

## What You Need to Know

### FDA's new antibiotic use rules for pigs began Jan. 1

**A**s 2017 begins, the U.S. Food and Drug Administration's (FDA) new rules regarding on-farm use of medically important (to human health) antibiotics are now fully in effect. Even though you likely know many of the basics of the new regulations by now, it's certainly understandable to have some remaining questions about what the FDA changes all mean and how they may affect your farm.

First, the new FDA rule ends the use of any antibiotics used for growth-promotion purposes associated with all food-animal species, including swine. This is known as Guidance 209. It also increases veterinary oversight of all remaining antibiotic uses on the farm.

"Antibiotics that are now prohibited as growth promoters are still available to treat specific health challenges," said Lisa Becton, DVM, swine health information and research director for the Pork Checkoff. "But access now will require a licensed veterinarian, who's familiar with the animals, to authorize a veterinary feed directive (VFD) for feed-based antibiotics or a prescription for products applied through the water."

While certain aspects of the new regulations may affect larger farms more, the rules apply whether you have one pig for the county fair or raise many thousands each year, Becton said. The bottom line goal of FDA's new rules is to ensure that antibiotics remain effective for people and animals alike.

"The U.S. pork industry's support of FDA's antibiotic strat-

egy and oversight aligns with our goal to ensure safe food, healthy people and healthy pigs," said National Pork Board President Jan Archer, a pork producer from Goldsboro, North Carolina.

"We have a proud history of raising pigs in ways that go beyond animal health and that are mutually beneficial to human and environmental health," Archer said. "Day in and day out, pork producers are committed to identifying ways to ensure responsible use of antibiotics, such as embracing the updated Pork Quality Assurance® Plus certification program."

At the same time, antibiotics remain essential tools for veterinarians and farmers to raise healthy livestock and produce safe food. Responsible use and following FDA's new rules are steps toward retaining those tools.

This newsletter offers answers to some of the most frequently asked questions regarding FDA's new antibiotics rules. The information is compiled from the FDA, USDA's Center of Veterinary Medicine, the American Association of Swine Veterinarians and others. For more information, visit the Pork Checkoff's Antibiotics Resource Center online at [pork.org/antibiotics](http://pork.org/antibiotics).



Visit [pork.org/antibiotics](http://pork.org/antibiotics)  
for more information.

**What you need to know about  
FDA's new antibiotic use rules**

# Q&A

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# Q&A

## Expanding the Herd-Health Partnership with Your Vet

### **Q: What are the U.S. Food and Drug Administration's (FDA) new antibiotic rules that began Jan. 1, 2017?**

**A:** FDA's Guidance 209 changed the rules for antibiotic use in all animals raised for food. Specifically, medically important (to human health) antimicrobials can only be used for therapeutic use – to treat, control or prevent specific disease under veterinary guidance. Access to feed-grade antibiotics now requires a veterinary feed directive (VFD) and a prescription for water-based treatments. All over-the-counter sales of antibiotics have voluntarily ended.

### **Q: Does this rule apply to everyone?**

**A:** FDA's new antibiotic rules apply to anyone and everyone who raise animals for food regardless of the type, size or location of the production site. Even if you only have one food animal, it applies to you.

### **Q: What is a Veterinary Feed Directive?**

**A:** A VFD is a written statement issued by a licensed veterinarian to allow the use of a VFD drug alone or in combination through animal feed. It authorizes the client (the owner or animal caretaker), as well as the feed distributor, to prepare and use feed with the specified drug to treat the client's animals for a specified time.

### **Q: What is a VFD drug?**

**A:** A VFD drug is a medically important (to human health) antimicrobial that is administered to animals through feed. VFD drugs can only be used under the professional supervision of a licensed veterinarian. A list of VFD drugs for swine can be found at [pork.org/antibiotics](http://pork.org/antibiotics).

### **Q: What about regulations on water-based medications?**

**A:** It's important to note that all medically important antimicrobials that are administered through water now require a veterinary diagnosis and prescription to gain access for treatment. Overall, everything that applies to a VFD also applies to a prescription.

### **Q: How do producers get access to a VFD or a prescription?**

**A:** A VFD or prescription must be issued by a veterinarian licensed to practice veterinary medicine and comply with the veterinarian-client-patient relationship (VCPR) requirements as defined by state or federal guidelines. The FDA will verify whether a state has valid VCPR requirements; if not, the federal rules apply. You can find a VCPR status list at [pork.org/antibiotics](http://pork.org/antibiotics). The list may change over time as states update their veterinary practice requirements.

### **Q: How is a VCPR defined?**

**A:** Having a VCPR means that a producer must have an interactive relationship with a licensed veterinarian. For a valid VCPR, the veterinarian must understand the production practices and health profile of a herd or group of pigs to make clinical judgements about treatment. This will include on-site visits and animal (i.e. pig) examinations.

The veterinarian also should provide follow-up evaluation or care as necessary. It's worth noting that a valid VCPR requires a veterinarian to visit the animals in person. Photos or videos of the animals alone will not suffice to obtain a valid diagnosis.

# Q&A

## Q: What is the scope of a VFD?

**A:** A VFD will involve only one veterinarian, not an entire clinic. The client is the person responsible for the care and feeding of the animals, which may or may not be the actual producer/owner. It will involve one feed manufacturer/distributor. It will designate one medication or combination medication. It can involve one or more animal production sites. (See below.)

## Q: Will the VFD specify the exact drug to be used?

**A:** The veterinarian is required to write the name of the drug on the VFD, but may choose to write in a trade name/pioneer drug or allow a generic drug to be used. The feed manufacturer may not substitute a pioneer drug with a generic drug unless the veterinarian allows it and designates it as such on the written VFD.

## Q: What other information will the VFD include?

**A:** Each VFD will outline the following: the animals or group; the health issue requiring treatment (in detail); the drug, dosage and duration of use. It also will include an expiration date, which specifies the last day the VFD feed can be fed. The authorizing veterinarian's signature in written or electronic form is required.

## Q: How is the VFD expiration date determined?

**A:** The expiration date for the VFD must not exceed the expiration date specified in the drug's approval, conditional approval or index listing. The veterinarian will use his or her medical judgment to determine what expiration date is appropriate for the VFD based on factors including, but not limited to, the type of animal production facility and operation, the VFD drug or combination drug at issue, the intended use of the VFD drug, and the animals' health status, treatment history and life cycle.

A veterinarian can write a VFD for a maximum of six months. If there is a need to extend the treatment beyond that time limit, a new VFD will be required.

## Q: Are there provisions to designate and treat groups of animals with antibiotics?

**A:** FDA recognizes there are groups of animals, similar in age, weight, etc., that are managed in a similar manner, with a common health status, but may be housed in different physical locations. For example, a group of weaned pigs may be moved to multiple finishing sites. The veterinarian may write a single VFD to treat the weaned pigs as a group (approximate number) at multiple physical locations provided there is a valid VCPR and a single feed manufacturer/distributor involved. If multiple feed suppliers are involved, it will require multiple VFDs.

## Q: What information is required to identify and locate an animal site?

**A:** A VFD will need to include information about the physical location of the animals that would allow someone to locate them. A street address for the facility would suffice. If not available, the premises identification number or global positioning system (GPS) coordinate may be used. From there, the veterinarian can decide whether to add more detail, such as the barn, pen, etc., provided the animals will remain in place until the VFD expiration date.





**Q: How can a VFD be transmitted to the feed distributor?**

**A:** A veterinarian must send the VFD to the feed distributor as a hardcopy by fax or electronically (i.e. via the Internet.) If the veterinarian sends a hardcopy, he or she must send the VFD directly to the distributor or through the client. A VFD order must be written and may not be issued verbally, including via a telephone call.

**Q: What are the record-keeping requirements for a VFD?**

**A:** The issuing veterinarian is required to keep the original VFD, and the client and the feed manufacturer/distributor must keep a copy of the VFD for two years. Prescriptions (i.e. for water medications) must be held for one year. Hardcopy or electronic versions of the VFD or prescription are allowed. Electronic records must meet FDA's specified requirements (see Guidance for Industry #233, VFD Common Format Questions and Answers at [pork.org/antibiotics](http://pork.org/antibiotics) on the FDA-info tab.)

Electronic services provided by vendors such as GlobalVetLINK provide compliant, easy-to-manage options. If you're considering using a service, just be sure to check that it is FDA-compliant. Any of the parties must be able to provide the records to FDA upon request. For example, in the case of contract growers, they do not have to have a copy of the VFD onsite but must be able to retrieve it within 24 hours.

**Q: Is extralabel use of a VFD drug allowed?**

**A:** Extralabel use (ELDU) of medicated feed containing a VFD drug or a combination VFD drug is not allowed. For example, feeding animals VFD feed for a duration that varies from the period specified on the label, feeding VFD feed formulated at a different drug level or feeding VFD feed to a species not designated on the label would all be considered ELDU. (See page 7 for more information.)

**Q: If a VFD drug is approved for use at multiple levels or within a range, will one or more VFD orders be issued?**

**A:** In cases where a VFD drug is approved for use at multiple drug levels, the veterinarian may issue a single VFD order covering all approved concentrations intended to be used, as well as the approved feeding duration(s). If a VFD drug is approved for use within a range of concentrations, the veterinarian may specify a level within the range or authorize any use within the range by including the entire authorized range on the VFD.

**Q: If a single group of pigs in a nursery needs two pulses of chlortetracycline (CTC) for two weeks each separated by several weeks, will one VFD suffice?**

**A:** A veterinarian cannot issue a VFD that authorizes a duration of use that is inconsistent with the directions for use described on the product labeling. In this example, the drug approval limits the treatment to 14 days, so the VFD can only authorize that approved duration. Issuing a VFD that authorizes a 14-day course to be repeated for the same animals would be considered an illegal, extralabel use. However, if the herd veterinarian reassesses the animals involved after a single course of therapy (i.e., drug administered according to the labeled dose and duration), he/she may decide that additional therapy is warranted and could issue a new VFD.

**Q: How do the new antibiotic rules affect pork producers who make their own feed?**

**A:** If the producer is not a feed distributor, he/she must have a VFD to receive Type B or C VFD medicated feed from a distributor. If the producer is obtaining a Type A medicated article that is not a VFD feed, the producer does not need to provide a VFD. However, the producer will need a VFD prior to feeding any Type B or C medicated feed that they mix from the Type A medicated article.

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FDA recognizes that producers who manufacture their own medicated feed may need to hold some Type A medicated articles or feed in inventory to allow them to quickly manufacture medicated feed for treatment after receiving the veterinarian's VFD authorization. However, the inventory should align with the expected amount of VFD feed needed to treat the designated animals.

**Q: How are feed-delivery records tied to a VFD? Since feed mills generally have these records, do producers and veterinarians need to have them as well?**

**A:** During an FDA inspection, the agency will review VFD orders and compare them to the feed manufacturing records. FDA would expect that the amount of medicated feed produced to fill a VFD, whether in one or several batches, would be commensurate with the amount of feed necessary for the approximate number of animals that the VFD authorizes to be fed. The producer and veterinarian are required to maintain the main VFD record, but they are not required to maintain feed-delivery records under the final VFD rule.

**Q: What if a mill breaks down or runs out of a VFD drug?**

**A:** The feed distributor that receives the VFD from the veterinarian or client should be the only one filling the entire order. In special circumstances, two mills may be required to fill the order. For example:

- If a mill runs out of a VFD drug and the client needs VFD feed to adhere to the treatment regimen
- If a feed mill goes down unexpectedly.

In such cases, the client and distributors should keep records documenting the situation to clarify that the animals received only VFD-authorized treatment.

**Q: How should leftover VFD feed be handled?**

**A:** Any VFD feed remaining after its related VFD has expired may not be fed to animals without obtaining a new VFD. Feed will need to be disposed of according to the state or local requirements for medicated feed.

**Q: What happens if a treated group of pigs rebreaks with a disease or requires another treatment?**

**A:** In such a case, the veterinarian will need to authorize another VFD or a water-medication prescription as appropriate.

**Q: How do FDA's new rules impact show pig exhibitors?**

**A:** Everyone who owns or raises pigs is affected by FDA's new antibiotic rules regardless of the number of animals. The exhibitor will need to establish a VCPR with a veterinarian who will need to visit each set of pigs to check on their health, housing and care.

For example: If you're feeding pigs for a series of summer shows, that's one set of pigs requiring a veterinary visit. Pigs that are being prepared for a fall show is a separate set, and so on. This is true even if they're on the same site or in the same barn. The veterinarian will need to see each set of pigs in order to write a VFD or a prescription for water medication if needed.

**Q: Can an FFA advisor/4-H leader serve as the caretaker of all the club's animals?**

**A:** Yes, provided the animals are housed within a common location where the FFA advisor or 4-H leader is responsible for the care and feeding of the animals. This would allow the advisor/leader to establish the VCPR and manage any VFDs or prescriptions. Otherwise, each individual exhibitor or site needs to establish its own VCPR.

**Q: If a youth exhibitor shows a pig at a jackpot show (a one- or two-day show where pigs will return home), does he/she need a copy of a VFD or a prescription at the show? Or, can an exhibitor produce it at a later date if asked by the FDA?**

**A:** The VFD final rule requires that "all involved parties must make the VFD and any other records specified in this section available for inspection and copying by FDA upon request." {21 CFR 558.6(a)(5)}. Therefore, an exhibitor's copy of a VFD or prescription should be readily available.

# Q&A

## Q: How will the new antibiotic rules be enforced?

**A:** FDA has initiated a pilot project to inspect the VFD process. This involves going to a feed distributor and reviewing three randomly selected VFD forms. Officials will select one to trace back to the veterinarian, investigating the VCPR and ensuring the producer/client applied the VFD feed correctly. The process also will check that all records are complete, accurate and stored properly.

Long term, FDA will engage in risk-based general surveillance, as well as for-cause inspection assignments. The agency will work closely with state regulatory partners and state boards of veterinary medicine.

## Q: What are the penalties for non-compliance of the new antibiotic rules?

**A:** There are several actions FDA can pursue to address a violation, including injunction, seizure, monetary penalties and criminal charges under Section 303(a) of the Food, Drug and Cosmetic Act.

## Q: Where can producers find more answers about the new antibiotic rules?

**A:** Numerous resources are available at the Pork Checkoff's Antibiotics Resource Center found at [pork.org/antibiotics](http://pork.org/antibiotics). Bookmark the website on your computer or smartphone. You also can email questions to FDA's Center for Veterinary Medicine at [askCVM@fda.gov](mailto:askCVM@fda.gov).

## Know Your Role in Extralabel

**Y**ou may have heard about extralabel drug use (ELDU) of certain drugs over the years, but it's never been more important to be knowledgeable about the critical role both veterinarians and producers play in keeping people and pigs healthy as it relates to proper and legal antibiotic use. Of course, only a licensed veterinarian can authorize the use of a drug in an ELDU manner and only if it is allowed by law.

Under the Animal Medicinal Drug Use Clarification Act of 1994, an ELDU is an FDA-regulated veterinary medical activity that allows veterinarians to prescribe extralabel uses of approved animal and human drugs when the health of an animal is threatened, or when suffering or death may result from failure to treat animals. In short, producers and veterinarians can use these drugs for conditions not listed on the label, but they are only available through a prescription from a veterinarian.

As before FDA's new antibiotic rules went into effect on Jan. 1, extralabel use of medicated feeds, including medicated feed containing a veterinary feed directive (VFD) drug or a combination VFD drug, remains illegal. Examples considered extralabel uses and therefore not permitted include:

- Feeding pigs a VFD feed for a duration of time different from what is specified on the label.
- Feeding VFD feed formulated with a drug level different from what is specified on the label.
- Feeding VFD feed to an animal species different than what is specified on the label.

Unlike medicated feeds, the use of injectable drugs in an ELDU manner remains allowable under a valid Veterinary Client Patient Relationship (VCPR), but with certain limits. For example, under a VCPR, a producer with veterinary oversight or a veterinarian could use injectable drugs to treat a joint infection in a sow, despite it not being a listed use on the label.

For more information and more FAQs, go to:  
[pork.org/antibiotics](http://pork.org/antibiotics)



# Drug Use

## Specific Criteria Must Be Followed for ELDU, Including:

- A valid VCPR is a prerequisite for all ELDU.
- Only a veterinarian can determine that ELDU is needed and can administer, prescribe or dispense a medication in an extralabel way.
- A veterinarian must direct or supervise ELDU in an animal.
- ELDU rules only apply to FDA-approved animal and human drugs.
- ELDU is intended for prevention, treatment and control purposes only when an animal's health is threatened. ELDU of drugs for production use and/or in feed is not approved.
- ELDU is not permitted if it results in an illegal food residue or any residue that may present a risk to public health.
- A veterinarian must not pursue use of certain FDA-prohibited drugs in food-producing animals (see sidebar at right).



## Extralabel Drug Use of an FDA-Approved Drug May Be Allowed If:

- There is no approved animal drug that is labeled for such use (a specified diagnosis) or that contains the same active ingredient in the required dosage form and concentration.
- Alternatively, an approved animal drug for that species and condition exists, but a veterinarian finds, within the context of a VCPR, that the approved drug is clinically ineffective for its labeled use.

Per federal regulations, ELDU of the following drugs is prohibited in food-producing animals, regardless of whether or not the criteria for ELDU are met:

1. Chloramphenicol
2. Clenbuterol
3. Diethylstilbestrol (DES)
4. Dimetridazole
5. Iprnidazole
6. Other nitroimidazoles
7. Furazolidone
8. Nitrofurazone
9. Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxyypyridazine)
10. Fluoroquinolones
11. Glycopeptides
12. Phenylbutazone in female dairy cattle 20 months of age or older
13. Cephalosporin (excluding cephalirin) use in cattle, swine, chickens and turkeys
  - Using cephalosporin drugs at unapproved dose levels, frequencies, durations or routes of administration is prohibited
  - Using cephalosporin drugs in cattle, swine, chickens or turkeys that are not approved for use in that species (e.g., cephalosporin drugs intended for humans or companion animals)
  - Using cephalosporin drugs for disease prevention

## A Special Note on Cephalosporins

Cephalosporins are a family of drugs that are used in both people and animals. The cephalosporins most pork producers are familiar with are the injectable ceftiofur-based products, such as Naxcel®, Excede® and Excenel®.

Because this class of drugs is used in human medicine, the FDA has sought to reduce the uses of cephalosporin antibiotics in animals. FDA's Center for Veterinary Medicine issued an order in 2012 that prohibited the extralabel use of cephalosporin drugs (not including cephalirin) in cattle, swine, chickens and turkeys. Since then, these drugs can only be used strictly according to their labels, even by veterinarians. In addition, the current rules prohibit use of cephalosporin drugs to prevent disease in all food animals.

As always, pork producers should create a whole-herd health plan with their veterinarians. This should include how, if needed, they will use antibiotics in any part of their farm to ensure that they are abiding by all federal regulations.

**Inside:** How do **FDA's new antibiotic use rules** impact your farm?



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*"As pork producers,  
we are always seeking  
new ways to do  
what's right for our  
animals, consumers  
and the environment."*

Jan Archer, North Carolina

## A Shared Responsibility

*By National Pork Board President Jan Archer, Goldsboro, North Carolina*

As the new year begins, pork producers are not alone in the renewed effort to use antibiotics responsibly. Everyone is doing their part to reduce the potential problems associated with antibiotic resistance – from your local doctor to your livestock counterparts around the world. This global concern has led to the worldwide effort known as One Health, which puts people, animals and the environment at the center of its focus. This echoes the National Pork Board's own emphasis on people, pigs and planet found in its strategic plan.

As the Centers for Disease Control and Prevention (CDC) points out, we have to take even better care of the antibiotics we have today so that we don't lose any of these critical tools in the future. Continuing to work closely with our veterinarians and building relationships with them helps us make the best possible health decisions for our animals and to meet our greater goal of good antibiotic stewardship.

Livestock farmers need to tell the story of how real change is underway on pig farms across America. We no longer use human medically important antibiotics for growth-promotion, and we are focused on responsible antibiotic use. This means using them only when necessary for the health and well-being of our animals.

As pork producers, we are always seeking ways to do what's right for our animals, our consumers and the environment. The changes that are now in effect for antibiotic use might be new, but they aren't an unusual challenge for us. Our industry has always been innovative. As we seek new ways to reduce the overall need for antibiotics, we'll do what we've always done – keep our livestock healthy and produce safe food.



*This special-topic newsletter is sent periodically to you by the Pork Checkoff.*

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