VETERINARY FEED DIRECTIVE: A VETERINARIAN'S PERSPECTIVE

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Introduction

The Veterinary Feed Directive (VFD), now in effect as of January 1st, 2017, is a major change within animal agriculture. As part of the FDA's larger initiative against antibiotic resistance, the VFD aims to bring all feed medications containing medically important antibiotics under the oversight and supervision of a licensed veterinarian. With the growing demand for transparency of animal care and antibiotic stewardship in animal agriculture, the VFD is a necessary next step to meet the demands of consumers. "The actions the FDA has taken to date represent important steps toward a fundamental change in how antimicrobials can be legally used in food producing animals," said Michael R. Taylor, FDA deputy commissioner for foods. "The VFD final rule takes another important step by facilitating veterinary oversight in a way that allows for the flexibility needed to accommodate the diversity of circumstances that veterinarians encounter, while ensuring such oversight is conducted in accordance with nationally consistent principles."[5]

Food safety is a key responsibility of any food animal veterinarian. Being a highly respected resource for animal health the public looks to veterinarians to help ensure the products the animal agriculture industries produce are safe and free of drug residues. In addition, consumers continue to ask the question "Where does my food come from and how is it raised?" Veterinarians and producers have the responsibility of using currently available medications properly, to eliminate potential antibiotic residues and combat antibiotic resistance.

History

In December of 2016, full implementation of FDA's Guidance #213 was expected to be completed significantly changing the way antibiotics have been used in animal agriculture. [2] Moving forward in 2017, these medically important antibiotics can only be used for prevention, control or treatment- judicious uses as defined by the FDA. Any use for production purposes or growth efficiency, as outline in FDA's Guidance 209, is now illegal and cannot be authorized.[3] Furthermore, all remaining legal uses will require authorization from a licensed veterinarian with a valid VCPR in order for a producer to obtain and feed VFD feeds.

As described in FDA's Guidance 152, certain classes of antibiotics are considered medically important in human medicine.[4] Shared class antibiotics considered medically important administered through the feed or water changed to VFD or Rx status, respectively, as of January 1st, 2017. See Figures 1 and 2.

Information required on a lawful VFD[5]

Veterinary Feed Directives are written by the authorizing veterinarian. The following information should be contained on every VFD:

- veterinarian's name, address, and telephone number;
- client's name, business or home address, and telephone number;
- location at which the animals specified in the VFD are located;
- date the VFD was issued;

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- expiration date of the VFD;
- name of the VFD drug(s);
- 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 of the VFD;
- 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 accordance with the approval;
- number of reorders (refills) authorized, if permitted by the drug approval, conditional approval, or index listing;
- 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
- a veterinarian's electronic or written signature.

The following optional information may also be seen on the VFD:

- 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.

Each party involved in the issuance, distribution and feeding of a VFD order all have responsibilities to create, fill and feed a VFD lawfully. Listed below are the responsibilities of each party involved.

Veterinarian Responsibilities[5]

- 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 veterinarian-client-patient-relationship (VCPR);
- 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;
- 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;

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- must retain the original VFD for two (2) years**, and
- must provide VFD orders for inspection and copying by FDA upon request.

**Veterinarians should check with their respective state licensing boards for state record retention requirements. In Wisconsin, veterinarians are required to maintain and store medical records for a period of three (3) years.

Producer Responsibilities[5]

As the client, a producer 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;
- not feed a VFD feed or combination VFD feed to animals after the expiration date on the VFD;
- provide a copy of the VFD order to the feed distributor if the issuing veterinarian sends the distributor's copy of the VFD through the client;
- maintain a copy of the VFD order for a minimum of two (2) years; and provide VFD orders for inspection and copying by FDA upon request.

Feed Distributor Responsibilities[5]

- file a one-time notice with FDA of intent to distribute VFD drugs;
- notify FDA within 30 days of any change in ownership, business name, or business address;
- fill a VFD order only if the VFD contains all required information;
- 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 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 VFD orders for two (2) years from date of issuance;
- retain records of the receipt and distribution of all medicated animal feed containing a VFD drug for two (2) years;
- provide VFD orders for inspection and copying by FDA upon request;
- retain records of VFD manufacturing for one (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 (see below) from the receiving distributor (consignee) before the feed is shipped; and
- retain a copy of each consignee distributor's acknowledgement letter for two (2) years.

All distributors of VFD feed must notify FDA before they distribute for the first time. A distributor must also notify FDA within 30 days of a change in ownership, business name, or business address.

An "acknowledgement letter" is a written (nonverbal) communication provided to you (consignor) from another distributor (consignee). Such letter, provided either in hardcopy or

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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.

Category I/II and Medicated Feed Articles[7]

New animal drugs approved for use in animal feed are placed in one of the following two categories:

- Category I--These drugs require no withdrawal period at the lowest use level in each species for which they are approved.
- Category II--These drugs require a withdrawal period at the lowest use level for at least one species for which they are approved, or are regulated on a "no-residue" basis or with a zero tolerance because of a carcinogenic concern regardless of whether a withdrawal period is required.

A "Type A medicated article" is intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. It consists of a new animal drug(s), with or without carrier (e.g., calcium carbonate, rice hull, corn, gluten) with or without inactive ingredients.

A "Type B medicated feed" is intended solely for the manufacture of other medicated feeds (Type B or Type C). It contains a substantial quantity of nutrients including vitamins and/or minerals and/or other nutritional ingredients in an amount not less than 25 percent of the weight. It is manufactured by diluting a Type A medicated article or another Type B medicated feed.

A "Type C medicated feed" is intended as the complete feed for the animal or may be fed "top dressed" (added on top of usual ration) on or offered "free-choice" (e.g., supplement) in conjunction with other animal feed. It contains a substantial quantity of nutrients including vitamins, minerals, and/or other nutritional ingredients. It is manufactured by diluting a Type A medicated article or a Type B medicated feed. A Type C medicated feed may be further diluted to produce another Type C medicated feed.

Conclusion

The Veterinary Feed Directive is an important step for bringing feed medications under veterinary oversight. Veterinarians, producers and feed distributors need to all work together and communicate to make this process work within our different industries. Animal agriculture has the awesome responsibility of producing safe and healthy food for consumers and therefore need to be transparent and accountable to how we are producing food.

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References

[2] Food and Drug Administration, Center of Veterinary Medicine, Guidance for Industry #209, "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals" 13 April, 2012.

[3] Food and Drug Administration, Center of Veterinary Medicine, Guidance for Industry #213, "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209", December, 2013.

[4] Food and Drug Administration, Center of Veterinary Medicine, Guidance for Industry #152 "Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern", 23 October, 2003.

[5] Food and Drug Administration, Center of Veterinary Medicine, http://www.fda.gov/AnimalVeterinary/ucm071807.htm, Accessed 19 December, 2016.

[6] "Subchapter E ----Animal Drugs, Feeds, and Related Products" – 21 C.F.R. 558.3, (2016).

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Figure 1

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, 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

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

Established drug name	Proprietary drug name(s)[$]
avilamycin	Kavault
florfenicol	Aquaflor, Nuflor
tilmicosin	Pulmotil, Tilmovet
tylvalosin	Aivlosin

[$]Type A medicated articles used to manufacture medicated feed

This information is up-to-date as of August 8, 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

Figure 2

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, Chlortetracycline 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, Oxytetracycline, 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