# Veterinary Feed Directive (VFD)

Educational Information Only
Compiled by the
West Virginia Department of Agriculture
Animal Health Division and
Regulatory and Environmental Affairs Division

Veterinary Feed Directive Drugs Transitioning from Over The Counter (OTC) to VFD Status

- chlortetracycline (CTC)
- chlortetracycline/sulfamethazine*
- chlortetracycline/sulfamethazine/penicillin*
- hygromycin B
- lincomycin
- oxytetracycline (OTC)
- oxytetracycline/neomycin*
- penicillin+
- sulfadimethoxine/ormetoprim*
- tylosin
- tylosin/sulfamethazine*
- virginiamycin

*Fixed-ration, combination drug
+Currently only approved for production uses

Current VFD Drugs

- avilamycin
- florfenicol
- tilmicosin

## What is a Veterinary Feed Directive Drug (VFD)

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 )).

## Who determines whether a drug is a 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).

## Drugs Transitioning from Over the Counter (OTC) to Prescription (Rx) Status

- chlortetracycline
- erythromycin
- gentamicin
- lincomycin
- lincomycin/spectinomycin*
- neomycin
- oxytetracycline
- Penicillin+
- spectinomycin
- sulfadimethoxine
- sulfamethazine
- sulfaquinoxaline
- tetracycline

*Fixed-ration, combination drug

Current Rx Water Soluble Drug
tylosin

**What specific information must the veterinarian include on the VFD order and what information is optional?**

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 (extra label 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.

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)).

- 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.

All distributors of VFD feed must notify the FDA before they distribute the first time. All distributors must send an acknowledgement letter to the FDA before receiving or selling VFD drugs.

All letters can be sent to:

Food and Drug Administration
Center for Veterinary Medicine
Division of Animal Feeds
(HVF-220)
7519 Standish Place
Rockville, MD 20855
Or faxed to:
240-453-6882

## What is expected of a Distributor of VFD drugs?

A distributor is any person who distributes a medicated feed containing a VFD drug to another person. The distributor must send the FDA a one time "acknowledgement letter" before distributing for the first time, and must notify the FDA within 30 days of a change in ownership, business name, or business address.

## What are the responsibilities as a distributor of VFD Drugs?

- fill a VFD order only if the VFD contains all the required information
- retain VFD orders for inspection and copying by FDA upon request
- retain VFD orders for two years from date of issuance
- retain records of the receipt and distribution of all medicated animal feed containing a VFD drug for two years
- 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
- ensure all labeling and advertising prominently and conspicuously displays the following cautionary statement: "Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian."
- retain 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
- obtain, as the originating distributor (consignor), an acknowledgement letter from the receiving distributor (consignee) before the feed is shipped
- Retain a copy of each consignee distributor's acknowledgement letter for two years

**Drugs Transitioning from Over-the-Counter (OTC) to Veterinary Feed Directive (VFD) Status**

Upon completion of their voluntary transition from OTC to VFD, all feed uses of the following drugs, alone and in a combination, will require a VFD as of January 1, 2017, except in cases where a sponsor chooses to voluntarily withdraw the drug application:

***Drugs Transitioning From OTC to VFD Status***

| Established drug name | Examples of proprietary drug name(s) $ |
|---|---|
| chlortetracycline (CTC) | Aureomycin, CLTC, CTC, Chloratet, Chlorachel, ChlorMax, Chlortet-racycline, 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 Sulfame-thazine |
| virginiamycin | Stafac, Virginiamycin, V-Max |

Note: apramycin, erythromycin, neomycin (alone), oleandomycin+, sulfamerazine, and sulfaquinoxaline are also approved for use in feed and are expected to transition to VFD status, but are not marketed at this time. If they return to the market after January 1, 2017, they will require a VFD

Type A medicated articles used to manufacture medicated feed, all products may not be marketed at

this time

*Fixed-ratio, combination drug

+Currently only approved for production uses

**Current VFD Drugs**

Type A medicated articles used to manufacture medicated feed

| Established drug name | Proprietary drug name(s) $ |
|---|---|
| avilamycin | Kavault |
| florfenicol | Aquaflor, Nuflor |
| tilmicosin | Pulmotil, Tilmovet |

This information is up-to-date as of January 19, 2016. As the industry transitions, CVM anticipates additional changes during the coming months to this information. Please check the link below for the most recent updates:
http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm

## Drugs Transitioning from Over-the-Counter (OTC) to Prescription (Rx) Status

Upon completion of their voluntary transition from OTC to Rx, all uses of the following drugs will require a prescription from a veterinarian as of January 1, 2017, except in cases where a sponsor chooses to voluntarily withdraw the drug application:

# *Water Soluble Drugs Transitioning From OTC to Rx Status*

| Established drug name | Examples of proprietary drug name(s) |
|---|---|
| chlortetracycline | Aureomycin, Aureomycyn, Chlora-Cycline, Chloronex, Chlortetracycline, Chlortetra-cycline Bisulfate, Chlortet-Soluble-O, CTC, Fermycin, Pennchlor |
| erythromycin | Gallimycin |
| gentamicin | Garacin, Gen-Gard, GentaMed, Gentocin, Gentoral |
| lincomycin | Linco, Lincomed, Lincomix, Lincomycin, Lincomycin Hydrochloride, Lincosol, Linxmed-SP |
| lincomycin/spectinomycin* | Lincomycin S, Lincomycin-Spectinomycin, L-S, SpecLinx |
| neomycin | Biosol Liquid, Neo, Neomed, Neomix, Neomycin, Neomycin Liquid, Neomycin Sulfate, Neo-Sol, Neosol, Neosol-Oral, Neovet |
| oxytetracycline | Agrimycin, Citratet, Medamycin, Oxymarine, Oxymycin, Oxy-Sol, Oxytet, Oxytetra-cycline, Oxytetracycline HCL, Oxy WS, Pennox, Terramycin, Terra-Vet, Tetravet-CA, Tetroxy, Tetroxy Aquatic, Tetroxy HCA |
| penicillin | Han-Pen, Penaqua Sol-G, Penicillin G Potassium, R-Pen, Solu-Pen |
| spectinomycin | Spectam |
| sulfadimethoxine | Agribon, Albon, Di-Methox, SDM, Sulfabiotic, Sulfadimethoxine, Sulfadived, Sulfamed-G, Sulforal, Sulfasol |
| sulfamethazine | SMZ-Med, Sulfa, Sulmet |
| sulfaquinoxaline | S.Q. Solution, Sulfa-Nox, Sulfaquinoxaline Sodium, Sulfaquinoxaline Solubilized, Sul -Q-Nox, Sulquin |
| tetracycline | Duramycin, Polyotic, Solu/Tet, Solu-Tet, Supercycline, Terra-Vet, Tet, Tetra-Bac, Tetracycline, Tetracycline Hydrochloride, Tetramed, Tetra- Sal, Tetrasol, Tet-Sol, TC Vet |

Note: apramycin, carbomycin/oxytetracycline*, chlortetracycline/sulfamethazine*, streptomycin, sulfachloropyrazine, sulfachlorpyridazine, and sulfamerazine/sulfamethazine/sulfaquinoxaline* are expected to transition to Rx status, but are not marketed at this time. If they return to the market after January 1, 2017, they will require a prescription from a veterinarian.

*Fixed-ratio, combination drug

### *Current Rx Water Soluble Drugs*

| Established drug name | Examples of proprietary drug names |
|---|---|
| tylosin | Tylan, Tylomed, Tylosin, Tylosin Tartrate, Tylovet |

This information is up-to-date as of January 19, 2016. As the industry transitions, CVM anticipates additional changes during the coming months to this information. Please check the link below for the most recent updates: http://www.fda.gov/AnimalVeterinary/SafetyHealth/ AntimicrobialResistance/JudiciousUseofAntimicrobials/default.htm

## What is expected of a client (farmer/rancher)?

A farmer or rancher of an animal feed containing a VFD drug or combination VFD drug must:

- Have a working relationship with a local veterinarian that you know and trust, and that knows your herd and its needs.
- 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.
- Feed a VFD feed or combination VFD feed to animals by no later than the expiration date on the VFD.
- Provide a copy of the VFD order to the distributor if the issuing veterinarian sends the distributor's copy of the VFD through you, the client.
- Maintain a copy of the VFD order for a minimum of 2 years
- Provide VFD orders for inspection and copying by FDA upon request.

Responsibilities of the Farmer or Rancher

## For any questions please contact:

Food and Drug Administration

AskCVM@fda.hhs.gov

Guidance for Industry #120

21 CFR 558. 6 (VFD)

21 CFR 225 (cGMP)

Website:

http://www.fda.gov/safefeed

## Get Assistance

Phone: 240-402-7002

Food and Drug Administration

7519 Standish Place

HFV-12

Rockville, MD 20855

# Quick Answers to some Common Questions

- **Do I need my local veterinarian to get these drugs in my feed or at the feed store?** ***YES***
- **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.

- **Do these regulations allow reorders and refills?** ***YES***

  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.

- **How can a VFD order be transmitted to the distributor?** ***FAX, Electronically, or copy***

  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.*

- **Is the veterinarian required to send the original VFD order to the distributor?** ***NO***

  **No**, the veterinarian is not required to send the original paper copy 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.

- **Can a VFD order be transmitted by telephone?** ***NO***

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

- **In what format can the "original" VFD' order be kept?** ***Always in its original form***

  The veterinarian must retain the original VFD in its original form (electronic or hardcopy)

- **Can a vet write a VFD order for an OTC drug?** ***NO***

  A practicing veterinarian may not write a VFD order for an OTC drug. A veterinarian may only write a VFD order for drugs approved, conditionally approved, or indexed as VFD drugs by the FDA (21 U.S.C. 354); nor may he or she write a VFD order to be used other than as specified on the labeling for that drug (i.e., extra label use is not permitted).

- **How do I cancel my VFD order?** ***Contact your veterinarian***

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

- **Is there a publicly available VFD distributor notification list?** ***YES***

  The list is available at: http ://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess /ucm071807.htm#listing.

- **I have more questions that I can't find an answer for?**

  *Contact the FDA at AskCVM@fda.hhs.gov or contact your local veterinarian*