



ANTIBIOTIC STEWARDSHIP FOR BEEF PRODUCERS



**A SAFE, WHOLESOME AND
HEALTHY BEEF SUPPLY**

A Beef Producers Guide for Judicious Use of Antibiotics in Cattle

1. **Prevent Problems:** Emphasize appropriate husbandry and hygiene, routine health examinations, and vaccinations.
2. **Select and Use Antibiotics Carefully:** Consult with your veterinarian on the selection and use of antibiotics. Have a valid reason to use an antibiotic. Therapeutic alternatives should be considered prior to using antimicrobial therapy.
3. **Avoid Using Antibiotics Important In Human Medicine As First Line Therapy:** Avoid using as the first antibiotic those medications that are important to treating strategic human or animal infections.
4. **Use the Laboratory to Help You Select Antibiotics:** Cultures and susceptibility test results should be used to aid in the selection of antibiotics, whenever possible.
5. **Combination Antibiotic Therapy Is Discouraged Unless There Is Clear Evidence The Specific Practice Is Beneficial:** select and dose an antibiotic to affect a cure.
6. **Avoid Inappropriate Antibiotic Use:** Confine therapeutic antibiotic use to proven clinical indications, avoiding inappropriate uses such as for viral infections without bacterial complication.
7. **Treatment Programs Should Reflect Best Use Principles:** Regimens for therapeutic antimicrobial use should be optimized using current pharmacological information and principles.
8. **Treat the Fewest Number of Animals Possible:** Limit antibiotic use to sick or at risk animals.
9. **Treat for the Recommended Time Period:** To minimize the potential for bacteria to become resistant to antimicrobials.
10. **Avoid Environmental Contamination with Antibiotics:** Steps should be taken to minimize antimicrobials reaching the environment through spillage, contaminated ground run off or aerosolization.
11. **Keep Records of Antibiotic Use:** Accurate records of treatment and outcome should be used to evaluate therapeutic regimens and always follow proper withdrawal times.
12. **Follow Label Directions:** Follow label instructions and never use antibiotics other than as labeled without a valid veterinary prescription.
13. **Extralabel Antibiotic Use Must follow FDA Regulations:** Prescriptions, including extra label use of medications must meet the Animal Medicinal Drug Use Clarification Act (AMDUCA) amendments to the Food, Drug, and Cosmetic Act and its regulations. This includes having a valid Veterinary-Client-Relationship.
14. **Subtherapeutic Antibiotic Use Is Discouraged:** Antibiotic use should be limited to prevent or control disease and should not be used if the principle intent is to improve performance.

Guidelines 1-13 adapted from AVMA, AABP and AVC Appropriate Veterinary Antibiotic Use

Beef cattle producers take pride in their responsibility to provide proper care to cattle.

The Code of Cattle Care below lists general recommendations for care and handling of cattle:

- Provide necessary food, water and care to protect the health and well-being of animals.
- Provide disease prevention practices to protect herd health, including access to veterinary medical care.
- Provide facilities that allow safe, humane, and efficient movement and/or restraint of cattle.
- Provide personnel with training/experience to properly handle and care for cattle.
- Make timely observations of cattle to ensure basic needs are being met.
- Minimize stress when transporting cattle.
- Keep updated on advancements and changes in the industry to make decisions based upon sound production practices and consideration for animal well-being.
- Persons who willfully mistreat animals will not be tolerated.

INTRODUCTION

The Beef Quality Assurance program is rooted in a cattleman's belief of doing the right thing. The judicious use of antibiotic technologies is no exception to the goal of producing high quality, wholesome, and healthy beef. BQA guidelines are designed to make certain all beef consumers can take pride in what they purchase – and can trust and have confidence in the entire beef industry.

BQA programs have evolved to include best practices around good record-keeping, and protecting herd health. Antibiotic stewardship has been a commonsense practice adopted by beef producers since before the start of the BQA program.

Responsible antibiotic use is important to ensure that animal health technologies remain viable for the beef industry. It is key that judicious use protocols are developed so that animals are never marketed with residues and that cattlemen responsibly treat sick cattle. Marketing beef with antibiotic residues, even unintentionally, is illegal and can result in significant consequences, both legally and financially.

The judicious use of antibiotics not only results in more profits for producers, but increases consumer confidence. When healthy cattle leave the farm and reach the marketplace, the producer, packer, and consumer all benefit.

When better quality beef reaches the supermarket, consumers are more confident in the beef they are buying, and this increases beef consumption.



RESIDUE

A residue refers to the presence of veterinary drugs or pesticides in meat. These residues are usually measured in parts per million or parts per billion. The overwhelming majority of meat products contain no residues or residues within the government prescribed tolerance levels. Veterinary drug tolerances are established by the U.S. Food & Drug Administration (FDA) under the Federal Food, Drug and Cosmetic Act. Environmental Protection Agency (EPA) establishes tolerances for registered pesticides under the Food Quality Protection Act.

The FDA approves veterinary drugs and the specific dosage rates to treat specific diseases or conditions. Farmers, ranchers and veterinarians are required by law to follow the FDA-approved label to administer the drug appropriately and correctly. Animal health companies must prove that their veterinary drugs are safe and effective for the intended animal patient, much like the drug approval process for human antibiotics. If the intended patient is a food-producing animal, there is an additional requirement to prove that the use of the antibiotic does not present a risk to human health.

The prevention of illegal antibiotic residues is a continuous, coordinated effort between government agencies, veterinarians, and livestock producers that begins before the antibiotic is ever used in animals. The drug approval process, on-farm antibiotic use measures and the U.S. National Residue Program are all specifically designed to prevent animal products with illegal drug residues from entering the food supply.



The FDA also sets withdrawal times for all veterinary drugs, including antibiotics. The withdrawal period is the time between the last dose of the antibiotic and the time when the animal can be safely slaughtered for food (or, with dairy cattle, the milk can be safely consumed). Practically, the withdrawal time is the amount of time required for the drug to be reduced to a safe tolerance level; the withdrawal time depends on the drug; but typically ranges from zero to 60 days.

The final step in protecting and preventing illegal antibiotic residues from entering the food supply is surveillance testing conducted by the United States Department of Agriculture (USDA) Food Safety Inspection Service (FSIS). The agency conducts tests for chemicals—including antibiotics and various other drugs, pesticides and environmental agents—in meat, poultry, and egg products destined for human consumption. The surveillance program consists primarily of two tiers of testing: scheduled and inspector generated. Scheduled antibiotic residue testing is pre-planned to provide a large sample across different food animal industries (beef cattle, veal calves, swine, poultry, dairy, etc.) and locations. The development of scheduled sampling plans is a process that proceeds in the following manner:

- 1. Determine which compounds are of food safety concern;**
- 2. Use algorithms to rank the selected compounds;**
- 3. Pair these compounds with appropriate production classes; and**
- 4. Establish the number of samples to be collected.**

Inspector generated samples are collected from animal carcasses that show signs of previous disease or medical treatments—animals that may present an above average risk for illegal antibiotic residues. In the rare cases when an illegal drug residue is confirmed, the beef product is considered “adulterated” and is never allowed to enter the food supply. The USDA and FDA then initiate a cooperative effort to investigate the reasons for the illegal use. Depending on the severity of the residue, the intent and history of the violations, the investigation may lead to a variety of outcomes for the animal owner, from a warning letter to injunction to criminal prosecution.

The FSIS Hazard Analysis Critical Control Points (HACCP) program implemented at slaughter facilities identifies the animals most likely to have drug residues. Animals that display lameness, injection site lesions or signs of illness are targeted for testing. If there is any doubt about the potential for drug residues in an animal, they should be withheld from market.

REPEAT VIOLATORS LIST

Producers who market animals that test positive for chemical residues more than a single time will be placed on the publicly available USDA FSIS Residue Repeat Violator List.

FSIS maintains a “Repeat Residue Violator List for Use by FSIS Inspection Personnel” that contains the names and addresses of producers who have more than one meat residue violation in a 12-month period in animals presented for slaughter. Specific information about the violation can also be found in this list, including the plant where the violation was determined, the drug residues discovered, and their concentrations and tolerances. Violators listed may have had multiple violations documented in the same processing facility or separate facilities. This list is intended to aid inspectors in discovering residue tolerance violations before they reach consumers. FSIS provides a user guide that explains the information contained in the list.

FSIS also maintains a “Residue Repeat Violator List for Use by Livestock Markets and Establishments” that contains similar information intended to assist plant owners and operators in identifying residue history of livestock suppliers. This second list documents only the source name and address information of repeat violators, so that livestock marketers and buyers may use precaution when marketing and processing animals from listed suppliers.



TISSUE RISK ASSESSMENT CHECKLIST

Low Risk

- Animal history is documented, recorded and available.
- Animal never treated with drugs

OR

- Single drug administration of lactating/non -lactating animal approved drug –

AND

- Followed drug label information for dose, route of administration, duration of therapy and withholding time.

OR

- Veterinary oversight of the use of drugs in an extra-label manner.

High Risk

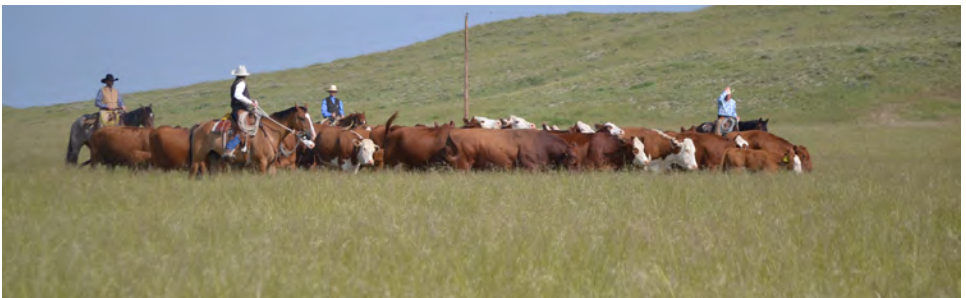
- Animal is displaying lameness, injection sites, surgical evidence or has signs of illness –

AND

Any of the below apply:

- History of animal treatment not documented or not communicated to person sending cattle to market.
- Route of administration that was used is not as prescribed on the label.
- Multiple drug administration without veterinary oversight.
- Drug not approved for animal status, e.g. lactating.
- Doses or withholding times not followed or unknown.
- Duration of therapy not followed.
- If any of the above high risk attributes exist, consult pharmaceutical, veterinary or screening test experts to determine status of animal before offered for sale –

When in doubt hold it out!





STEPS TO PREVENT A VIOLATIVE RESIDUE

- **Identify and segregate all animals treated.**
- **Record all treatments:** Date, animal ID, serial/lot number, dose given, route of administration, the person who administered the treatment and the withdrawal time.
- **Strictly follow label directions for product use.**
- **Use newer technology antibiotics when possible.**
- **Reduce unwanted depot effect.** Select low volume product when available.
- **Select generic medications and vaccines with an animal health professional.**
- **Avoid inferior products.** They may cause performance loss or damage quality.
- **Select with short withdrawal when antibiotic choice is equivalent.**
- **Never give more than 10 cc per IM injection site.**
- **Avoid Extra-Label Drug Use (ELDU) of antibiotics.**
- **Use label dose and route of administration under a valid VCPR.**
- **Avoid using multiple antibiotics at the same time.**
- **Don't mix antibiotics in the same syringe.**
- **Check ALL medication/treatment records before marketing:**
 - Don't market cattle with less than 60 withdrawal days without examining their treatment history.
 - Extend the withdrawal time if the route or location of administration is altered.
 - Extend the withdrawal time to the longest withdrawal period of all products given.
 - Extend the withdrawal for all penicillin given at doses which exceed the label dose
- **Testing urine may not detect injection site residues that will test positive by the USDA-FSIS.**
- **Never inject gentamicin or neomycin. The estimated withdrawal is more than 24 months**
- **Testing urine may not detect a kidney that will test positive by the USDA-FSIS.**
- **Don't market cattle that have relapsed without examining the treatment history.**
- **Don't market cattle with suspected liver or kidney damage without examining the treatment history.**
- **Don't market cattle with antibiotic injection site knots without examining the treatment history**

Screen the urine for antibiotics of all cattle identified in the above steps. It is best to use broad spectrum microbial inhibition test such as the Pre-Harvest Antibiotic Screening Test (PHAST), a microbial growth inhibition test which uses *B. megaterium* as the test organism. Test results should be compared to FDA-Center for Veterinary Medicine (CVM) violative residue tolerances (Maximum Residue Limit).

Food Animal Residue Avoidance Databank (FARAD)

FARAD is a national, USDA-sponsored, cooperative project, with a primary mission to prevent or mitigate illegal residues of drugs, pesticides and other chemicals in foods of animal origin. Producers should work with the veterinarian with whom they have a valid VCRP for drug residue information first. The veterinarian is the ideal resource to discuss FARAD-specific information regarding withdrawal times, especially for extra-label drug use.

FARAD provides the following services

- *Advice on residue avoidance or mitigation*
- *VetGram search for required withdrawal times for approved food animal drugs*
- *FARAD-recommended withdrawal intervals for extra-label use of approved food animal drugs*

Visit www.farad.org for more information.

CLASSIFICATION

There are three classes of animal drugs: Over-the-Counter (OTC), Prescription (Rx), and Veterinary Feed Directive (VFD). OTC drugs can be sold by any person or establishment without a veterinary prescription. Rx drugs can only be sold to the farmer by a veterinarian or pharmacist, and only with a veterinary prescription. VFD is a drug intended for use in or on feed which is limited by an approved application to use under the professional supervision of a veterinarian who is licensed in the state where the animals are being kept. It is illegal to use any VFD drugs in an extra-label manner.



REGULATIONS REGARDING ANIMAL HEALTH PRODUCTS

VCPR

The veterinarian-client-patient relationship (VCPR) is the basis for interaction among veterinarians, their clients, and their patients and is critical to cattle health and well-being. There is a federal definition for a VCPR and state definitions for VCPRs exist under the state veterinary practice acts. In reference to the VFD, FDA has identified a list of the VCPR jurisdiction for the state or federal definition at the following link: <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm460406.htm>

In general, a VCPR exists when:

- The veterinarian has assumed the responsibility for making clinical judgments regarding the health of the animal and the need for medical treatment, and the client has agreed to follow the veterinarian's instructions.
- The veterinarian has sufficient knowledge of the animal to initiate at least a general or preliminary diagnosis of the medical condition of the animal. This means the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal by virtue of an examination of the animal or the medically appropriate and timely visits to the premises where the animal is kept.
- The veterinarian is responsible for maintaining and evaluating case and treatment records, and is readily available for follow up evaluation in the event of adverse reactions or failure of the treatment regimen.





According to the American Association of Bovine Practitioners (AABP) the following areas are considered critical components for establishing and maintaining a valid VCPR:

Written Agreement

- A veterinary practice or individual should establish a written agreement with the client that identifies the farm veterinarian who is accountable for drug use and treatments administered to the cattle on the farm operation. If more than one veterinarian or veterinary practice has a working relationship on the operation, then the agreement should establish which one has the overall responsibility for treatment protocols, drug inventories, prescriptions, personnel training, oversight and drug use on the operation. The identified veterinarian is referred to as the Veterinarian of Record.

Veterinary Oversight

- The Veterinarian of Record is the responsible party for providing appropriate oversight of drug use on the farm operation. Such oversight is a critical component of establishing, maintaining and validating a VCPR. This oversight should include, but may not be limited to, establishment of treatment protocols, training of personnel, review of treatment records, monitoring drug inventories, and assuring appropriate labeling of drugs
- Veterinary oversight of drug use should include all drugs used on the farm regardless of the distribution of the drugs to the farm. Regular farm visits are an essential component to providing such oversight, however this can be supplemented through laboratory data evaluation, records evaluation, and telephonic and electronic communication. The timeliness of farm visits should be determined by the Veterinarian of Record based on the type and size of the operation.

Relationship with Consultants and other Veterinarians

- If a veterinarian who is not the Veterinarian of Record provides professional services in any type of consultative or advisory capacity, then it is incumbent on that veterinarian to ensure that the Veterinarian of Record is contacted and informed of their findings and recommendations. No protocols or procedures that have been established by the Veterinarian of Record should be changed unless or until there is an agreement by all parties about such changes. The agreement between the Veterinarian of Record and the client should establish which management groups of the farm operation are covered in the agreement. For instance, reproduction, milk quality, youngstock/replacement, feedlot, cow-calf, and sick animal treatments are possible identifiable areas.

Treatment Protocols

- Protocols and treatment guidelines for commonly occurring, easily recognizable conditions should be established in writing and agreed upon by all parties involved, signed and dated. Training of personnel authorized to use drugs on the operation should be undertaken and periodically reviewed. The frequency of such training and review should be determined by the size and type of the operation, the rate of personnel turnover, and the changes in protocols and procedures. The treatment protocols and procedures should include all drugs used on the operation (over the-counter, prescription, extra-label, Veterinary Feed Directive, water soluble). All protocols should clearly define when to quit treating and seek professional help (poor response, increase in severity of signs).

Written/Electronic Treatment Record

- Written/electronic treatment records of all animals or groups of animals treated are an essential component of maintaining and establishing the VCPR and to decrease the risk of violative drug residues. Such records should include, at a minimum, the date, identification of animal(s), drug(s) used, frequency, duration, dose, route, appropriate meat/milk withdrawal intervals, and the person administering the treatment. Periodic and timely review of the treatment records, drug inventories and usage is an important part of oversight by the Veterinarian of Record.

Prescription Drugs

- Provision of drugs or drug prescriptions should be for specific time frames appropriate to the scope and type of operation involved and only for the management groups within the operation for which the Veterinarian of Record has direct involvement and oversight. Additionally, failure to follow agreed upon protocols and procedures should be grounds for denial of provision of drugs or prescriptions except for an individual patient needing treatment at the time of examination. Routine examination of drug inventories on farm and product purchase records (pricing information is unnecessary) review are recommended. Cooperation with distributors is encouraged. Establishment of a VCPR for the sole purpose of the sale of drugs or increased sales of a particular brand of drug product is not a valid or ethical reason for having a VCPR.



VETERINARIAN/CLIENT/PATIENT RELATIONSHIP VALIDATION FORM



Producer

Product Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Farm Name and Location: _____

Section: _____ Township: _____

County: _____

Premises ID Number (optional): _____

Producer Signature: _____

Date: _____

Veterinarian

Product Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Clinic Name: _____

Phone Number: (_____) _____

I hereby certify that a valid Veterinarian/Client/Patient Relationship (VCPR) is established for the above listed owner and will remain in force until canceled by other party.

Veterinarian Signature: _____

Date: _____

Adapted from the Center for Dairy Excellence

Guidance 209 and 213

The FDA published Guidance for Industry (GFI) 213 in December 2013, establishing procedures for voluntarily phasing out growth promotion indications for medically important antibiotics in alignment with GFI 209. In GFI 209, published in April 2012, animal pharmaceutical companies will voluntarily revise the FDA-approved use conditions for these products to remove production indications.

GFI 209 limits the use of the medically important antimicrobial drugs used in feed and water for animals to these uses:

- Considered necessary for assuring animal health (therapy, prevention, and control issues) and not for feed efficiency or growth promotion.
- That include veterinary oversight or consultation.

GFI 213 defines the implementation of GFI 209 to include that by December 31, 2016 Drug Sponsors will change drug labels so production uses will be removed. With label changes, it will no longer be legal to use the medically important antibiotics in feed/water for feed efficiency uses. Therapeutic Uses (treatment, control, and prevention) will be retained. Beginning January 1, 2017 GFI 213 requires a transition to Veterinary Oversight including a prescription for water soluble products (medicated drinking water) and a Veterinary Feed Directive (VFD) for medically important antibiotics used in or on feed and requires use to be authorized by a licensed veterinarian in context of a VCPR. After implementation of GFI 209/213 on January 1, 2017, it will be necessary for all producers to have established a VCPR with a veterinarian to obtain these products.





On Farm Practices for Antibiotic Use

Needle Selection and Care

- **Needles contribute to injection site defects.** Use needles that are no larger than necessary to adequately complete the injection, but large enough to prevent needle bending or breaking off in muscle tissue. The leading cause of needle bending is improper restraint, but using dull, damaged or poor quality needles may also contribute to the problem. Under no circumstances can animals with broken needles in them be sent to a harvest facility.

Primary considerations in needle selection

- Route of administration
- Size of animal
- Location or site of injection (BQA requires all injections be given in the neck, unless directed otherwise by a veterinarian or per label instruction)

Secondary consideration in needle selection

- Viscosity and volume/amount of fluid injected

Injectable Viscosity	Route of Administration								
	SQ (1½ to ¾ inch needle)			IM (¾ to 1 inch needle)			IV (1 to 1½ inch needle)		
	Cattle Weight			Cattle Weight			Cattle Weight		
	< 300	300-700	< 700	< 300	300-700	< 700	< 300	300-700	< 700
Thin Example: Most Vaccines	18 gauge	18-16 gauge	16 gauge	20 gauge	18-16 gauge	18-16 gauge	18-16 gauge	18-16 gauge	16-14 gauge
Thick Example: Thick Antibiotics	18-16 gauge	18-16 gauge	16-14 gauge	18-16 gauge	18-16 gauge	16-14 gauge	18-16 gauge	18-16 gauge	16-14 gauge

Select the needle to fit the cattle size (use the smallest practical size with out fear of bending).

Needle Guidelines

Needle selection and use in a nut shell:

- Use proper restraint and high quality needles
- Select needle size to fit the size of the cattle
- Diameter (gauge) to fit the viscosity, adjusted to the cattle weight
- Length to fit the route of administration, adjusted to the cattle weight

Change needles

- Immediately if the needle bends (DO NOT USE A BENT NEEDLE)
- If needles become contaminated with feces, dirt, or irritating chemicals
- If the needle point is damaged/burr develops
- Before the needle becomes dull
- Between cattle with KNOWN blood borne infectious disease
- Under the instruction of the herd veterinarian

Needle care

- Protect needles from contamination (feces, dirt or irritating chemicals)
- Store unused needles in protected area

Needle disposal

- Follow local, state, and federal EPA guidelines for disposal of used needles and other Sharps
- Seal Sharps container and dispose of in an approved land fill

Disinfectants

- Use all disinfectants carefully
- Do not use disinfectants on needles used for fluid injectables
- Disinfectants kill Modified Live Vaccines
- Disinfectants can cause severe tissue irritation





Administration of Injectables

Regardless of animal's age, injections (All IM and routine SQ medications and vaccines) should be given in front of the shoulders (unless directed otherwise by a veterinarian or per label instruction); never give an injection in the rump or back leg. In order to avoid adverse tissue reactions, whenever possible restrict administration of drugs to SQ, IV, IN or oral use. It is against BQA guidelines to give SQ injections along the ribs or in the elbow region. Giving injections above the curve of the ribs could cause excessive trim in the area of the "rib-roll" or "prime rib" cut of meat. If intramuscular medications must be used, administer them in the neck and never exceed 10 cc per IM injection site. For example, if 24 cc is the calculated dose, use three 8 cc injections instead of two 12 cc injections. There are no restrictions to the volume of SQ injections other than as indicated by the product label or as instructed by the herd veterinarian.

Recordkeeping is Essential to Document Antibiotic Use and Monitor Withdrawal Times

- Recordkeeping is a key element of BQA, and it's simply a good business practice. There are many software programs on the market that are designed for both commercial and purebred cattle operations. Pen and paper can also be an acceptable recordkeeping system if appropriately organized.
- The important thing is to find a method that you are comfortable with, which allows you to maintain accurate, thorough and timely documentation of your herd health program, nutrition program and other important production factors. It's also essential to controlling your costs of production and keeping your eye on other pieces of data that help you make informed management decisions.
- For example, animal health records tell the manager and veterinarian what treatments are being used so they can make sure that recommendations are being followed and help them decide whether treatment protocols need to be adjusted.
- To inspire consumer confidence we must be able to document the responsible use of products and demonstrate that we have control over risk factors that have residue potential. Good records are also important if your operation is inspected (for example, if one of your market cows is found to have a violative residue) by any state or federal agency.

- Should your operation get cited for a residue violation and you believe it's a case of mistaken identity, good records are your only evidence that the animal in question does not belong to you. Or, if it is your animal, then your records may help prove the animal was not given the particular drug in question by you.
- Effective documentation showing appropriate training, inventory control, product use, animal identification, withdrawal and disposal is the only way to avoid liability from a residue contamination. The only way to accurately determine if you are in compliance with withdrawal times is to know exactly what was given, how much was given, where it was given, how it was given and when it was given to the animal.
- Updated records also allow you to make well-informed decisions about marketing cattle without worrying whether enough time has elapsed since the last treatment. Records should also be kept on your use of pesticides, herbicides and other chemicals.
- Understand the remarks and safety restrictions with regard to withdrawal times and animal types (pregnant, lactating, etc.) that should not be treated or exposed to treated areas.

What to include in a record

Keep all records for at least two years from the date of transfer or sale of the cattle.

In case a problem arises later, your records will help you track the treatment history of the animal when it was in your possession.

The treatment record should contain the following information:

- Treatment date
- Animal or group identification
- Approximate weight of animal or group average
- Product administered
- Product lot/serial number
- Earliest date the animal could clear withdrawal time
- Dose given
- Route of administration (IM, SQ, etc.)
- Location of injections
- Name of person who administered the drug

A copy of the appropriate records should be made available to the buyer of your cattle or as they are transferred from one unit of your ranch to another. Records should include all individual and group treatment processing history and other information as deemed appropriate.

EXTRA LABEL DRUG USE

Extra-label drug use (ELDU) is using a drug at a dose, by a route, for a condition, indication, frequency or duration, or in a species not on the label. Extra-label drug use is not permitted in the feedstuff for food-producing animals. ELDU is only legal within the context of a valid VCPR.





Extra label Drug Use Decision Flow-Chart for Food Animals

You made a careful diagnosis in the presence of a Valid Veterinarian Client/Patient Relationship. You are contemplating extra-label drug use. You must ask yourself ... **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
- ▶ is clinically effective?

YES

You must use this drug per label, as extra-label drug use is unnecessary. Observe label directions and withdrawal time.

NO

Is there a drug approved for food animals which could be used in an extra-label manner?

YES

Proceed with the extra-label use of food animal drug. Establish extended withdrawal time. Observe label directions and withdrawal time.

NO

Is there a human drug or drug approved for non-food animal which could be used in an extra-label manner?

YES

Is there adequate scientific information available to determine withdrawal time?

NO

If compounding of approved drugs will prevent pain and suffering, refer to CPG 608 400 for compounding guidance ***

YES

Proceed with extra-label drug use of human or non-food animal drug. Establish extended withdrawal time. Ensure food safety. Maintain required records. Label drug appropriately.

NO

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

*** Compounding of bulk drugs is generally illegal.

Adapted from Farmers Assuring Responsible Management



Compounding

The use of drugs compounded from bulk ingredients in cattle is currently illegal. FDA has exercised enforcement discretion when compounding from bulk ingredients in the case of certain poison antidotes and euthanasia agents (refer to the Compliance Policy Guideline on compounding and its Appendix).

Compounding from bulk ingredients to manufacture other medications for cattle under any circumstance is inappropriate. There are circumstances, however, where minor compounding might be considered appropriate under the AMDUCA algorithm. The AMDUCA regulations state that compounded preparations are required to be prepared from FDA-approved animal or human drugs, and that if possible, an animal-labeled drug is to be used for compounding rather than a human-labeled drug.

Drugs that are not approved for cattle or that are not approved for the production class of cattle being treated should only be used after following AMDUCA regulations. Medications that are labeled for cattle or for that production class should always be considered first for treatment, control and prevention of disease. If the prescribing veterinarian has determined that the labeled medication is or will be clinically ineffective for the disease condition being treated, and extra-label use is indicated, then an extended withdrawal period for meat and milk should be provided. The Food Animal Residue Avoidance Databank (FARAD) may be of help in establishing these recommendations.

The labeled withdrawal period from the manufacturer does not apply if the drug is used in an extra-label manner such as changing the dose, route, duration, frequency or production class of animal. The FDA considers the use of medications in a production class of animal not approved on the label to be an extra-label use. When a veterinarian prescribes this extra-label use in an unapproved class of livestock, there is no tolerance in edible tissues or milk. Any detectable level of the medication in such a scenario is a violative residue. Therefore, the withdrawal time for meat and milk must be significantly extended to ensure there is no detectable level of residue in the animal product. When an appropriate withdrawal time cannot be established, use of the drug precludes the animal or its products from entering the food chain.

(AABP April, 2015)

Employee Training

Employees administering animal health products should be properly trained according to BQA guidelines and proper protocols. For employee training resources visit www.bqa.org.

FDA Approved Drugs

For a list of drugs approved by the Food and Drug Administration, please visit bqa.org.





For more information visit:
www.bqa.org



Funded by the Beef Checkoff.