Affirmation of intent (for combination VFD Drugs) (check one box)*:
(*For VFD drugs for which there are no approved VFD combinations, only the first affirmation statement should be included 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 VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component:

Drug(s)	Drug Level(s) and any Special Instructions
CureX	100-200 g/ton; For complete information read the label for this combination

☐ 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.

Withdrawal Time (if any): This VFD Feed must be withdrawn 5 days prior to slaughter

VFD Date of Issuance: 05/15/17 (Month/Day/Year) VFD Expiration Date: 08/01/17 (Month/Day/Year) (As specified in the approval; cannot exceed 6 months after issuance)

Veterinarian's Signature: My signature, DVM or VMD

All parties must retain a copy of this VFD for 2 years after the date of issuance