

risk awareness alert veterinary feed directive (VFD)

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Understanding the VFD and potential liability risks

Do you treat any patients that are of a food animal species? FDA is implementing new policies and rules for the use of medically important antibiotics in food animal species that are administered in feed or drinking water. These **changes will take effect January 1, 2017** and will include changes to the labeled indications for these products. The marketing status for medically important antimicrobials administered to food animals in or on feed will become Veterinary Feed Directive (VFD) drugs, and any production indications will be removed from the labeling. Likewise, the marketing status for medically important antimicrobials administered to food animals in drinking water will become prescription drugs. Both of these categories are restricted to use under the authorization of a veterinarian. Veterinarians should follow the applicable federal and/or state VCPR requirements. **Any veterinarian who treats food animals must be familiar with the new rules and product labels.**

With these changes in marketing status, some veterinarians are concerned about potential liability. Widespread, significantly increased liability is not foreseen. Veterinarians make therapeutic product selection decisions on a daily basis in their practices, and potential liability for such decision-making in a healthcare context is a fact of life. To reduce your risk, remember some of the basic risk mitigation steps that are applicable anytime a veterinarian is involved in the diagnosis and treatment of patients. Issue orders, prescriptions, or VFDs, in the context of a VCPR as required by federal

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Visit avmaplit.com/vfd for resource links to help you understand the Veterinary Feed Directive (VFD).

Tips to avoid liability risks related to the VFD

- 1 | **Consider using an electronic VFD service to help prevent errors** in writing VFDs, as they typically only provide options for label indications, dosing, species, and duration that are contained in the approved product labeling.
- 2 | Ensure you have a VCPR with the producer before providing a VFD or prescription.
- 3 | Be licensed and validly practicing under a VCPR in the state where the animals are located.
- 4 | Maintain clear and complete records supporting your diagnosis, treatment decisions, and the establishment of a VCPR.
- 5 | Do not write VFD orders for Extra-Label Drug Use (ELDU). Do write VFD orders that conform to the approved labeling. Federal law prohibits ELDU for feed additives. Veterinarians, feed mills and producers must follow the label directions for the dose, therapeutic indication, species, production class, and duration of use. ELDU in milk replacer or milk is not allowed.
- 6 | Write VFDs with expiration dates (i.e. the time the medicated feed can be fed/consumed) that are in accordance with the label or for a maximum of six months if there is no expiration specified on the product label. The expiration date is not the same thing as the duration of use. Make sure you know the difference.
- 7 | Do not write VFD orders for the combined use of more than one medicated feed unless the specific combination is approved. All combinations must be contained in FDA approved labeling.
- 8 | There are currently no VFD drug approvals that allow refills, but there may be in the future. Therefore, use caution when writing a VFD that allows refills. A VFD may be written to allow refills only if refills/reorders are explicitly permitted in the approved labeling. If refills are not explicitly allowed, they are not permitted. Where refills are not allowed, a new VFD order must be written for each treatment cycle if allowed and medically indicated.
- 9 | Maintain the original VFD in its original form (written or electronic) for a minimum of two years. You may be required to maintain VFDs longer under state law as part of your medical records. Give the client and the feed distributor each a copy of the VFD.
- 10 | Write the amount of drug on the VFD order in grams per ton of feed. If the label provides a dose level without mixing instructions, the veterinarian must convert the dose level (e.g. mg/head/day, mg/lb bodyweight/day) to grams per ton (g/ton) of feed manufactured. If the label is written in mg/lb or another dosing schedule, the veterinarian must calculate the proper grams per ton for the VFD order based on the weight of the animals and estimated consumption. The Association of American Feed Control Officials (AAFCO) provides medicated feed calculators at www.aafco.org/Regulatory/Medicated-Feed-Calculators.
- 11 | Proactively coordinate among you, any consulting veterinarians, the client, and the feed mill to help reduce the risk of errors.

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and/or state authorities where you are licensed. Maintain clear and complete records supporting your diagnosis, treatment decisions, and the establishment of a VCPR. Fill out prescription or VFD orders correctly and accurately.

Because extra-label use of VFD drugs is not authorized under the Federal Food Drug & Cosmetic Act, VFDs must be in compliance with the product label. Using an electronic VFD service is a good way to reduce the potential for authorizing a VFD in a manner inconsistent with the label. Failure to write VFDs in compliance with the product label will weaken the defense of a veterinarian in litigation or before a state board of veterinary medicine. For those who treat minor species, FDA is aware of the paucity of available therapeutic drugs. FDA is expected to provide a new Compliance Policy Guide (CPG) addressing the use of VFD drugs in minor species. Once finalized, veterinarians should follow the conditions set forth in the CPG when authorizing VFDs for minor species.

Environmental concerns

Some have also asked whether authorizing VFDs carries the risk of liability under environmental laws, especially in light of the close scrutiny currently given to concentrated animal feeding operations. The risk is considered small when the veterinarian is neither the owner nor the operator of the site and is not acting as an environmental consultant.

Correct and accurate VFDs or prescriptions are the best risk mitigation. To be sure, a farmer or rancher who mishandles feed, carcasses, or manure that results in authorized VFD

or prescription drugs entering streams or ponds could face liability for discharging a pollutant into protected waters. However, a veterinarian who prescribes drugs in conformity with VFD regulations will most likely be considered too far removed from the producer's conduct to incur civil liability for a polluting discharge of drugs. Courts have on occasion said that a person whose actions contribute to an unlawful discharge can be held liable for that discharge as an "aider and abettor" if he or she knew of and had some control over the discharge, but more recent court interpretations suggest that the Clean Water Act is not so broad. Strict compliance with FDA regulations should protect veterinarians from Clean Water Act liability in all but the most extraordinary circumstances. Veterinarians should also avoid acting as an environmental consultant or providing environmental advice, as such activity could potentially change this evaluation and, depending upon the individual circumstances, may not be considered the practice of veterinary medicine.

Livestock can be pets too

In addition to those animals that immediately come to mind as food animals or livestock, FDA considers rabbits, pot-bellied pigs, goats, deer, and backyard poultry as food animals. This is true even if the animals are "pets" and not intended for food production. Practitioners treating these animals must follow the same rules and procedures as those treating other food animals or livestock.

More Information on the Veterinary Feed Directive

As of 1 January 2017, FDA will implement new policies and rules that will impact a number of products for use in food animal species. Medically important antimicrobials administered to food-producing animals in or on medicated feed will transition from over-the-counter (OTC) to Veterinary Feed Directive (VFD) marketing status. Additionally, medically important antibiotics administered to food-producing animals in drinking water will transition from OTC to Prescription marketing status. To implement these policies, FDA updated the VFD rule in the code of federal regulations and issued several new guidance documents.

In a guidance document titled *Judicious Use of Medically Important Antimicrobial Drugs in Food Producing Animals*¹, FDA addresses using medically important antimicrobial drugs in or on medicated feed and in drinking water for food-producing animals. **The overarching principals in this policy are to limit use of medically important antimicrobial drugs in food-producing animals to uses necessary for assuring animal health (i.e. prevention, control and treatment of disease) and to have these products utilized under veterinary oversight.**

FDA has also worked with the companies that hold the impacted drug approvals to voluntarily withdraw the approved production uses of their medically important antimicrobial new animal drugs and combination new animal drug products. At the same time, FDA has worked with the impacted companies to voluntarily revise the labels for the impacted products to reflect the need for the professional oversight of a licensed veterinarian. This transition has resulted in a change from OTC to VFD status for medicated feed products and from OTC to Rx status for medicated drinking water products. There is a separate FDA guidance document that addresses the *Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions* with the judicious use guideline². Each of the specific drug product approvals affected by these policies are posted on FDA's website³.

The updated FDA rule on Veterinary Feed Directives was published in

the Federal Register⁴. FDA has also published a guidance document of frequently asked questions about the new VFD rule⁵. Multiple resources to better understand the VFD requirements are listed on the back page.

VFD regulations

These new policies only impact antibiotics delivered in or on feed or in drinking water for food-producing species; injectables and other oral antibiotics are not affected. It is also important to note that non-medically important antimicrobial products are not affected. Those products will continue to have growth promotion or feed efficiency claims, and will not require a VFD. Such new animal drugs administered in or on feed that are not affected by these policies (unless used in combination with a VFD drug), include ionophores (e.g. monensin, lasalocid), hormones (e.g. melengestrol acetate), bambermycin, bacitracin, and beta-agonists (e.g. ractopamine, zilpaterol).

Use of medically important antimicrobials in food-producing animals will require a prescription (Rx) for water soluble medications or a VFD order for feed medications as of January 1, 2017.

The veterinarian who writes the VFD order or prescription must be legally practicing veterinary medicine in the state in which the animals are ingesting the medicated feed or drinking the medicated water. If a farm has operations in multiple states, the veterinarian will need to be licensed in each state to be legally practicing veterinary medicine, not just the state of the farm's home office.

A veterinary-client-patient relationship (VCPR) must exist for the veterinarian to write a lawful VFD order or a lawful prescription. Many states have a VCPR definition that meets key elements of the federal VCPR definition and which "cover" VFD orders so the veterinarian will follow the state VCPR definition. However, if the state VCPR does not have the key elements or if it does not apply to VFD orders, then the veterinarian must follow the federal VCPR definition. FDA maintains a web page that defines the VCPR in each state⁶. The American Association of

Bovine Practitioners has a publicly accessible guideline for maintaining and establishing a VCPR⁷, and the AVMA also has a VCPR policy⁸.

Veterinarians and producers must also be aware that the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) does not provide authority to veterinarians for extra-label use of drugs used in or on animal feed. Using new animal drugs in feed for food-producing species in any manner not listed on the label is a violation of federal law. This means that the veterinarian, producer, and feed mill must follow the label dose, duration, indication, production class, and other label requirements. Veterinarians cannot write VFDs for a longer duration than permitted by the approved label, for use not on approved labels, for a higher dose than the approved labeling, or for use in a production class not on the label such as non-lactating dairy cattle.

Combination feeds must also be considered in regards to extra-label drug use. Using a VFD product with another feed grade antimicrobial is considered extra-label drug use if it is not an approved combination. Do not use medications in milk that are not labeled to be fed in milk. Milk and milk replacer are feed and therefore a veterinarian may not add medications to milk or milk replacer that do not have that use on the label.

VFD drugs are not prescription drugs and therefore do not require a pharmacist to dispense them. Water soluble drugs are Rx and therefore may require a pharmacist or veterinarian for dispensing depending on state law. The veterinarian must submit the VFD order to the producer/client, and may also submit it to the feed mill/distributor. All parties must keep a copy of the VFD order for at least two years. The veterinarian must keep the original VFD order in the manner in which it was created. If the order was created electronically through a VFD service then electronic storage is acceptable. However, if the order was on paper and then scanned and submitted electronically, then the veterinarian must keep the paper copy for at least two years. Veterinarians should check with their state veterinary licensing board

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to determine whether record retention requirements for the VFD order are longer than two years.

The expiration date of the VFD is the last date the VFD authorizes feeding the product to the animals. The expiration date if not listed on the VFD label is a maximum of six months. A veterinarian can choose to write the expiration date for less than six months. If the feed is not fed within the expiration date time period, a new VFD order must be written to use the feed. A VCPR must be in place for the issuance of a second VFD. The duration of use is the amount of time the animals are ingesting the feed. If a second round of treatment is needed, a new VFD order must be written if it is allowed for that medication. Although refills are allowed in the VFD rule, they are only allowed if stated on the product label; currently no products are approved with refills on the label, so a new VFD must be written for each use.

Requirements for the VFD order include the veterinarian's name, address, and phone number, and the client's name, address, and phone number. The VFD date of issuance as well as the VFD expiration date must be stated on the order. The name of the VFD drug, description of the location of the animals (i.e. premise ID, address, farm description), species and production class, and the approximate number of animals to be fed the VFD feed are also required. According to the label, the veterinarian must list the indication for the VFD feed, the level of the drug in grams per ton on an as fed basis, the duration of use, and the withdrawal times. The veterinarian must state if a generic can be substituted or if only the pioneer product can be used and also state if there are any approved drug combinations for this VFD order to be used with in the final feed.

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Do you work with bees?

Christopher J Cripps, DVM, Betterbee

Honey bees are considered food animals by FDA. With the elimination of OTC antibiotics, beekeepers may be calling to obtain antibiotics that they feed to their bees to prevent and treat certain bacterial diseases that affect their babies (brood). Antibiotics labeled for honey bees are administered by mixing them with sugar and feeding them to the colony. Only one of these drugs is a VFD drug requiring a VFD order; the others are water soluble formulations that require a prescription. Because of the package sizes and the prohibition against extra label drug use of VFD drugs, a prescription may be better for the veterinarian and the beekeeper. Visit sites such as BeeVets.com, which carry more information on veterinary medicine for honey bees.

FDA web resources

FDA VFD resources

www.fda.gov/AnimalVeterinary/ucm071807.htm

Guidance #209

¹www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf

Guidance #213

²www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf

Impacted drug approvals

³www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm390429.htm

VFD final rule

⁴www.gpo.gov/fdsys/pkg/FR-2015-06-03/pdf/2015-13393.pdf

Guidance #120

⁵www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052660.pdf

VCPR definition by state

⁶www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm460406.htm

Brochure for veterinarians

www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/UCM455481.pdf

Brochure for producers

www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/UCM455419.pdf

Search Animal Drugs

<https://animaldrugsatfda.fda.gov/adafda/views/>

Other resources

AVMA – Veterinary Feed Directive Basics and VCPR

www.avma.org/vfd123

⁸www.avma.org/KB/Policies/Pages/Veterinarian-Client-Patient-Relationship.aspx

AABP – VCPR Guidelines

⁷www.aabp.org/resources/aabp_guidelines/vcprguidelinefinal11-2013.2.pdf

Beef Cattle Institute VFD Resources

www.vfdinfo.org

Farm Foundation – VFD rules

www.farmfoundation.org/VFDrules

For a coverage comparison and quote, call **800-228-7548**, **option 2** or visit avmaplit.com/quote.

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