

# Alabama Beef Quality Assurance: Understanding Proper Drug Use and Storage

ANR-1279

One of the advantages of participating in a quality assurance program is the constant review of procedures for handling, using, and storing drugs. Whether reducing waste or improving drug effectiveness, there is a potential for improved profit. All products purchased for cattle have a purpose. If these products are not handled or used properly, the benefits may be lost.

## Use Only Approved Drugs

Food and Drug Administration-approved drugs meet stringent requirements. They have been thoroughly tested to demonstrate that they consistently perform the way the manufacturer says and that they will not harm the animal when administered according to label directions.

FDA-approved over-the-counter (OTC) drugs are those that can be purchased by anyone without a veterinarian's prescription. Drugs are labeled for OTC sale when adequate instructions for a nonveterinarian can be printed on the label.

If adequate instructions for use cannot be printed on the label, the drug is a prescription drug. All prescription drugs must carry the following statement on the label: "CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

## Extra-label Use

An exception to the rule on both OTC and prescription drugs is called extra-label use. This means using animal health products in ways not specified on the label for example, at higher doses or in different species. Extra-label drug use requires a veterinarian's prescription. In addition, these FDA criteria must be met:

- Establish a valid veterinarian-client-patient relationship.
- The veterinarian agrees to take responsibility for making judgments regarding the health of the animals

- The client agrees to follow the veterinarian's instructions.
- Make a determination whether there is an approved drug labeled to treat the condition, or whether the treatment at the recommended dosage would be effective.
- A record of any animal given extra-label treatment must be maintained.
- Significantly extend the withdrawal time before marketing an animal for slaughter, as determined by the veterinarian.

Extra-label drug use for production purposes, such as weight gain, feed efficiency, or milk production, is inappropriate. Extra-label use of drugs in animal feeds is not permitted.

You are ultimately in charge of making sure meat does not contain illegal drug residues. The following are your responsibilities:

- To make sure a careful diagnosis has been made based on herd-health history.
- To identify all treated animals and keep treatment records.
- To follow veterinarian-recommended extended withdrawal times.

## Understanding Drug Labels

Become familiar with requirements for drug labeling. You are ultimately responsible for any drug residues in their animals. Fortunately, you should not have to worry about labeling, because the drug manufacturer must meet all requirements to get a drug approved, and your veterinarian is responsible for all other labels on drugs that he or she prescribes for your animals. All drugs, whether OTC or prescription, must contain the following basic information on the label:

- name of drug
- active ingredients

- instructions for use
- withholding times
- quantity of contents
- name of distributor

In addition to these basic requirements, prescription drugs must contain the following information on the label:

- name and address of the dispensing veterinarian, not just the veterinary clinic
- the statement: “CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.”
- directions for use
- prescribed withholding times, even if zero
- any other cautionary statements

Drugs to be used in an extra-label or off-label manner require additional caution. They often have special instructions because they are prescribed for a particular animal or a particular herd by a veterinarian who is familiar with the animal or herd. Labels for drugs used in an extra-label manner must have these components:

- name, address, and phone number of the veterinarian who prescribed the drug
- active ingredients, indications, and directions for use
- prescribed withholding time before slaughter
- any cautionary statements
- exact directions for use

To reduce the chance of reactions and minimize the risk of residues, check and follow these instructions on each label:

- dosage (for example, 4 ml or cc)
- timing—how often and how many times given (for example, 2 doses, 3 to 4 weeks apart)
- route of administration (see ANR-1280, “Alabama Beef Quality Assurance: Administer Drugs Properly”)
- warnings or indications (e.g., “not for use in pregnant animals”)
- withdrawal times, if any (e.g., “do not use within 28 days of slaughter”)
- storage (e.g., “store at 2 degrees to 7 degrees C”)
- disposal (e.g., “burn container and all unused contents”)
- shelf life (expiration date)

Be familiar with the different label types that follow. Failure to know the labeling requirements is not a defense if meat from an animal is found to contain drug residues.

## Storing Drugs Correctly

Drug performance declines if the expiration date has passed, if the storage temperature is too hot or too cold, or if the drugs have been exposed to air or light. All the information needed to meet these requirements should be on the label of the drug container.

Check the expiration date on the label.

Do not save vaccines. They will not be effective for later use and may be contaminated.

Some drugs, and most vaccines, need to be refrigerated at 40 to 50° F and must not be frozen. Keep an accurate thermometer in the refrigerator to monitor the temperature.

Use disposable syringes. Use clean needles to draw contents from multidose bottles. Change needles every 10 to 15 animals to minimize disease spread and drug contamination. Do not store medication in syringes. They cannot be labeled easily.

Avoid exposing vaccines and other medicines to direct sunlight. This may degrade the product. Use an insulated cooler for storing syringes and drugs while working on cattle to avoid sunlight and maintain the proper temperature.

Collect used needles in a rigid plastic container. Dispose of them by returning them to your veterinarian. Destroy disposable syringes so they cannot be reused or misused. Read labels. Some drugs and vaccine containers require incineration before disposal. Used needles, scalpels, and other such materials are considered medical waste and must be handled and disposed of in accordance with the laws which govern them.

Consult your local veterinarian regarding any questions on proper use of medications.

## EXAMPLE OF PACKAGE INSERT INFORMATION

<p><b>COWBIOTIC®</b>  <b>(hydrocillin and steptazolidin in aqueous suspension)</b></p> <p>For Use in Beef Cattle, Lactating and Nonlactating Dairy Cattle, and Swine. Read Entire Brochure Carefully Before Using This Product</p> <p>For Intramuscular Use Only</p> <p><b>Composition:</b> Cowbiotic is an effective antimicrobial preparation containing hydrocillin and steptazolidin. Each ml of this suspension contains 200,000 units of hydrocillin and 250 mg of streptazolidin. The combination permits treatment of many mixed bacterial infections with the convenience of a single dosage form.</p> <p><b>Indications:</b> Cattle: Bronchitis; footrot; leptospirosis; mastitis; metritis; pneumonia; wound infections and other infections caused by or associated with hydrocillin and streptazolidin-susceptible organisms.</p> <p><b>RECOMMENDED DAILY DOSAGE</b>          Continue treatment for 1 to 2 days after symptoms disappear.</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">CATTLE</th> <th style="text-align: left;"><u>Body Weight</u></th> <th style="text-align: left;"><u>Dosage</u></th> </tr> </thead> <tbody> <tr> <td></td> <td>Up to 100 lbs.</td> <td>2 ml</td> </tr> <tr> <td></td> <td>100 to 300 lbs.</td> <td>2 to 6 ml</td> </tr> <tr> <td></td> <td>300 to 700 lbs.</td> <td>6 to 10 ml</td> </tr> <tr> <td></td> <td>700 lbs or more</td> <td>10 to 15 ml</td> </tr> </tbody> </table> <p><b>Caution:</b> 1. Cowbiotic should be injected subcutaneously in the neck. Do not inject this material in the hip or rump, into a blood vessel, or near a major nerve. 2. If improvement does not occur within 48 hours, the diagnosis should be reconsidered and appropriate treatment initiated. 3. Treated animals should be closely observed for at least one-half hour. Should a reaction occur, discontinue treatment and administer epinephrine and antihistamines immediately. 4. COWBIOTIC must be stored between 2 to 8 degrees C (36 to 46 F). Warm to room temperature and shake well before using. Keep under refrigeration when not in use. <b>Warning:</b> Milk that has been taken from animals during treatment and for 48 hours (4 milkings) after the latest treatment must not be used for food. The use of this drug must be discontinued for 30 days before treated animals are slaughtered for food.</p> <p><b>How Supplied:</b> COWBIOTIC is available in vials of 100 ml and 250 ml containers.</p>	CATTLE	<u>Body Weight</u>	<u>Dosage</u>		Up to 100 lbs.	2 ml		100 to 300 lbs.	2 to 6 ml		300 to 700 lbs.	6 to 10 ml		700 lbs or more	10 to 15 ml	<div style="border: 1px solid black; padding: 5px; margin-bottom: 10px; text-align: center;">Species &amp; Animal Class</div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 10px; text-align: center;">Approved Uses</div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 10px; text-align: center;">Dosage</div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 10px; text-align: center;">Route of Administration</div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 10px; text-align: center;">Additional Information</div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 10px; text-align: center;">Storage Requirements</div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 10px; text-align: center;">Withdrawal Times</div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 10px; text-align: center;">Sizes Available</div>
CATTLE	<u>Body Weight</u>	<u>Dosage</u>														
	Up to 100 lbs.	2 ml														
	100 to 300 lbs.	2 to 6 ml														
	300 to 700 lbs.	6 to 10 ml														
	700 lbs or more	10 to 15 ml														

## EXAMPLES OF LABEL TYPES

### OTC PRODUCT

Name of Drug

Instructions for Use

Quantity of Contents

**COWBIOTIC**  
(hydrocillin and streptazolidin)  
Directions for use: See package insert  
Warning: The use of this drug must be discontinued for 30 days before treated animals are slaughtered for food. Exceeding the highest recommended dosage level may result in antibiotic residues in meat or milk beyond the withdrawal time.  
Net contents: 100 ml

Distributed by: Alabama Animal Health

Active Ingredients

Withdrawal Times

Name of Distributor

Name of Drug

Instructions for Use

Quantity of Contents

**BULLMYCIN 300**  
(Wondercine Hcl)  
Directions for use: See package insert  
Caution: Federal law restricts this drug to be used by or on the order of a licensed veterinarian.  
Warning: The use of this drug must be discontinued for 28 days before treated animals are slaughtered for food. Exceeding recommended dose, or number of days treatment, or 10 ml. per injection site may result in antibiotic residues beyond the withdrawal period.  
Net Contents: 100 ml.

Distributed by: Alabama Animal Health

Active Ingredients

Prescription Legend

Withholding Times

Name of Distributor

Name & Address of Veterinarian

Instructions for Use

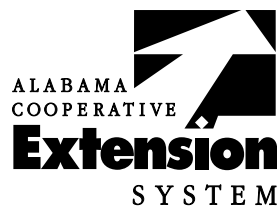
Cautionary Statements

LABEL PROVIDED BY VETERINARIAN  
FOR "EXTRA-LABEL" USE

Veterinarian \_\_\_\_\_ Phone \_\_\_\_\_  
Address \_\_\_\_\_ Date \_\_\_\_\_ Exp \_\_\_\_\_  
Owner/Farm \_\_\_\_\_ ID# \_\_\_\_\_  
Active ingredients \_\_\_\_\_  
\_\_\_\_\_  
Indications \_\_\_\_\_  
\_\_\_\_\_  
Directions: Give \_\_\_\_\_ cc's/bolus/oz.  
\_\_\_\_\_ times each day for \_\_\_\_\_ days.  
Prescribed withholding time \_\_\_\_\_  
Hours of milk withhold/Send samples  
Y/N; Days slaughter Withhold/  
Appropriate Drug Tag.

Animal Class and Health Problem

Prescribed Withholding Times



*Your Experts for Life*

**ANR-1279**

**W.F. "Frank" Owsley**, *Extension Animal Scientist*, Associate Professor, Animal Sciences, Auburn University;  
**James G. Floyd Jr.**, *former Extension Veterinarian*.

**For more information**, call your county Extension office. Look in your telephone directory under your county's name to find the number.

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