

FACT SHEET: Veterinary Feed Directive Final Rule and Next Steps

Background

Over the past several years, the FDA has taken important steps toward fundamental change in how medically important antibiotics can be legally used in feed or water for food-producing animals. Now, the agency is moving to eliminate the use of such drugs for production purposes (i.e., growth promotion and feed efficiency) and bring their remaining therapeutic uses in feed and water under the supervision of licensed veterinarians – changes that are critical to ensure these drugs are used judiciously and only when appropriate for specific animal health purposes. The Veterinary Feed Directive (VFD) final rule is an important part of the agency’s overall strategy to ensure the judicious use of medically important antimicrobials in food-producing animals.

VFD Final Rule

The VFD final rule outlines the process for authorizing use of VFD drugs (animal drugs intended for use in or on animal feed that require the supervision of a licensed veterinarian) and provides veterinarians in all states with a framework for authorizing the use of medically important antimicrobials in feed when needed for specific animal health purposes.

The Veterinary Feed Directive (VFD) final rule continues to require veterinarians to issue all VFDs within the context of a veterinarian-client-patient-relationship (VCPR), and specifies the key elements that define a VCPR. These key elements include that the veterinarian engage with the client (i.e., the animal producer) to assume responsibility for making clinical judgments about patient (i.e., animal) health, have sufficient knowledge of the patient by virtue of patient examination and/or visits to the facility where the patient is managed, and provide for any necessary follow-up evaluation or care. The final rule will require veterinarians to follow state-defined VCPR requirements; in states where the FDA determines that no applicable or appropriate state VCPR requirements exist, veterinarians will need to issue VFDs in compliance with federally defined VCPR requirements. All veterinarians will need to adhere to a VCPR that includes the key elements in the final rule.

The rule facilitates veterinary oversight in a way that allows for the flexibility needed to accommodate the diversity of circumstances that veterinarians encounter, while at the same time ensuring that veterinarians in all states are conducting such oversight in accordance with nationally consistent principles. FDA will defer to individual states for the specific criteria for acceptable veterinary professional conduct when those standards require a VCPR for the issuance of a VFD and include the key elements of the federal VCPR standard. The FDA will require adherence to the federally-defined VCPR for those states with VCPR requirements that do not include the key elements of the federally-defined VCPR, or that do not require a VCPR for issuing a VFD. The agency will work with each state to review their VCPR requirements and determine if they are consistent with the federal standards.

Veterinarians play an important role in animal and human health and their oversight, as an integral part of the VFD process, will help ensure that medically important antimicrobial drugs will be used in feed according to label directions and only when appropriate to meet specific animal health needs. Currently, none of these medically important antimicrobial drugs that fall under the FDA's judicious use strategy are VFD drugs and do not require veterinary oversight or involvement. After the changes outlined in the judicious use strategy are made, medically important antimicrobials approved for use in animal feed will fall under the VFD regulation.

Next Steps: Continuing to ensure the Judicious Use of Medically Important Antimicrobials

Full implementation of FDA's Guidance #213 in December 2016 will significantly change the way medically important antibiotics have been used in animal agriculture for decades. Once the changes are fully implemented, it will be illegal to use these medically important antibiotics for production purposes, and animal producers will need to obtain authorization from a licensed veterinarian to use them for prevention, control or treatment of a specifically identified disease. All 25 affected drug sponsors have committed to implementing the changes described in Guidance #213 by the December 2016 target date.

The FDA acknowledges the important role medically important antimicrobials play in treating, controlling, and preventing disease in food-producing animals. However, the agency has been actively engaging veterinary organizations, animal producer organizations and other stakeholders to express our position that medically important antibiotics labeled for continuous or undefined durations of use is not consistent with judicious use principles, as outlined in previously-released guidance documents.

In the case of disease prevention, the FDA believes it is important such use is appropriately targeted to animals at risk for a specific disease and the use duration is limited and risk-based.

The FDA has examined the approved labels for medically important antibiotics used in feed and water and has identified that, on approximately 30 percent of the labels, there is at least one use that does not specify how long the drug should be used. However, many of these products are not currently being marketed. Once changes under Guidance #213 are fully implemented, the agency anticipates the number of products of concern will be fairly limited. The FDA is continuing to analyze this issue and examine the specific animal health conditions that are associated with open-ended or long-term duration of use. The agency is particularly interested in whether alternative approaches could better manage such conditions. This may include more targeted use of antibiotics based on labels revised to align with judicious use principles, alternative non-antibiotic therapeutic options, changes in management/production practices, or other interventions.

Long-term or open-ended prevention uses are not covered by the phase-out process for production uses described in Guidance #213. However, the **National Action Plan for Combating Antibiotic-Resistant Bacteria** (https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf) calls for the identification and implementation of measures to foster stewardship of antibiotics in animals. The FDA believes long-term or open-ended use of medically important antibiotics is a significant stewardship issue and intends to seek broad public input on this issue in the summer of 2015.

Data Collection

Gathering information on the way medically important antibiotics are used is essential to measuring the impact of the FDA's judicious use strategy.

The FDA is collaborating with the U.S. Department of Agriculture and the Centers for Disease Control and Prevention to develop a plan for collecting additional data on antibiotic use to supplement existing sales data on antibiotic drugs sold for use in food-producing animals (reported under section 105 of the Animal Drug User Fee Amendments of 2008 (ADUFA 105)) and data on antibiotic resistance (collected under the **National Antimicrobial Resistance Monitoring System** ([//AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/default.htm](http://AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/default.htm))). When combined with new on-farm data, this will provide a more comprehensive and science-based picture of antibiotic drug use and resistance in animal agriculture.

This data collection plan is intended to provide the data needed to a) assess the rate of adoption of changes outlined in the FDA's Guidance #213, b) help gauge the success of stewardship efforts and guide their continued evolution and optimization, and c) assess associations between antibiotic use practices and resistance trends over time.

The FDA is continuing to work with the USDA and CDC in developing this plan and expects to hold a public meeting in the summer of 2015 in order to obtain input from the public.

<u>More in Development & Approval Process</u> <u>(//AnimalVeterinary/DevelopmentApprovalProcess/default.htm)</u>	
<u>Food Additive Petitions for Animal Food</u> (//AnimalVeterinary/DevelopmentApprovalProcess/ucm056809.htm)	
<u>Public Master Files (PMFs) Supporting Applications for Major Use and Major Species Drugs</u> <u>(//AnimalVeterinary/DevelopmentApprovalProcess/ucm416607.htm)</u>	
<u>Veterinary Feed Directive (VFD)</u> (//AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm)	
<u>Veterinary Master Files</u> (//AnimalVeterinary/DevelopmentApprovalProcess/ucm071808.htm)	
<u>User Fees</u> (//AnimalVeterinary/DevelopmentApprovalProcess/UserFees/default.htm)	
<u>Electronic Submissions</u> <u>(//AnimalVeterinary/DevelopmentApprovalProcess/ElectronicSubmissions/default.htm)</u>	
<u>Minor Use/Minor Species</u> <u>(//AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies/default.htm)</u>	▼
<u>Environmental Impact Considerations</u> <u>(//AnimalVeterinary/DevelopmentApprovalProcess/EnvironmentalAssessments/default.htm)</u>	▼
<u>Genetic Engineering</u> (//AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/default.htm)	▼

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