

# The Veterinary Feed Directive

Dr. Dave Pyburn  
National Pork Board



# Antibiotic Regulation

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- US Food and Drug Administration regulates animal and human antibiotics
- State pharmacy boards have authority over veterinary prescribing

# Antibiotic Label Claims

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- Disease Treatment
- Disease Control
- Disease Prevention
  - Treatment, Control and Prevention are considered therapeutic
  - FDA has said they are necessary for animal health and welfare
- Growth Promotion or Improvement of Nutritional Efficiency

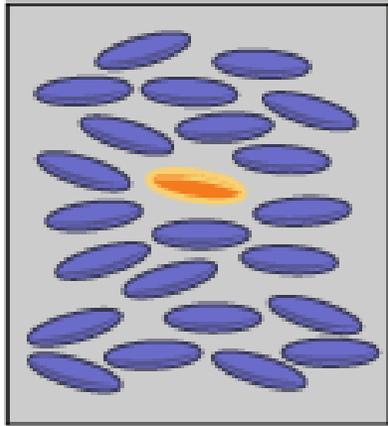
# Antibiotic Classes

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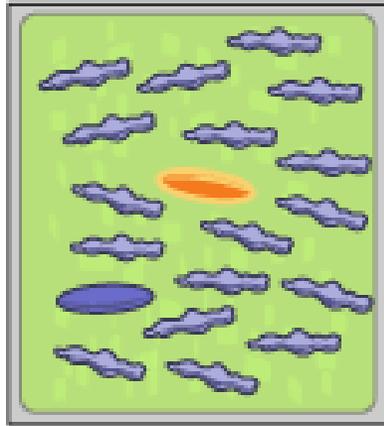
- Medically important (as defined by FDA)
  - Same, or in same classes, as antibiotics used to treat humans
  - Most antibiotics approved for use in animal feed are medically important with possible exceptions:
    - Swine: bacitracin, mecadox, narasin, bambarmycin, and tiamulin

# Antibiotic Resistance Development

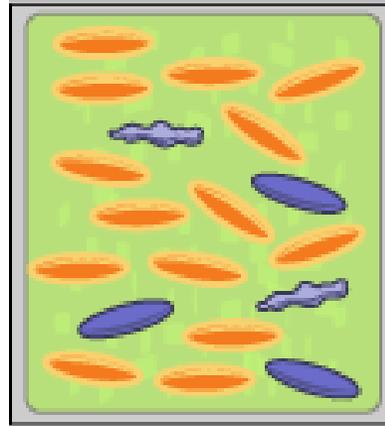
1  
A bunch of bacteria,  
including a resistant  
variety...



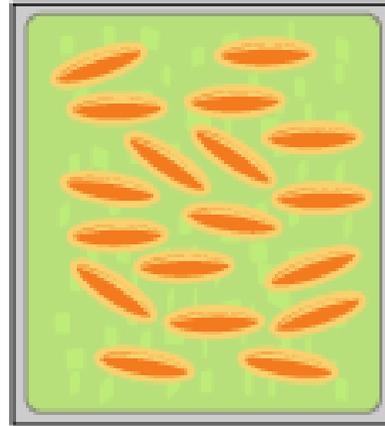
2  
...get bathed in  
antibiotics. Most  
of the normal  
bacteria die.



3  
The resistant  
bacteria multiply  
and become more  
common.



4  
Eventually, the  
entire infection  
evolves into a  
resistant strain.



 normal bacterium

 dead bacterium

 resistant bacterium

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# Regulatory Action on Antibiotics



# FDA Regulatory Action

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- On Jan. 1, 2017, the U.S. Food and Drug Administration's (FDA) new regulations addressing on-farm antibiotic use in food-animal production will take effect.

# FDA Regulatory Action

#209

## Guidance for Industry

**The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals**

#213

## Guidance for Industry

**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**

**DRAFT GUIDANCE**

This draft guidance document is for comment purposes only.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 558**

[Docket No. FDA-2010-N-0155]

**Veterinary Feed Directive; Draft Text for Proposed Regulation**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification; draft text for proposed regulation.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of draft text for a proposed regulation intended to improve the efficiency of FDA's Veterinary Feed Directive (VFD) program. The Agency is making this draft text for a proposal available because of the complex scientific and regulatory issues

# FDA Regulatory Action

<p style="text-align: right;">#209</p> <p style="text-align: center;"><b>Guidance for Industry</b></p> <p style="text-align: center;"><b>Removal of growth promotion/nutritional efficiency use of medically important (to human illness) antibiotics</b></p> <p><b>Antimicrobial Drugs in Food-Producing Animals</b></p>	<p><b>DEPARTMENT OF HEALTH AND HUMAN SERVICES</b></p> <p><b>Food and Drug Administration</b></p> <p><b>Veterinary Feed Directive; Draft Text for Proposed Regulation</b></p> <p><b>AGENCY:</b> Food and Drug Administration,</p> <p><b>SUMMARY:</b> The Food and Drug Administration (FDA) is announcing the availability of draft text for a proposed regulation intended to improve the efficiency of FDA's Veterinary Feed Directive (VFD) program. The Agency is making this draft text for a proposal available because of the complex scientific and regulatory issues</p>
<p style="text-align: center;"><b>Bringing therapeutic use (treatment, control prevention) under increased veterinary oversight</b></p> <p style="text-align: center;"><b>Guidance for Industry</b></p> <p><b>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</b></p> <p style="text-align: center;"><b>DRAFT GUIDANCE</b></p> <p style="text-align: center;">This draft guidance document is for comment purposes only.</p>	

# Guidance for Industry #209

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- FDA intent and recommendations regarding:
  - Removal of growth promotion uses of medically important antibiotics in food animal production
  - Increased veterinary oversight of the remaining therapeutic applications (prevention, treatment and control) of medically important antibiotics
- This action applies to both feed-grade and water-based antibiotics.

# Guidance for Industry #213

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- FDA request to animal-health companies to outline intentions to voluntarily remove any production/growth-promotion uses from product labels of medically important antibiotics.
- All animal health companies have agreed.
- Jan. 1, 2017, is when implementation must be completed.

# Veterinary Feed Directive

- The final rule outlines specific requirements of the VFD process for medically important (to treat human infections) feed-grade antibiotics.



# FDA Medically Important

- All swine antibiotics will be affected under Guidance 209 except

- Bacitracin (BMD)
- Carbadox (Mecadox)
- Bambermycin (Virginiamycin)
- Tiamulin (Denagard)
- Ionophores (Skycis)

These antibiotics will remain available for growth promotion and/or over-the-counter (OTC) in feed and water

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# Changes in Antibiotic Regulation – What Will It Mean On the Farm?



# What Does This Really Mean?

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- Most growth promotion uses (all medically important antibiotics) will end by Dec. 31, 2016.
- Most feed-grade antibiotics will no longer be available over-the-counter but will require a veterinary feed directive (VFD).
- Antibiotics in water will require a prescription.

# What Does This Really Mean?

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- This is a significant regulatory step that will change how antimicrobials are used in food animal production on farms of all sizes.
- Once those labels are changed, it will be illegal to utilize the medically important antibiotics to promote growth.
- Producers will need a VFD or prescription to use these products for therapeutic uses in feed and water.

# How Will This Affect Pork Producers?

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- Producers are going to lose some antibiotics or uses of antibiotics.
- The new FDA rule will require additional time and effort on the part of producers and their veterinarians.
- Producers will need a close relationship with their veterinarian – access to veterinarians in rural areas?
- Disproportionately impact small producers that mix their own feed or buy floor stock?

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# Basics of On-Farm VFD Compliance



# Basics of On-Farm VFD Compliance

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- Key Steps:
  - The issuing veterinarian is required to keep the original VFD; the feed mill/distributor and producer (client) must each keep a copy of the VFD. Hardcopy or electronic versions are allowed.
  - The VFD and records of the related feed distribution must be kept for a period of two years.

# Basics of On-Farm VFD Compliance

- Key Steps Cont.
  - Each VFD includes a specific expiration date. Any VFD feed remaining after its related VFD has expired may not be fed to animals without obtaining a new VFD. This would include any remaining feed in a bin or feeder.

**Take Home Message for Producers: Talk with your veterinarian about using any antibiotics that fall under the new VFD requirement.**

# VFD Final Rule

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## Previous Rule

- 2 year record retention
- Original document to mill
- No extra-label use
- Order for tons of feed
- No refills, unless on label
- Written for one group of animals on a premise
- VCPR required

## Revised Rule

- 2 year record retention
- May email or fax document
- No extra-label use
- Order for number of days
- No refills, unless on label
  - None at this time
- Attached list of premises
  - For each mill
- State VCPR required
- Max of 6 mo. expiration

# Veterinary-Client-Patient Relationship

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- The new FDA antibiotics regulations will require pig farmers to have a valid veterinary-client-patient relationship (VCPR).
- This means a pig farmer will need to have a good relationship with their veterinarian and expect to spend more time in developing a plan that satisfies all VFD requirements.
- Your veterinarian should be familiar with the state and/or federal VCPR requirements.

# Veterinary-Client-Patient Relationship - Oregon

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“Veterinary Client Patient Relationship (VCPR)”: Except where the patient is a wild or feral animal or its owner is unknown; a VCPR shall exist when the following conditions exist:

- The veterinarian must have sufficient knowledge of the animal to initiate at least a general or preliminary diagnosis of the medical condition of the animal. This means that the veterinarian has seen the animal within the last year and is personally acquainted with the care of the animal by virtue of a physical examination of the animal or by medically appropriate and timely visits to the premises where the animal is kept.

# Record-keeping Priorities

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- Producers with Pork Quality Assurance<sup>®</sup> Plus (PQA Plus<sup>®</sup>) certification should be well familiar with requirements for accurate and complete record-keeping.
- The record-keeping commitment will involve keeping hard copies or electronic versions of all VFDs for two years and one year for all prescriptions.

# On Farm Feed Manufacturing

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- Will not need to register as a distributor unless producing feed for commerce
- Will need VFD to buy medicated premix (Type B)
- Will not be able to have medicated feed in bin after expiration of the VFD

# FDA VFD Pilot

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- FDA pilot field assignment to conduct inspections at VFD distributors with additional follow-up at veterinarians and producers.
- Intended to measure compliance with the VFD rule utilizing a new VFD Inspection Tool

# FDA VFD Pilot

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- Pilot begins with investigator visiting a feed distributor
- Randomly selects and examines 3 VFD forms to evaluate the information on the form
- Select one of the forms to track back to the veterinarian and forward to the producer

# FDA VFD Pilot

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- Specifically looking at:
  - Vet
    - Is the VFD form completed correctly
    - Proper licensure
    - VCPR in effect (eg. medical records with the client's animals named)
    - Proper recordkeeping
  - Distributor
    - Letter of intent and acknowledgement letters on file
    - Recordkeeping
    - Cautionary statements on the feed label
    - Accurate feed manufacture

# FDA VFD Pilot

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- Specifically looking at:
  - Producer
    - Recordkeeping
    - Number of animals fed
    - Duration of feeding
    - Follow withdrawal period and any special instructions

# FDA VFD Pilot

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- Focus on...
  - Determining whether further education about the new rule is needed and, if so, who needs that education (i.e., feed mills, retailers, veterinarians, or producers)
  - Feedback for revision of the inspection tool.

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# Producer Resources



# Checkoff Funding

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**By yearend 2016, NPB will have committed nearly \$2 million in Checkoff funding for scientific research, producer education and consumer awareness programs**



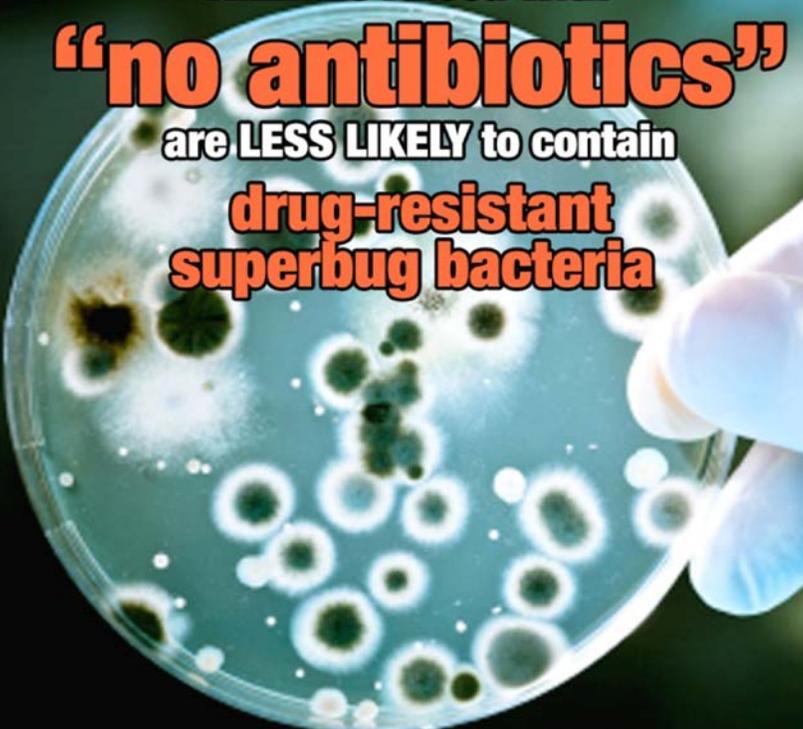
# The Media Blitz

In just **11 months**, we saw 230,000 online and social media mentions and nearly **2,300 articles**

JUL 15 NO BUGS AND NO BURNS TOP-RATED INSECT REPELLENTS AND SUNSCREENS | PROTECT YOUR CREDIT CARDS

## ConsumerReports®

Animals raised with  
**“no antibiotics”**  
are LESS LIKELY to contain  
**drug-resistant  
superbug bacteria**

A petri dish containing a blue agar medium with several distinct bacterial colonies of varying sizes and colors, including white, green, and black. A gloved hand is visible on the right side, holding the edge of the dish.

REUTERS

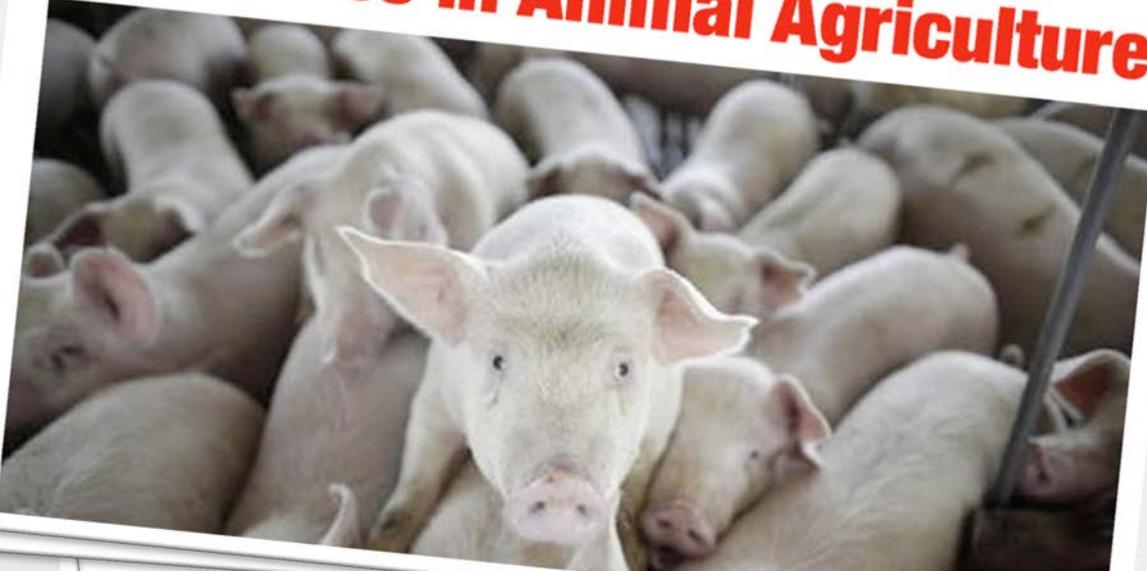
July 6, 2011

## THE HUFFINGTON POST

UNITED KINGDOM

FRONT PAGE POLITICS WORLD ENTERTAINMENT STYLE LIFESTYLE CELEBRITY COMEDY TECHNOLOGY BLOGS

# Reduce Use of Antibiotics in Animal Agriculture

A photograph showing a large group of white piglets in a crowded pen. One piglet in the foreground is looking directly at the camera.

# Pig Farming is an industry under pressure

Our No. 1 priority is to shape the ABX dialogue through demonstrating stewardship.

- Media pressure
- Food chain and influencer pressure
- Preserve efficacy and antibiotics role as a critical on-farm tool

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PAID ADVERTISEMENT

## Dear Subway Management Team and Franchisee Owners:

Any policy decision to eliminate antibiotics from your protein supply sources – poultry, pork and beef – would be a significant departure from what many other food companies are doing in regards to improving responsible antibiotic use. This policy decision could put our food system in jeopardy.

We share the opinion that everyone needs to do their part to use antibiotics responsibly – and reduce the antibiotic resistance threat. This includes quickly phasing out any use of medically important antibiotics (to treat human illness) for growth promotion in farm animals as well as increasing veterinarian oversight, which are actions that farmers and ranchers are already taking.

**We believe a move to NO antibiotics of any kind – Subway's position – could leave livestock without access to animal health medicines and could result in the unnecessary suffering or death of such animals.**

Subway is not saying "no" just to those antibiotics used in human medicine. Subway isn't saying "use antibiotics only when animals are sick." Subway is saying no antibiotics ever – even when animal health and safety could be at risk. We think that such a policy could compromise the safety of our food system. Sick animals in the food system are not a good idea. Healthy animals help farmers produce safe food.

How will a hog farmer react to a fast-moving disease outbreak that could have been prevented with medicine administered in time? The potential for thousands of animals to unnecessarily die or suffer is a real possibility. These are the consequences that farmers will have to face.

We should all leave open the ability to use antibiotics responsibly when animals are sick or at risk of getting sick. On the best managed ranch or farm, animals can get sick, just as people can get sick in the cleanest and best run households. We believe that insisting on absolutely no antibiotics ignores best practices established by veterinarians, the pork industry and individual farmers who have a direct interest in the welfare of their animals.

Some interest groups may applaud your policy decision. Will those same groups stand with you if large populations of livestock are adversely affected by your new policy?

An opportunity for meaningful input from the national pork industry associations, who represent farmers who care for animals day and night, could have been helpful to you prior to your policy announcement. Our opinion is that these associations could have provided valuable scientific evidence, facts and common sense perspectives that could have helped better inform your policy-making process.

**We ask you to meet with us to consider a more balanced approach.** We are eager to share with you the pork industry's commitment to continuous improvement and antibiotic stewardship. We clearly disagree with your policy. **Responsible antibiotic use makes sense. Continuous improvement makes sense.** Please remain open-minded to the view that banning all antibiotic use is simply not the answer.

We stand ready to engage in a dialogue with you.

Sincerely,

America's Pig Farmers  
[www.porkcares.org](http://www.porkcares.org)



# NPB Antibiotic Stewardship Policy

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- Using antibiotics responsibly
- Preventing disease, rather than treating disease
- Protecting the efficacy of antibiotics
- Reducing the need to use medically important antibiotics

# Key Affirmation

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*Responsible use of medically important antibiotics protects animal health and well being, ensures food safety and preserves their effectiveness for animals and humans.*

# 2016 Industry Research Priorities

1. Analysis and assessment of **preventive uses of antibiotics at therapeutic doses** in pork production to optimize swine health and public health.
2. Analysis and assessment of specific **animal population antibiotic treatment vs. individual animal treatment** in pork production to optimize swine health and public health.
3. Evaluation of on-farm challenges to antibiotic **record keeping** and identification of strategies to improve antibiotic record keeping practice for continuous improvement of responsible antibiotic use on the farm.
4. Characterization and assessment of the **environmental fate** of antibiotics, antibiotic metabolites, antibiotic resistant bacteria and antibiotic resistant genes on swine farms.
5. Exploration of strategies to protect herd health and **minimize the need** for antibiotics.



A quality assurance program of America's Pork Producers.

EDITION 3

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EDUCATION HANDBOOK



(800) 456-7675 - pork.org



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# Guidelines For Responsible Antibiotic Use

## Guideline 1

Use professional veterinary input as the basis for all antibiotic decision-making.

## Guideline 2

Antibiotics should be used for prevention, control or treatment only when there is an appropriate clinical diagnosis or herd history to justify their use.

## Guideline 3

Limit antibiotic use for prevention, control or treatment to ill or at-risk animals, treating the fewest animals indicated.

# Guidelines For Responsible Antibiotic Use

## Guideline 4

Antibiotics that are important in treating infections in human or veterinary medicine should be used in animals only after careful review and reasonable justification.

## Guideline 5

Mixing together injectable or water medications, including antibiotics, by producers is illegal.

## Guideline 6

Minimize environmental exposure through proper handling and disposal of all animal health products, including antibiotics.

# PQA Plus Site Assessment

## SITE ASSESSMENT FORM PAGE 2

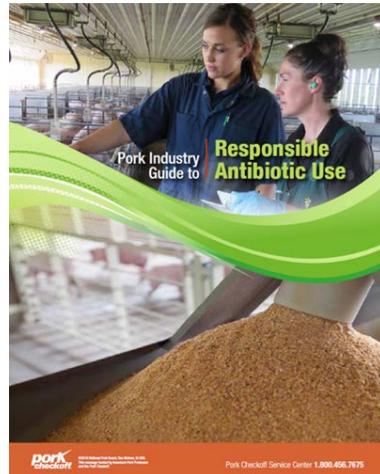
Question	Acceptable	Develop/Implement an Action Plan	Observations/Comments
22. Does the site have a valid VCPR?	Yes		
23. Does the site have compliant medication and treatment records?	Yes		
24. Are medication and treatment records retained for 12 months?	Yes		
25. Are VFD's records retained according to FDA guidelines? NA for sites not using products requiring a VFD.	Yes/NA		

## SITE ASSESSMENT FORM PAGE 3

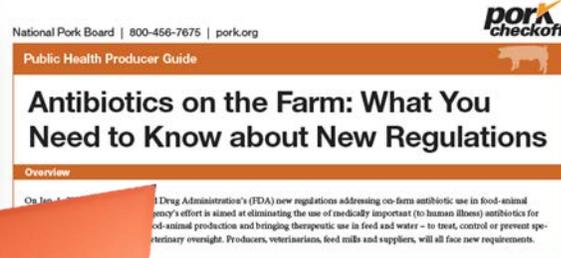
Question	Acceptable	Develop/Implement an Action Plan	Observations/Comments
26. Can caretakers articulate their method for tracking what treatments have been administered and how long each animal has been receiving treatment?	Yes		

# Producer Antibiotic Resource Center

- Antibiotic Resource Center located at: [www.pork.org/antibiotics](http://www.pork.org/antibiotics)
  - All resources
  - FAQs
  - Additional clarifications from FDA



# Education and Communication



**DON'T WAIT... BE READY!**  
**NEW ANTIBIOTICS RULES**  
2017  
The NEW Veterinary Feed Directive (VFD) for medically important feed-grade antibiotics and prescription rule for water-based antibiotics  
TAKE EFFECT ON JANUARY 1, 2017.

**YOUR CHECKLIST FOR SUCCESS**

- Understand the new feed (VFD) and water (W) rules
- Strengthen your vet-client-patient relationship (VCP)
- Communicate with your feed mill
- Assess your herd health and welfare strategies
- Renew your commitment to responsible antibiotic use
- Ensure your record-keeping compliance

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

**ANTIBIOTICS RESOURCE CENTER**  
Visit [pork.org/antibiotics](http://pork.org/antibiotics) for more information.  
Pork Checkoff Service Center 1.800.456.7675

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**Pork Checkoff Report Newsletter**  
**Antibiotic Changes: 18 months and Counting**

By the end of 2016, the U.S. Food and Drug Administration will implement a new policy aimed at reducing use of antibiotics in food animal production. The agency's goal is to work with the production sector to eliminate the use of medically important (or human-derived) antibiotics for growth promotion and to bring therapeutic use—its strict, control or possess specific disease—under veterinary oversight. Pork producers should be taking steps now to prepare for the changes.

"Antibiotics aren't going away, but on-farm use will change. Producers should sit down with their veterinarians to discuss how to apply veterinary feed directives (VFD) and other feed health strategies."

—Janette Korman, DVM, Pork Checkoff

"That sounds like a long way off, but producers need to start getting ready," said Jennifer Korman, DVM, Pork Checkoff's director of producer and public health. "Antibiotic use isn't going away, but on-farm use will change. Producers should sit down with their veterinarians to discuss how to apply veterinary feed directives (VFD) and other feed health strategies."

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**INDUSTRY INSIGHTS**  
The final countdown for antibiotic changes  
**PRODUCERS URGED TO TAKE ACTION NOW**  
By May 15, 2017, the U.S. Food and Drug Administration (FDA) will implement a new policy aimed at reducing use of antibiotics in food animal production. The agency's goal is to work with the production sector to eliminate the use of medically important (or human-derived) antibiotics for growth promotion and to bring therapeutic use—its strict, control or possess specific disease—under veterinary oversight. Pork producers should be taking steps now to prepare for the changes.

**DON'T WAIT... BE READY!**  
The NEW Veterinary Feed Directive (VFD) for medically important feed-grade antibiotics and prescription rule for water-based antibiotics TAKE EFFECT ON JANUARY 1, 2017.  
2017  
pork.org/antibiotics for more information.  
DECEMBER 2016  
1 2 3 4 5  
6 7 8 9 10 11 12  
13 14 15 16 17 18 19  
20 21 22 23 24 25 26  
27 28 29 30 31

# Your Checklist for Success (USCARE)

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- **U**nderstand the new feed (Veterinary Feed Directive) and water (prescription) rules.
- **S**trengthen your veterinary-client-patient relationship (VCPR).
- **C**ommunicate with your feed mill.
- **A**ssess your herd health and welfare strategies.
- **R**enew your commitment to responsible antibiotic use.
- **E**nsure your record-keeping compliance.

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# Carbadox



# Carbadox (Mecadox)

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- Mainly used in young pigs during the transition from the sow to nursery to prevent disease and treat specific diarrheal diseases
- 42-day withdrawal
  - Set by FDA, on label, and followed by producers
  - 1 violative residue in 15 years of FSIS testing
- Not a humanly important antibiotic

# The Issue

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- FDA CVM
  - First step toward rescinding its approval (1972) of the use of Carbadox because the drug may leave trace amounts of a carcinogenic residue.
- Phibro
  - Providing the data to the FDA as it is generated and to date that evidence has been positive regarding the safety of Carbadox

# FDA states that pork is safe to eat

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- FDA raises concerns about pork liver, a product not widely consumed in the United States, but is not recommending that consumers remove pork liver or any other pork products from their current diet

# Where are we at today?

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- FDA's proposal to rescind approval of carbadox is not based on complete data. Before any final decision on the continued use of carbadox is made, the science to support the decision should be made available

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