The U.S. pork industry has a proud tradition of producing safe and nutritious pork for consumers the world over. That tradition includes addressing issues arising from the use of animal health products, including antibiotics. In 1989, the Pork Quality Assurance™ (PQA™) program was launched as a way to provide producers with the education needed to fulfill their commitment to producing safe wholesome pork. Today, the vast majority of pigs that go to market come from producers who have been educated through the PQA program.

The Pork Checkoff’s Take Care – Use Antibiotics Responsibly™ program takes our commitment to the next level by encouraging producers and their veterinarians to follow specific principles and guidelines to minimize the risk of antibiotic resistance.

Physicians and their patients and veterinarians and their clients share responsibility to use antibiotics properly. Whether antibiotics are used for treatment, prevention, or nutritional efficiency, pork producers and their veterinarians should carefully consider the issue of antimicrobial resistance and the potential impact for their particular situations. The Pork Quality Assurance program is one example of the proactive approach producers take to enable the production of a safe, quality product. Today, producers can use the Take Care – Use Antibiotics Responsibly program to assist in the discussion with their veterinarian to help make the right decisions on antibiotic use.

Producers, veterinarians, and other food chain participants share the concerns regarding the use of antibiotics as tools utilized in the production of our food supply. The responsible use of these products is beneficial both for the health and welfare of the animal and for food safety and human health. It is important to use antibiotics responsibly to minimize the development of antibiotic resistance, preserve their effectiveness and to maintain availability of these products. Antibiotics, and other animal health products, while important tools for good animal health management, are only one component in a comprehensive herd health program. Antibiotics should not be used to replace good management, but rather as a supplement to management when appropriate.

Putting these guidelines into practice in all pork production operations is essential to preserving public and animal health, maintaining public trust, production of a safe, quality product, and the timely, cost-efficient availability of effective animal health products.
Pork producers use antibiotics for three purposes: treatment of illness, prevention of disease, and to improve the nutritional efficiency of their animals.

**Treatment of Illness** – The use of antibiotics in animals to combat a clinical illness. Antibiotics used for treatment are delivered by injection, in feed or in water.

**Prevention of Disease** – The use of antibiotics in animals that have been, or are being, exposed to a bacterial infection, or are in operations that have historically experienced clinical outbreaks of disease at certain production stages. Antibiotics for prevention are typically delivered in feed or water.

**Improve Nutritional Efficiency** – Antibiotics used to enhance the efficiency of pigs in converting feed. Antibiotics used to enhance nutritional efficiency are typically delivered in the feed.

There has been an ongoing effort in agriculture and in veterinary and human medicine to address antibiotic resistance. Specifically related to pork production, the American Association of Swine Veterinarians (AASV) and the National Pork Board have issued position statements on the use of antibiotics in pork production. These statements are found in Appendix 1. Information about antibiotic use is also found in the Pork Quality Assurance (PQA) program.

**Prevention of Disease:** Response may be greater in younger animals.
- Using antibiotics in nursery age pigs at levels that promote nutritional efficiency and growth has been clinically shown to improve health.
- Using antibiotics in the finisher at levels that promote nutritional efficiency and growth may prevent disease on specific farms depending on the pathogens present.
The following section will provide guidelines and instructions for the Responsible Use of Antibiotics.

**Take Care Responsible Use Principles.**

The basis for using antibiotics responsibly during pork production involves evaluating their use to protect animal health, optimize effectiveness, and minimize the risk of developing antibiotic resistance, thereby protecting public health.

The National Pork Board has developed the following five principles to help producers use antibiotics responsibly.

1. Take appropriate steps to decrease the need for the application of antibiotics.
2. Assess the advantages and disadvantages of all uses of antibiotics.
3. Use antibiotics only when they provide measurable benefits.
4. Complete the Pork Quality Assurance program and fully implement the management practices described for responsible use of animal health products into daily operations.
5. Follow the Take Care Responsible Use Guidelines.
Take appropriate steps to decrease the need for the application of antibiotics.

A. Using preventive strategies, such as implementing biosecurity programs, appropriate animal husbandry, hygiene, routine health monitoring, and vaccination programs, can help decrease the need for antibiotics.

- A comprehensive herd health plan is key to maintaining animal health and productivity. Maintaining a healthy herd will minimize the need for antibiotic use. This includes talking with your veterinarian about the health status of your herd – how it can be improved and how it can be protected.

- Consult with your veterinarian and other professionals to establish a herd health plan that includes:
  1. Monitoring herd health.
  2. Establishing preventive measures to protect the health of your herd.
  3. Establishing genetic, nutritional, and environmental programs.

You should work with your veterinarian to protect the health of your herd. Include an analysis of your vaccination program, your biosecurity protocols, your hygiene practices, your pig flow, and other animal husbandry practices. Review all your medication uses regularly to determine if they continue to be needed. Other professionals should be consulted, as needed, to review your genetics, nutritional, and environmental programs.
Assess the advantages and disadvantages of all uses of antibiotics.

Producers should consider the advantages and disadvantages of all uses of antibiotics, including animal health, welfare, environmental, food safety and economic impact. Analysis of risks should include consideration of the potential for development of resistant bacteria that may impact animal and/or human health and consideration of consumer confidence and the public image of the pork industry.

A. Other management options should be considered prior to, or concurrent with, utilizing antibiotic therapy.

- Supportive care could include management changes in ventilation or housing, or the administration of antipyretics such as aspirin or other anti-inflammatory medications.
- Examples might include acidification of feed or water or electrolyte therapy.

Antibiotic treatment may not always be the most effective strategy. Consider management options that could be as, or more, effective than antibiotics. Medication should not always be the first option in addressing a health problem. When antibiotics are needed, remember that management changes and other supportive therapies may increase the effectiveness of the treatment plan.

B. Antibiotic use should be minimized by treating only for as long as needed for the desired clinical response.

- Antibiotic use involves both dose (amount and frequency) and duration (length of treatment).
- Label instructions can provide valuable guidance on the optimum dose and duration of treatment. It is illegal to deviate from the label when using antibiotics in the feed.
- Use of antibiotics in chronic, non-responsive cases may not be effective.
- Withdrawal times must always be considered during the selection of antibiotics. Compare the withdrawal time with the anticipated date for marketing.

Work with your veterinarian to put together protocols for all uses of antibiotics. Make sure that you follow label recommendations for withdrawal times.
C. Periodically assess the need for continuing preventive antibiotic therapy. 

Formally review all uses of antibiotics on a regular basis with your herd veterinarian. Assess if there are other management changes you can make to reduce the need to use antibiotics. Is the condition that was initially diagnosed, and that required antibiotic treatment, still present? Don’t let antibiotic use become so routine that it is continued when it is no longer needed.

D. Consider the other impacts, in addition to animal health, of using antibiotics.

- According to the report of the World Health Organization’s meeting, The Medical Impact of the Use of Antimicrobials in Food Animals, the use of antibiotics to improve nutritional efficiency results in reduced waste product output.

Swine manure provides valuable nutrients for crop production. Consider if you have appropriate land area to utilize the manure produced by your operation and if there is a benefit in reducing the amount of manure produced.
A. Assess the measurable benefits of all uses of antibiotics.

- Reduced mortality, morbidity and improved animal welfare are measurable benefits that can result from the treatment and prevention of disease.
- The measurable benefit from increased nutritional efficiency can be reduced days to market, better feed utilization and a reduction in animal waste.
- Producers should evaluate these benefits on their farms to ensure there are measurable benefits from using antibiotics.
- The Food and Drug Administration (FDA) approves products based on their safety (human, animal, and environmental) and efficacy. The agency considers the risk to public health from foodborne antibiotic resistant bacteria. (See Appendix 2.)
- The FDA does not consider economic benefit in the approval decision. Producers have to assess potential economic benefits for their operation when deciding on product use.
- Producers may have the option of supplying markets that require certain protocols for antibiotic use based on marketing decisions. Producers should consider pig welfare, management implications and economic impact of adopting those specified production practices when choosing if they will participate in that market.

B. Assessing the measurable benefits of antibiotic use for nutritional efficiency should be based on scientific data.

- Data published in scientific journals, university publications, and clinical trials are examples of science-based data that could be used in making the decision about using antibiotics to enhance nutritional efficiency. Properly designed on-farm trials can provide science-based data to determine measurable benefits of antibiotic use.

Work with your veterinarian or nutritional advisor to help you design scientifically valid on-farm trials. Improperly designed trials will not provide you reliable information you can use to make decisions. If your herd health or management changes, you should reevaluate antibiotic uses to determine if there is still a measurable benefit. Review those uses regularly with your veterinarian and nutritionist.
Complete the Pork Quality Assurance Program & fully implement into daily operations the Good Production Practices described for responsible use of animal health products.

A. Complete the Pork Quality Assurance program and fully implement the Good Production Practices.

PQA is recognized as the industry’s commitment to the production of safe and wholesome pork. Implementation of the PQA Good Production Practices is an important step toward meeting the Take Care Responsible Use Guidelines. Implementation of PQA Good Production Practices will also help you ensure that there are no violative drug residues in the animals you deliver to the packing plant. The issue of drug residues is separate from, and not related to, antibiotic resistance.

B. Accurate records of treatment and outcome should be used to evaluate effectiveness.

Pork producers have long been required to follow the guidelines set forth in the FDA’s published Compliance Policy Guide (CPG) 7125.37 (Proper Drug Use and Residue Avoidance by Non-veterinarians):

- Use treatment records as described in the PQA program.
- Accurate animal or group identification must be employed within a production system for evaluation of your herd health plan and for residue avoidance.

Make sure to keep written records of all medication uses. Whether the drug is used according to the label or in an extra-label manner; or it is a Veterinary Feed Directive (VFD) product, the written records should include identification of the animals, the drug, its route of administration and dosage, the withdrawal time, and the name of the veterinarian prescribing the drug.

Maintain Medication and Treatment Records (Medication and treatment records are covered in the PQA program Good Production Practice #2)

Written records are essential for verifying that you are using antibiotics wisely. In this instance, the job isn’t done until it is written down. Protect yourself, public health, your industry, and the confidence consumers and government agencies have in your ability by keeping a written record of every antibiotic use on your farm.
Follow the Take Care Responsible Use Guidelines.

**Guideline A.** Use professional veterinary input as the basis for all medication decision-making.

- Responsible use of antibiotics, when under the direction of a veterinarian, should meet all requirements of a veterinarian/client/patient relationship.
- Prescription, VFD, and the use of antibiotics in a manner other than what is on the label (extra-label drug use) must meet all the requirements of a veterinarian-client-patient relationship.
- The law prohibits extra-label use of antibiotics in the feed, even by a veterinarian.

*Even though it is legal to obtain and use some veterinary antibiotics “over-the-counter” (OTC), pork producers must protect public health and consumer confidence through responsible use. Also, although a product may be available OTC, any change to its labeled use—dosage, interval, condition being treated, age or class or animal treated, etc.—can only occur under the direction of the veterinarian for your operation. Doing otherwise is illegal even though the medication is available OTC. Getting the advice of the veterinarian before purchasing and using OTC products will meet these obligations, save you money because antibiotic use, expense, and time won’t be wasted. Following these steps will help you comply with the Take Care Responsible Use Principles.*

Using a Veterinarian/Client/Patient Relationship (VCPR) as the Basis for Medication Decision Making is addressed in the PQA program as Good Production Practice #4

Refer to the glossary for the definition of a VCPR and remember that a VCPR includes:

1. Medical decisions about your animals should be made by you and your veterinarian.
2. You implement those decisions as agreed.
3. The veterinarian must visit your facilities regularly enough to have sufficient knowledge of your animals and their keeping and care.
4. The veterinarian must be readily available for follow-up treatment/consultation.
• Extra-label antibiotic therapy must be used only in accordance with the Animal Medicinal Drug Use Clarification Act (AMDUCA) and the Food, Drug, and Cosmetic Act and their regulations. (See Appendix 3)
  • The following drugs are **expressly prohibited for extra-label use** in food animals: chloramphenicol, clenbuterol, diethylstilbestrol, dimetridazole, ipronidazole, other nitroimidazoles, furazolidone, nitrofurazone, sulfonamide drugs in lactating dairy cows (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxypyridazine), fluoroquinolones, glycopeptides (e.g., vancomycin), and phenylbutazone in female dairy cattle 20 months of age or older.

*Before a drug is used in a manner not in accordance with the approved drug labeling (change in dosage, frequency or route of administration, duration of treatment, disease or condition treated, age, class or animal species), a veterinarian MUST be involved. Work with your veterinarian to make sure that all extra-label drug use meets the requirements of the AMDUCA regulation.*

• Veterinarians and producers should use the latest information on animal health care products to optimize the course of antibiotic therapy.

*Important information is included on the label and in the package insert that comes with the antibiotic. If there is any question about the appropriate regimen (dosage, directions for use, frequency, route of administration, cautions and withdrawal times if necessary), ask your veterinarian.*

**Guideline B.** Antibiotics should be used for treatment only when there is an appropriate clinical diagnosis.

• Diagnosis is supported by clinical signs, necropsy, laboratory tests, herd history, etc.
• An accurate diagnosis includes identification of factors contributing to the cause of the disease.
• Culture and sensitivity results can aid in the selection of antibiotics.
Insist on an accurate diagnosis, including culture and sensitivity results. This will save you money by saving time in treatment and by establishing a pattern of bacterial susceptibility on your farm. Look for other management factors such as ventilation, pig flow, etc, that may be contributing to disease.

**Guideline C.** Limit antibiotic treatment to ill or at-risk animals, treating the fewest animals indicated.
- Consider group morbidity and mortality rates when deciding whether or not to initiate herd, group, or individual therapy.
- Consider the herd health history when selecting antibiotics.
- When the above factors are appropriately considered, prevention of disease in at-risk animals is a responsible use of antibiotics.

*There are times when using antibiotics to prevent disease will ultimately mean less antibiotics will be used than if treating the same group of animals following an outbreak. Responsible use of antibiotics during treatment includes using antibiotics only when necessary, to the smallest number of animals feasible, and for the least amount of time necessary to prevent reoccurrence of the disease.*

**Guideline D.** Antibiotics that are important in treating antibiotic resistant infections in human or veterinary medicine should be used in animals only after careful review and reasonable justification.
- Culture and sensitivity results should be considered when selecting antibiotics used for treatment.
- Discuss product options with your veterinarian to select the most appropriate therapy for your specific situation.

*Ask your veterinarian which antibiotics are recommended for any disease condition on your farm, and how they could impact antibiotic resistance on your farm and in human health. Work with your veterinarian to consider product choices and develop treatment protocols to minimize development of resistance or cross-resistance. Have a written action plan for antibiotic use and review it regularly with your veterinarian.*
Guideline E. Mixing together injectable or water medications, including antibiotics, by producers is illegal. As an example, it is illegal to mix an antibiotic and iron together on the farm for use while processing piglets. Certain FDA-approved commercially available feed administered medications may be legally mixed on-farm by the producer. If a combination is not approved by FDA, then it should be considered illegal. (Information about these combinations is available from your veterinarian, your nutritional advisor or the Feed Additive Compendium through www.feedstuffs.com.)

Some products are not compatible when administered or mixed with others. This can affect the products’ efficacy, the withdrawal time prior to market, and/or cause animal welfare concerns from product reactions and muscle scarring. You should never combine medications in the same syringe or in the drinking water. However, veterinarians may legally mix some drugs under certain circumstances in the course of their practice. This is a form of extra-label drug use called “compounding” that is only legal when specific FDA regulations are followed. Remember, it is illegal for anyone, even a veterinarian, to mix or use feed medications other than according to labeled directions.

Guideline F. Minimize environmental exposure through proper handling and disposal of all animal health products, including antibiotics. Water medicators and feeders need to be properly adjusted to deliver the desired dose and avoid spillage and waste. Ensure proper handling and disposal of any outdated or unused animal health products through communication and employee training.

American Association of Swine Veterinarians
Position statements

(AASV) Position Statement on Judicious Use of Therapeutic Antimicrobials Approved 1999

“When a condition exists that threatens or impairs animal health and well being, it is essential that an accurate clinical diagnosis be obtained. Appropriate diagnostic techniques and clinical experience should substantiate a presumptive diagnosis. Once the decision is reached to use antimicrobials for therapy, veterinarians strive to optimize therapeutic efficacy, minimize resistance to antimicrobials, and protect public and animal health.

“The American Association of Swine Veterinarians supports and is committed to the following objectives as developed by the American Veterinary Medical Association’s Steering Committee on Judicious Therapeutic Antimicrobial Use:

- Support development of a scientific knowledge base that provides the basis for judicious therapeutic antimicrobials use.
- Support educational efforts that promote judicious therapeutic antimicrobials use.
- Preserve therapeutic efficacy of antimicrobials.
- Ensure current and future availability of veterinary antimicrobials.”

National Pork Board Position on Antimicrobial Use in Pork Production Issued July 2002

National Pork Board Background Statements:

- To preserve the availability and effectiveness of antimicrobials, a coordinated and appropriate response to the issue of antimicrobial resistance is necessary.
- Producers and their veterinarians must have the flexibility to responsibly address animal health and production in a timely, cost-effective manner.
- Producers continue in their science-based commitment to ensure the safety of pork and to maintain consumer confidence.
- The National Pork Board and the nation’s pork producers are supportive of educational efforts to ensure that antimicrobial use does not compromise food safety.
• The National Pork Board supports a rigorous U.S. Food and Drug Administration process that reviews the scientific data, that evaluates product safety and efficacy and that approves antimicrobials for use in animals.

• If, based on sound science, additional oversight of antimicrobial use and distribution is necessary, stakeholders should discuss the best implementation strategies to achieve the desired result.

• The National Pork Board supports the development of effective and affordable alternatives to the use of antimicrobials for enhancing production. It has charged its Non-Antimicrobial Production Enhancement Working Group to review the knowledge with regard to the efficacy and economy of the use of non-antimicrobial alternatives to enhance production, to identify the confounding variables that must be controlled to scientifically evaluate the success of these products and/or management techniques, to recommend a research agenda to address knowledge gaps, and to develop a plan of action to educate pork producers about these products and/or management techniques.

**National Pork Board Position:**

It is essential to public health and food safety, animal health and well-being, and the environment to maintain the effectiveness and availability of antimicrobials. All decisions affecting the availability of antimicrobials for animal use need to be transparent and based on sound science.

The National Pork Board supports the use of antimicrobials only when they provide demonstrable benefits and urges producers to:

• Take appropriate steps to decrease the need for their application.
• Adhere to responsible use guidelines.
• Assess the benefits and costs of all uses of antimicrobials.
• Complete the Pork Quality Assurance program and fully implement the management practices described for responsible use of animal health products into their daily operations.
Antibiotics for use in animals are regulated by the FDA’s Center for Veterinary Medicine (CVM). They undergo a rigorous approval process to determine human, animal and environmental safety as well as efficacy. In October 2003 CVM released the document *Guidance for Industry: Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern* (Guidance #152). This document provides an outline for a qualitative risk assessment on antibiotics used in animals and also includes risk management strategies.

- Prior to approval, the CVM requires a drug sponsor to provide a risk assessment as outlined in Guidance #152 so that appropriate risk management actions are applied. Existing products will be reviewed by priority of their importance to human health.
- Guidance #152 provides a list of classes of antibiotics that FDA considers critically important to human health. These drugs are considered critically important to human health if they are used to treat foodborne infections AND they are the sole therapy or one of few alternatives to treat serious human diseases. The FDA has said that with additional information, they may change the current categorization of these and other antibiotics.
- Risk management strategies outlined in Guidance #152 include restricting antibiotic use to individual animal only dosing, availability of the antibiotic by prescription only, and prohibiting extra-label use of the antibiotic.
- FDA has listed the following four classes of drugs as critically important to human health:
  - fluoroquinolones,
  - macrolides,
  - 3rd generation cephalosporins and
  - trimethoprim/sulfa.

Ask your veterinarian if any of the antibiotics you use are in these categories, or if their use could select for bacteria resistant to antibiotics in these categories.
A. The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) allows veterinarians to prescribe extra-label uses of certain approved animal drugs and approved human drugs for animals under certain conditions (see algorithm on page 20).

- Extra-label use refers to the use of an approved drug in a manner that is not in accordance with the approved label directions. The key constraints of AMDUCA are that any extra-label use must be by, or on the order of, a veterinarian within the context of a veterinarian/client/patient relationship, must not result in violative residues in food-producing animals, and the use must be in conformance with the implementing regulations published at 21 CFR Part 530.

- The complete rule can be accessed at http://www.fda.gov/cvm/index/amducca/530.pdf.

- The following activities are illegal under the AMDUCA regulations:
  - Extra-label use of animal or human drugs by a lay person, except when under the supervision of a licensed veterinarian.
  - Extra-label use of animal or human drugs in animal feed.
  - Extra-label use of animal or human drugs for production, not therapeutic reasons.
  - Extra-label use resulting in any residue which may present a risk to public health.
  - Extra-label use resulting in any residue above an established safe level, concentration or tolerance.

B. Compounding is a form of extra-label drug use that allows the mixing of certain drugs.

The American Veterinary Medical Association’s Statement on Compounding states: “The use of a compounded drug may result in drug concentrations that lead to the development of an adverse drug event, including therapeutic failure. In order to minimize the risk of adverse events associated with compounded drugs, the following actions are recommended:

1. The decision to use a compounded drug should be veterinarian (not pharmacy) driven, based on a valid veterinarian/client/patient relationship.
2. Compounding must be implemented in compliance with the Animal Medicinal Drug Use Clarification Act (AMDUCA) and the FDA Compliance Policy Guide 608.400 titled Compounding of Drugs for Use in Animals. Use of compounded drugs in food animals is accompanied by food safety concerns that preclude their use unless information exists to ensure avoidance of illegal tissue residues.

3. Use of a compounded drug should be limited to:
   - Those drugs for which both safety and efficacy have been demonstrated in the compounded form in the target species;
   - Disease conditions for which response to therapy or drug concentration can be monitored; or
   - Those individual patients for which no other method or route of drug delivery is practical.

4. Use of a compounded drug should be accompanied by the same precautions followed when using a drug in its original form, including counseling of the client regarding potential adverse reactions and attention to the potential for unintended human or animal exposure to the drug."

*Work with your veterinarian to make sure that any drugs used in an extra-label manner are used according to regulation. Be especially careful to discuss appropriate withdrawal times to avoid any violative residues that could occur due to this use.*
EXTRA-LABEL DRUG USE ALGORITHM FOR VETERINARIANS

This algorithm was developed for veterinarian use to determine whether it is legal to use a drug in an extra-label manner. In it, the use of “you” refers to the veterinarian.

You made a careful diagnosis in the presence of a valid Veterinarian/Client/Relationship. You are contemplating Extralabel drug use. Are the animals to be treated food animals?

YES

Does a drug labeled for food animals exist which fulfills all of the following:
• Contains the needed ingredient,
• In the proper dosage form,
• Labeled for the indication,
• And is clinically effective?

YES

You must use this drug per label, as Extralabel drug use is unnecessary. Observe label directions & withdrawal time.

NO

Is there a drug approved for food animals which could be used Extralabelly?

YES


NO

Is there a human drug or drug approved for non-food animals which could be used Extralabelly?

YES

Is there adequate scientific information available to determine a withdrawal time?

NO

If compounding of approved drugs will prevent animal pain and suffering, refer to CPG 608.400 for compounding guidance.*

YES


NO

Drug must not be used, or treated animal must not enter food supply.

*Compounding of bulk drugs is generally illegal.
A drug labeled for food animals exists which fulfills all of the following:
• Contains the needed ingredient,
• In the proper dosage form,
• Labeled for the indication,
• And is clinically effective?

Yes

You must use this drug per label, as Extralabel drug use is unnecessary.

No

Is there a drug approved for food animals which could be used Extralabelly?

Yes


No

Is there a human drug or drug approved for non-food animals which could be used Extralabelly?

Yes

Is there adequate scientific information available to determine a withdrawal time?

No

If compounding of approved drugs will prevent animal pain and suffering, refer to CPG 608.400 for compounding guidance.*

Yes


No

Drug must not be used, or treated animal must not enter food supply.

Drugs Prohibited for Extralabel Use in Food Animals
(Current as of June 1, 2003. Check for updates on the FDA web site at www.fda.gov/cvm)

Chloramphenicol
Clenbuterol
Diethylstilbestrol (DES)
Dimetridazole
Ipronidazole
Other Nitroimidazoles
Furazolidone, nitrofurazone, other nitrofurans
Sulfonamide drugs in lactating dairy cows (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxypyridazine)
Fluoroquinolones
Glycopeptides (example: vancomycin)
Phenylbutazone in female dairy cattle 20 months of age or older

*Compounding of bulk drugs is generally illegal

Graphic courtesy of the American Veterinary Medical Association
These terms are important for a thorough understanding of how to use antibiotics responsibly. If you are not familiar with them or if you have any questions, ask your veterinarian. He/she is the appropriate source of information about all uses of antibiotics in your operation.

**Antibiotic** – a chemical substance produced by a microorganism which has the capacity to inhibit the growth of or to kill other microorganisms.

**Antimicrobial** – an agent that kills bacteria or suppresses their multiplication or growth. This includes antibiotics and synthetic agents. This excludes ionophores and arsenicals.

**Narrow Spectrum Antimicrobial** – an antimicrobial effective against a limited number of bacterial genera; often applied to an antimicrobial active against either Gram-positive or Gram-negative bacteria.

**Broad Spectrum Antimicrobial** – an antimicrobial effective against a large number of bacterial genera; generally describes antibiotics effective against both Gram-positive and Gram-negative bacteria.

**NOTE:** For the purpose of this document the term “Antibiotic” has been used to signify both antibiotic and antimicrobial agents.

**Antibiotic Resistance** – a property of bacteria that confers the capacity to inactivate or exclude antibiotics or a mechanism that blocks the inhibitory or killing effects of antibiotics.

**Compounding** – mixing of two or more drugs together, reformulation of drugs to make a new dosage form, or formulation of a drug into a novel delivery system. It is illegal for producers to compound drugs. Veterinarians have the option to compound certain drugs from approved products, and under no circumstances are allowed to compound drugs from bulk products. The FDA regulates compounding and has issued Compliance Policy Guide 608.400 titled *Compounding of Drugs for Use in Animals* to provide guidelines for legal compounding.

**Environmental Impact** – includes not only proper handling and disposal, but careful consideration of the impact of antibiotic use on manure management. Enhancing nutritional efficiency through the appropriate use of antibiotics reduces the total amount of feed consumed and manure produced. This can limit the potential environmental impacts related to manure management.

**Extra-label** – actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. This includes, but is not limited to, use in species not listed in the labeling, use for indications (disease or other conditions) not listed in the labeling, use at dosage levels,
frequencies, or routes of administration other than those stated in the labeling, and deviation from the labeled withdrawal time based on these different uses.

**Immunization** – the process of rendering a subject immune or of becoming immune, either by conventional vaccination or exposure.

**Monitoring** – includes periodic health surveillance of the population or individual animal examination.

**Nutritional efficiency** – using antibiotics to increase the ability of pigs in converting feed to meat. Using antibiotics at levels that promote nutritional efficiency and growth has been shown to prevent disease in nursery pigs and may prevent disease in finisher pigs on specific farms. Increasing nutritional efficiency also reduces the total amount of feed consumed and manure produced which can reduce the potential environmental impacts of manure management.

**Therapeutic** – treatment, control, and prevention of bacterial disease.

**Veterinarian/Client/Patient Relationship (VCPR)** – A VCPR exists when all of the following conditions have been met:

1. The veterinarian has assumed the responsibility for making clinical judgments regarding the health of the animal(s) and the need for medical treatment, and the client has agreed to follow the veterinarian’s instructions.

2. The veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of an examination of the animal(s) or by medically appropriate and timely visits to the premises where the animal(s) is(are) kept.

3. The veterinarian is readily available for follow-up evaluation, or has arranged for emergency coverage, in the event of adverse reactions or failure of the treatment regimen.

**Veterinary Feed Directive (VFD) Drug** – a category of medicated feeds created by the Animal Drug Availability Act of 1996 to provide an alternative to prescription status for certain animal drugs for use in feed. Any animal feed bearing or containing a VFD drug shall be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian in the course of the veterinarian’s professional practice.