Pork Industry Antibiotics Update

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Building Trust – Responsible Antibiotic Use

On-farm antibiotic use is on the minds of customers and consumers

• FDA regulated
• Involves food safety and human health
• Not pork-specific (crosses all species)
• No real, strong advocates
• For customers, changes are a brand differentiator
Antibiotic Resistance is Not a New Issue

Since antibiotic resistance is a global concern, the worldwide “One Health” approach to combat antibiotic resistance is critical to human and animal health.

- Collaborative effort of multiple stakeholders to attain optimal health for people, animals and the environment.
- Medical doctors and patients, veterinarians and farmers, along with government, academia and industry stakeholders, are cooperating.
Pork producers play an important role in the shared effort to use antibiotics responsibly to help minimize the potential emergence of antibiotic resistant bacteria.
Changes in Antibiotic Regulation – What Will It Mean On the Farm?
Antibiotic Label Claims

• 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

• 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, bambermycin, and tiamulin
Regulatory Action
U.S. Tightens Rules on Antibiotics Use for Livestock
FDA Regulatory Action

• 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

Removal of growth promotion/nutritional efficiency use of medically important (to human illness) antibiotics

Bringing therapeutic use (treatment, control prevention) under increased veterinary oversight

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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DRAFT GUIDANCE

This draft guidance document is for comment purposes only.
FDA Medically Important

• All swine antibiotics will be affected under Guidance 209 except
  – Bacitracin
  – Carbadox
  – Bambermycin
  – Ionophores
  – Tiamulin

  These antibiotics will remain available for growth promotion and/or over-the-counter (OTC) in feed and water
Guidance for Industry #213

• 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.
The final rule outlines specific requirements of the VFD process for medically important (to treat human infections) feed-grade antibiotics.
What Does This Really Mean?

• Most growth promotion uses (all medially important antibiotics) will end by Dec 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.
How Will This Affect Pork Producers?

- Availability and use of antibiotics will change.
  - Some uses will no longer be legal.
  - Some medications will no longer be available.
- The new FDA rule will require additional time and effort for producers and their veterinarians.
  - Time to develop VCPR
  - Time to fill and manage prescriptions and VFD orders
- Will there be enough veterinarians to fulfill the new requirements?
Helping Producers Prepare
National Pork Board Actions

✓ **ACTION:** National Pork Board adopted the new position and policy statement as presented in the June 2015 Board meeting.

✓ **ACTION:** The National Pork Board intends to allocate up to $1.4 million in funding of scientific research, producer education and consumer awareness programs.

  - Focus on assessment of use, group vs individual treatments, record keeping, environmental impact of antimicrobials and other strategies to reduce the need to antimicrobials
  - Full-time subject matter expert (Dr. Peter Davies) in 2016 who will evaluate models and metrics to assess antibiotic stewardship and use in the U.S. swine industry.
Checkoff Stewardship Plan

National Pork Board’s Three-Point Antibiotic Stewardship Plan

1. EDUCATION
   - The National Pork Board will collaborate with allied partners, including swine veterinarians, feed organizations, breed associations and show-pig groups, animal health companies and associated commodity groups to develop educational materials for more than 60,000 pork producers and the academic and swine veterinarian community about the new FDA regulations and antibiotic stewardship.

2. RESEARCH
   - The National Pork Board will make antibiotic use and resistance a top research priority in its 2016 budget. Since 2000, the Pork Checkoff has invested $5.3 million in research on the epidemiology of antibiotic resistance, as well as efforts to define alternatives to antibiotic use. The board will invest close to a million dollars of new money in additional research in 2016.

3. COMMUNICATION OUTREACH
   - Communication regarding antibiotics to all segments of the pork chain will continue to be a main emphasis for the National Pork Board, with special emphasis on pig farmers and the upcoming new FDA rules.

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Antibiotic Fact Sheet

Public Health Producer Guide

Antibiotics on the Farm: What You Need to Know about New Regulations

Overview

On Jan. 1, 2017, the U.S. Food and Drug Administration’s (FDA) new regulations addressing the use of antibiotics in food animal production will take effect. The agency’s effort is aimed at eliminating the use of medically important (to human health) antibiotics for growth promotion purposes in food animal production and bringing therapeutic uses in food and water – to treat, control or prevent specific disease – under additional veterinary oversight. Producers, veterinarians, feed mills, and suppliers, will all face new requirements.

FDA’s New Regulations Defined

All sectors of animal agriculture, from drug companies to producers and veterinarians to feed mills, are collaborating to implement the new FDA antibiotic regulations.

Guidance 209: On Jan. 1, 3003, FDA outlined its intent and recommendations regarding growth promotion uses of medically important antibiotics in food animal production. FDA also specified that veterinary oversight will increase for the remaining therapeutic applications (prevention, treatment and control) of medically important antibiotics. This action applies to both feed-grade and water-based antibiotics.

Guidance 210: On Dec. 13, 2013, FDA initiated a three-year transition process to complete its food animal antibiotic strategy. This action requests animal health companies to outline intentions to voluntarily remove any production/growth-promotion uses from product labels of medically important antibiotics. The guidance also eliminates over-the-counter status of those medications and increases veterinary oversight for on-farm therapeutic use by requiring a veterinary feed directive (VFD) for all applications and a prescription for water treatments. Jan. 1, 2017, is when implementation must be completed.

Final VFD Rules: On June 3, 2015, FDA announced the Final VFD rules. The final rules outline specific requirements of the VFD process for medically important (to treat human infection) feed-grade antibiotics.

Basics of On-Farm VFD Compliance for Producers

The biggest change for pork producers, veterinarians, and feed mills will be the expanded Veterinary Feed Directives (VFD) process. Previously, only these products required a VFD, and all were labeled for veterinary use. While the current VFD regulations may offer some flexibility within the compliance process, the new FDA rules will require additional administrative effort on the part of producers and their veterinarians. Here are some key steps required to comply:

- The owner or veterinarian must keep the original VFD copy, the feed distributor/farmer, and producer must each keep a copy of the VFD. Identiﬁcation or electronic versions are not acceptable.
- The VFD and records of the related feed distribution must be kept for a period of three years.
- Each VFD includes a speciﬁc expiration date. Any VFD that remains 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.
- The take-home summary for producers: Talk with your veterinarian about using antibiotics that fall under the new VFD requirement. Most antibiotics labeled for use in swine will be affected by the VFD rules; however, a few compounds of interest will not be affected. These include bacitracin, tylosin, lomonomycin, and tilmicosin. For a list of products that are affected, go to www.pork.org/antibiotics.
Ongoing Expert Input

- Director, Producer and Public Health
- Producer, Public Health and Workplace Safety Committee
- Topical working groups (PQA, Antibiotics, Food Attribution, others)
- Blue Ribbon Panel of third-party animal and human health experts, along with consumer marketing experts
Producer Antibiotic Resource Center

• Antibiotic Resource Center located at: www.pork.org/antibiotics
  – All resources
  – FAQs
  – Additional clarifications from FDA
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 (Rx) rules
- Strengthen your vet-client-patient relationship (VCPR)
- 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 for more information.

Pork Checkoff Service Center 1.800.456.7675

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NEW ANTIBIOTICS RULES
2017
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Visit pork.org/antibiotics for more information.

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Print / Digital Media Investment

• Key Publications:
  – *Pork Network* (total circulation: 35,000)
  – *National Hog Farmer* (total circulation: 18,000)
  – *Feedstuffs* (print circulation: 12,596)
  – Penton Regional Publications (total circulation: 229,348)
    • *Prairie Farmer* (IL), *Prairie Farmer* (IN), *Wallaces Farmer* (IA), *The Farmer* (MN), *Ohio Farmer*

• Digital Placements:
  – PORK Daily E-news, PorkNetwork.com, NHF E-news, NationalHogFarmer.com
Producer Awareness

- 4-Page Fact Sheet
- 10-Panel Pocket Brochure
- 12-Page Pork Industry Guide for Responsible Use of Antibiotics (as supplement to PQA Plus®)

Public Health Producer Guide

Antibiotics on the Farm: What You Need to Know about New Regulations

Overview

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. The agency’s effort is aimed at eliminating the use of medically important (to human health) antibiotics for growth promotion purposes in food-animal production and bringing therapeutic use in feed and water – i.e., treat, control or prevent specific disease – under additional veterinary oversight. Producers, veterinarians, feed mills and suppliers, will all face new requirements.

FDA’s New Regulations Defined

All sectors of animal agriculture, from drug companies to producers and veterinarians to feed mills, are collaboerating to implement the new FDA antibiotic regulations.

Guidance 2015: In 2015, FDA outlined its intent and recommendations regarding growth-promotional uses of medically important antibiotics in food animal production. FDA also specified that veterinary oversight will increase for the

Basics of On-Farm VFD Compliance for Producers

The biggest change for pork producers, veterinarians and feed mills will be the updated Veterinary Feed Directive (VFD) process.

For example, only those products registered a VFD and all are labeled for revine use. While the current VFD regulation may offer some difficulty with the compliance process, the new VFD rule will require some additional time and effort on the part of producers and their veterinarians. Here are some key steps required to comply:

The prescribing 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.

Each VFD includes a specific expiration date. Any VFD feed containing active on-farm 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.

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.

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Remember “USCARE” this Year

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

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Message delivery throughout 2016

• Continue with regular Checkoff delivery methods
  – Checkoff Report (Magazine and Newsletter issues), pork.org

• Additional antibiotic focus with new Pork Industry Guide for Responsible Use of Antibiotics

• Visit pork.org/antibiotics for more information.
Breeds/ Show Pigs/ Youth Awareness

- Ad placements in the National Swine Registry’s Seedstock Edge
- Seedstock Edge Industry Insights column each month
- National Junior Swine Association (NJSA) World Pork Expo and Summer Spectacular Exhibitor Program ads
- Social media content will be provided to youth associations (NJSA and Team Purebred)
- Considering placements in Breeders Digest (publication for Berkshire, Chester, Poland and Spot associations)
2016 State Tradeshows/Meetings

• See the Countdown to 2017 at 30 State Tradeshows and/or Annual Meetings.
Antibiotics-Related Promotional Items

DON'T WAIT... BE READY!
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Visit pork.org/antibiotics for more information.
Summary

1. “Be Ready” for the new antibiotic changes.
2. Implement USCARE for success.
3. To stay informed on the VFD and related regulations. Visit pork.org/antibiotics for the latest information and resources about antibiotics throughout 2016.
For specific questions, please contact Dr. Jennifer Koeman
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