CDFA: Safe Animal Feed Education Program

Information for:

Veterinarians who plan on issuing medicated VFD feed

FDA VFD Video Overview for Veterinarians

http://www.fda.gov/AnimalVeterinary/SafetyHealth/AnimalFeedSafetySystemAFSS/ucm529920.htm

VFD- **V**eterinary **F**eed **D**irective

VCPR- **V**eterinarian-**C**lient-**P**atient-**R**elationship

What is a VFD Drug?

- A drug that is intended for use in livestock feed that is limited to use under the professional supervision of a licensed veterinarian.

What is a combination VFD Drug?

- A combination of drugs, in which at least one o the drugs is a VFD drug, and the combination must be approved for use in animal feed.
- This combination VFD drug must be used under the professional supervision of a licensed veterinarian.

Veterinarian-Client-Patient Relationship.

- Per the FDA VFD Regulations a valid Veterinarian-Client-Patient Relationship (VCPR) can be defined by either the FDA VFD Regulation definition or as stated below, it can be defined by the individual State definition.
  - (ii) Be operating in 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.

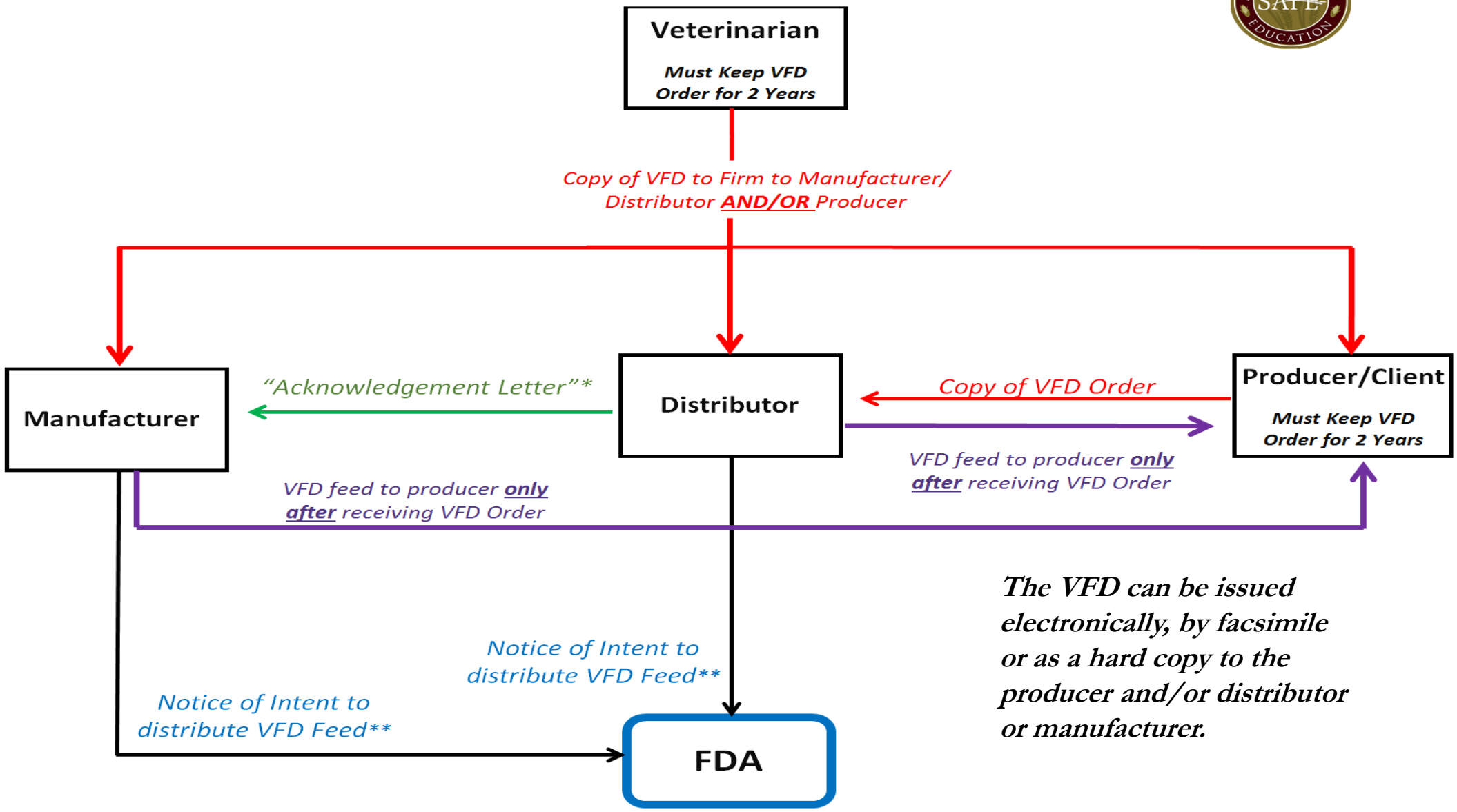
California's definition of a Valid VCPR per **16 CCR § 2032.1**

- **b) A veterinarian-client-patient relationship shall be established by the following:**
  - (1) The client has authorized the veterinarian to assume responsibility for making medical judgments regarding the health of the animal, including the need for medical treatment,
  - (2) The veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian is personally acquainted with the care of the animal(s) by virtue of an examination of the animal or by medically appropriate and timely visits to the premises where the animals are kept, and
  - (3) The veterinarian has assumed responsibility for making medical judgments regarding the health of the animal and has communicated with the client a course of treatment appropriate to the circumstance.

Clarification of Refills

- Refills on VFDs may only be authorized if the drug approval, conditional approval, or index listing states that refills are permitted.
- VFD refills are allowed if the VFD order has a designated number of allowable refills.
- **Currently there are no VFD drugs approved for refills.**

Veterinary Feed Directive (VFD) Document Trail



The VFD can be issued electronically, by facsimile or as a hard copy to the producer and/or distributor or manufacturer.

An "Acknowledgement Letter" must be submitted to the manufacturer of the VFD Feed from the distributor of the VFD Feed.

The "Acknowledgement Letter"

An "acknowledgement letter" is a written (nonverbal) communication provided to you (consignor) from another distributor (consignee). Such letter, provided either in hardcopy or through electronic media, must affirm: (1) that the distributor will not ship such VFD feed to an animal production facility that does not have a VFD; (2) that the distributor will not ship such VFD feed to another distributor without receiving a similar written acknowledgment letter; and (3) that the distributor has complied with the distributor notification requirements. If you issue VFD feed only to a client under a VFD order, you will not need to have an acknowledgement letter.

An Acknowledgement letter is required from each manufacturer supplying feed requiring a VFD.

Notice of Intent to distribute VFD Feed is submitted one time only to the FDA.

The "One-Time" Distributor Notification

It must include the following:

- 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.

The notification should be mailed to:

Food and Drug Administration
Center for Veterinary Medicine
Division of Animal Feeds (HFV-220)
7519 Standish Place
Rockville, MD 20855

or faxed to: 240-453-6882

All VFD Feed must be labeled with the following 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."

Drugs Transitioning From OTC to VFD Status

Established drug name	Examples of proprietary drug name(s)[$]
chlortetracycline (CTC)	Aureomycin, CLTC, CTC, Chloratet, Chlorachel, ChlorMax, Chlortetracycline, Deracin, Inchlor, Pennchlor, Pfichlor
chlortetracycline/sulfamethazine*	Aureo S, Aureomix S, Pennchlor S
chlortetracycline/sulfamethazine/penicillin*	Aureomix 500, Chlorachel/Pficlor SP, Pennchlor SP, ChlorMax SP
hygromycin B	Hygromix
lincomycin	Lincomix
oxytetracycline (OTC)	TM, OXTC, Oxytetracycline, Pennox, Terramycin
oxytetracycline/neomycin*	Neo-Oxy, Neo-Terramycin
penicillin[+]	Penicillin, Penicillin G Procaine
sulfadimethoxine/ormetoprim*	Rofenaid, Romet
tylosin	Tylan, Tylosin, Tylovet
tylosin/sulfamethazine*	Tylan Sulfa G, Tylan Plus Sulfa G, Tylosin Plus Sulfamethazine
virginiamycin	Stafac, Virginiamycin, V-Max

The Current list of Approved New Animal for Feed

21 CFR Part 558- New Animal Drugs Approved for use in Animal Feeds

http://www.ecfr.gov/cgi-bin/text-idx?SID=cfa766f303b174427e48d39ae58fc334&mc=true&node=pt21.6.558&rgn=div5#sp21.6.558.a

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FDA Blue Bird Labels

http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/BlueBirdLabels/default.htm

New Animal Drugs Approved for use in Animal Feeds

§558.55 Amprolium.
§558.58 Amprolium and ethopabate.
§558.59 Apramycin.
§558.68 Avilamycin.
§558.76 Bacitracin methylenedisalicylate.
§558.78 Bacitracin zinc.
§558.95 Bambermycins.
§558.115 Carbadox.
§558.128 Chlortetracycline.
§558.140 Chlortetracycline and sulfamethazine.
§558.175 Clopidol.
§558.185 Coumaphos.
§558.195 Decoquinate.
§558.198 Diclazuril.
§558.205 Dichlorvos.
§558.235 Efrotomycin.
§558.248 Erythromycin.
§558.254 Famphur.
§558.258 Fenbendazole.
§558.261 Florfenicol.
§558.265 Halofuginone.
§558.274 Hygromycin B.
§558.295 Iodinated casein.
§558.300 Ivermectin.
§558.305 Laidlomycin.
§558.311 Lasalocid.
§558.325 Lincomycin.
§558.340 Maduramicin.
§558.342 Melengestrol.
§558.348 Mibolerone.
§558.355 Monensin.
§558.360 Morantel tartrate.
§558.363 Narasin.
§558.364 Neomycin sulfate.
§558.365 Nequinate.
§558.366 Nicarbazin.
§558.415 Novobiocin.
§558.430 Nystatin.
§558.450 Oxytetracycline.
§558.455 Oxytetracycline and neomycin.
§558.464 Poloxalene.
§558.465 Poloxalene free-choice liquid Type C feed.
§558.485 Pyrantel.
§558.500 Ractopamine. §558.515 Robenidine.
§558.550 Salinomycin.
§558.555 Semduramicin.
§558.575 Sulfadimethoxine and ormetoprim.
§558.582 Sulfamerazine.
§558.586 Sulfaquinoxaline.
§558.600 Thiabendazole.
§558.612 Tiamulin.
§558.618 Tilmicosin.
§558.625 Tylosin.
§558.630 Tylosin and sulfamethazine.
§558.633 Tylvalosin.
§558.635 Virginiamycin.
§558.665 Zilpaterol.
§558.680 Zoalene.

Clarification on Extra-Label Use

- **Prescription drugs cannot be added to feed.**
- **Drugs that are approved for medicated feed can only be used in accordance with the federal approval.**
- **There is NO Extra-label use permitted.**

Veterinarian Responsibilities

- Must be licensed to practice veterinary medicine
- Must be operating in the course of the veterinarian's professional practice and in compliance with all applicable veterinary licensing and practice requirements
- Must write VFD orders in the context of a valid client-patient relationship.

Veterinarian Responsibilities continued

- Must 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
- Must prepare and sign a written VFD providing all required information
- May enter additional discretionary information to more specifically identify the animals to be treated/fed the VFD feed.

Veterinarian Responsibilities continued

- Must include required information when a VFD drug is authorized for use in a drug combination that includes more than one VFD drug
- Must restrict or allow the use of the VFD drug in combination with one or more OTC drug(s)
- Must provide the feed distributor with a copy of the VFD
- Must provide the client with a copy of the VFD order

Veterinarian Responsibilities continued

- Must provide the client with a copy of the VFD order
- Must retain the ***original*** VFD for 2 years
- Must provide VFD orders for inspection and copying by FDA upon request

Preventing Antibiotic Residues

- It is critical that the producers follow all withdrawal times, special instructions, and cautionary statements on the VFD.
- Example: Withdrawal Time: This VFD feed must be withheld 5 days prior to slaughter.
- There is no extra-label use of a VFD feed. It must be fed according to the instructions on the feed label.

Example VFD Order Form

The following slide includes examples from FDA Guidance for Industry #233, Veterinary Feed Directive Common Format Questions and Answers

Link:
http://www.fda.gov/downloads/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm474640.pdf

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. 21 CFR 558.6(a)(4)

Contains Nonbinding Recommendations

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: _____

What must be included on the VFD?

- Veterinarian's name, address, and telephone number
- Clients name, business or home address, and telephone number
- Premises at which the animals specified in the VFD are located
- Date of VFD issuance
- Expiration date of the VFD
- Name of the VFD drug(s)

What must be included on the VFD?

- Species and production class of animals to be fed the VFD feed
- Approximate number of animals to be fed the VFD feed by the expiration date
- Indication for which the VFD is issued
- Level of VFD drug in the feed and duration of use
- Withdrawal time, special instructions, and cautionary statements necessary for use of the drug in conformance with the approval

What must be included on the VFD?

- 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)
- The veterinarian’s electronic or written signature

Optional information that can be included

- A specific description of the location of the animals (e.g. pen number, barn, etc.)
- The approximate age range of the animals
- The approximate weight of the animals
- Any other information that the vet deems appropriate to identify the animals at issue

Links VFD Guidance Material

- The CDFA's Feed and Livestock Drug Inspection Program: Safe Animal Feed Education Program website: https://www.cdfa.ca.gov/is/ffldrs/safe.html
- The following slide includes examples from FDA Guidance for Industry #233, Veterinary Feed Directive Common Format Questions and Answers: http://www.fda.gov/downloads/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm474640.pdf
- FDA Guidance for Industry #120, Small Entity Compliance Guide Veterinary Feed Directive Regulation Questions and Answers: http://www.fda.gov/downloads/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm052660.pdf

FAQ

- **Is January 1, 2017 a firm date or is there a phase out period for VFD feed?**
  - Yes, as of January 1, 2017 all "medically important antibiotic" feed will need a VFD to be fed. There is no phase out period
- **Does all inventory of medicated feed that will require a VFD as of January 1, 2017 need a VFD to be fed after January 1, 2017?**
  - YES
- **Who is responsible for ensuring the VFD expiration dates are followed?**
  - The manufacturer can no longer distribute under an expired VFD order.
  - The producer cannot feed under an expired VFD feed.

FAQ cont'd

- **Should the VFD have the proprietary name (trade name) or established name of the VFD drug(s)?**
  - The VFD drug name is required to be included on the VFD. The veterinarian can either write an established drug name or the specific trade name of a VFD drug.
  - If a VFD drug is listed by a proprietary name (trade name), then the veterinarian may choose to specify that a substitution by the feed manufacturer is not allowed (i.e. checking the box for "[ ] Drug product substitution is not allowed if checked." on the VFD Order form)
  - If the VFD drug is listed by a proprietary name and the veterinarian does not specify that a substitution is not allowed, then the feed manufacturer may use either an approved pioneer or an approved generic drug.

Questions?

CDFA's: Safe Animal Feed Education Program

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