

# Antimicrobial Stewardship in the Face of Changing Federal Regulations: Prudent Use Guidelines for Cattle

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## INTRODUCTION

One of the primary goals of a cattleman or cattlegirl is the production of safe and wholesome products for future human consumption. In order to reach that goal, cattle must remain healthy, and producers should utilize good management practices to optimize the health of their herd. Nevertheless, bacterial infections still occur, and antimicrobials are necessary to protect animal health and welfare. In recent years, antimicrobial use practices in production animal agriculture have come under intense scrutiny. As a result, new state and federal regulations have been implemented that will have had dramatic impact on how antimicrobials are used in food producing species. Most producers are familiar with the existing Veterinary Feed Directive (VFD) regulations that affect the use of common antimicrobials in the feed and water of production livestock. However, few are familiar with new regulations that go into effect within the next year.

The purpose of this document is to outline the restrictions laid out in FDA Guidance for Industry 263 (GFI 263), provide cattle producers with judicious antimicrobial use strategies that will protect animal health, maximize antimicrobial efficacy by strategically managing the development of antimicrobial resistance, and preserve antimicrobial availability.

## FDA GUIDANCE FOR INDUSTRY 263

In September 2019, the FDA published a draft of GFI 263 and finalized it on June 11, 2021. This document proposes a timeline and strategy to transition all medically important antimicrobials that are currently available over the counter (OTC) to prescription status only. As of June 11, 2023, GFI 263 will require the order of a licensed veterinarian for sale and dispersal of medically important antimicrobials. In other words, these products will now be prescription only. While the previously implemented VFD regulations were targeted at production livestock, the restrictions proposed in GFI 263 affect all veterinary species, companion type animals included, and are not focused on one specific animal class. Moreover, because selling, dispensing, or filling orders for prescription drugs requires a license from the state pharmacy board, local farm and agriculture/agricultural supply stores will be required to obtain a license to continue to stock and sell these products. As a result, availability of antimicrobials to producers might become limited if these stores are not willing to obtain a pharmacy license. A list of the commonly used, over the counter antimicrobials that are affected by GFI 263 can be found in Table 1 below.

**Table 1. Antimicrobials affected by GFI 263**

Antibiotic	Product Examples
Cephapirin	ToDAY and ToMORROW intramammary tubes
Lincomycin	Lincomix 100; Lincomix 300; LincoMed 100; LincoMed 200
Procaine Penicillin G	Pencillin injectable; Dura-Pen; Pro-Pen-G
Oxytetracycline	LA-200; Noromycin 300; BioMycin 200; Agrimycin 200; Terramycin scours tablets; Oxy 500 Calf boluses
Tylosin	Tylan 50; Tylan 200
Sulfadimethoxine	Di-Methox 40%; Sulfimed 40%; Albon
Sulfamethazine	Sustain III Cattle and Calf boluses; Supra Sulfa Cattle and Calf Boluses

## PRUDENT ANTIMICROBIAL USE GUIDELINES

Implementation of the antimicrobial use guidelines outlined here can help reduce animal pain and suffering, protect the economic livelihood of cattle producers, ensure the continued production of safe and wholesome food, and minimize the development of antimicrobial resistance in important human and cattle pathogens. The following recommendations will help you navigate the regulations imposed by GFI 263 and improve antimicrobial use practices on cattle operations:

- 1. Focus on disease prevention** – Strategic use of vaccines, dewormers, biosecurity, appropriate nutrition, and good husbandry will reduce the incidence of disease and the need for antimicrobials. Herd management protocols should be reviewed frequently and revised as needed.
- 2. Diagnose sick animals quickly and accurately** – Not all diseases require treatment with an antibiotic. Even when animals have an infection caused by bacteria, there may be other treatment options available that could be more effective. Long term, this will minimize the need for and use of antimicrobials on the farm.
- 3. Select antimicrobials appropriate for the condition being treated** – Veterinary and laboratory advice can guide the selection of drugs that are most appropriate for the diseases encountered on different operations. Not all antimicrobials are created the same. Different antimicrobials have different efficacies against different bacteria. In addition, some antimicrobials are targeted to certain body systems at the expense of others. Veterinarians should understand these intricacies and be able to provide advice on which drugs work better for specific conditions.
- 4. Keep records** – Record animal or group identification, the drug used, date treated, dosage used, route given, and who administered the product. Keep all records and review them regularly.

## IMPLEMENTATION OF PRUDENT USE GUIDELINES ON AN OPERATION

### Have a Veterinary-Client-Patient Relationship

One of the most important principles as it relates to prudent antimicrobial use is developing a working relationship with a veterinarian familiar with your herd, a relationship termed the veterinarian-client-patient relationship (VCPR). To establish a valid VCPR, the following requirements must be met:

- The veterinarian knows your operation, your management, your cattle, and is involved in diagnosis and treatment. This requires regular and timely visits to the operation in question.
- The veterinarian must be available for follow-up in case of treatment failures.
- A producer is willing to follow a veterinarian's recommendations for antimicrobial usage.

A valid VCPR is not in place if a veterinarian solely writes prescriptions, sells drugs, or makes drugs available to their producers. As noted above, a valid VCPR requires that a veterinarian see the animals that he or she is treating so that an appropriate diagnosis can be made. This also allows for the most appropriate therapy to be prescribed. Veterinarians that engage in such practices are breaking federal law and can jeopardize the livelihood of their clients and patients. Moreover, this type of practice adds little value to the farming operation. The goal of a cattle veterinarian should be to add value to a cattle operation and become a crucial part of the management team. A veterinarian that writes prescriptions and provides drugs without seeing the operation or animals only adds cost without providing much benefit.

Today, veterinary practices are busier than ever before, and certain areas of the state have a limited availability of trained livestock practitioners. As a result, getting veterinarians on farm when emergent situations arise can be difficult, if not impossible. In order to ensure optimal care, livestock operations need to have a relationship with a veterinarian in place before an emergency arises. Producers who only contact veterinarians for an emergency are going to find it difficult to navigate the new restrictions and challenges that GFI 263 may create. Cattlemen and cattlemen must begin to use scheduled preventive health services for their operations in order to remain successful. Over the long term, this wise investment will pay dividends in improved animal productivity and farm profitability. Additionally, many producers will see the need for antimicrobials decrease quite significantly because of a reduction of the disease burden that they face. On a similar but unrelated note, increased demand of veterinary services will help drive the supply of competent and readily available livestock practitioners. Thus, investing in preventive care and regularly scheduling veterinary visits to assess the herd as a whole is critical to improving the shortage of veterinary care over the long term.

### Establish written treatment protocols

In many cases, diagnosis and treatment of diseases may be possible without directly consulting a practicing veterinarian. Recognition of many diseases (pink eye, respiratory disease, foot rot) is relatively straightforward, and treatment of cattle with these diseases can be done effectively and economically by producers or farm staff. Nevertheless, establishing written disease diagnosis and treatment protocols with a veterinarian can help simplify decision-making and improve response to treatment. In addition, written protocols provide accountability and determine liability should questions about a treated animal arise. Complete treatment protocols should include a definition of the disease and detailed directions for treatment (drug, dose, route, duration, withdrawals, etc). Ultimately, working with a veterinarian to develop these protocols is essential to ensuring their efficacy.

### Understand what constitutes extra-label drug use (ELDU)

Drugs are approved for the treatment of particular diseases, in specific species, at a pre-determined dose, route, duration, and frequency of administration, all of which are indicated on the drug's label. Any use that deviates from what the label allows is considered ELDU and requires a valid VCPR. ELDU issues are important because approved withdrawal times are based on label directions; any other use may result in violative residues in edible tissues. There are certain drugs that are prohibited by law from ELDU in food-producing animals. These drugs are as follows:

- a. Chloramphenicol
- b. Clenbuterol (Ventipulmin)
- c. Diethylstilbestrol
- d. Metronidazole (and other members of the same antimicrobial class)
- e. Nitrofurazone
- f. Sulfonamides in lactating dairy cattle
- g. Phenylbutazone (Bute) in dairy cattle
- h. Fluoroquinolones (Baytril, Advocin)
- i. Glycopeptides (Vancomycin)

Examples of illegal ELDU would be the use of Baytril to treat diarrhea in a calf and the use of nitrofurazone puffers to treat pinkeye in cattle. It is also important to understand that any ELDU done without the order of a licensed veterinarian is illegal, regardless of what allowances may or may not exist with a specific drug.

There are other drug classes that are allowed to be used in an extra-label manner but carry significant restrictions on their use. The class that is most relevant to cattle producers is the cephalosporin class (Excenel, Naxcel, Excede). Any use of cephalosporins in ways that deviate from the label dose, route of administration, or duration of therapy is a violation of ELDU policy. For example, the administration of Excede in the muscle of the neck as opposed to the base of the ear is considered illegal. In addition, the administration of Excenel at a dosing rate or dosing frequency higher than what the label allows for longer than the label allows (2 ml/100 lbs once daily for 3-5 days) is illegal.

### **Train people who work with livestock on operations**

People working with livestock must be trained to recognize and treat disease according to farm protocols established with a veterinarian. These individuals should have input on the development and implementation of protocols and may provide insight that improves management of different disease conditions. All personnel should be trained using guidelines appropriate for Beef Quality Assurance programs and all protocols should be reviewed regularly with changes made as needed.

### **CONCLUSION**

As new federal regulations come into effect and consumer preferences and demand change, cattle producers must be willing to adapt in order to remain competitive. Federal law and public pressure dictate that the patterns of antimicrobial use change. Producers and veterinarians must be committed to a culture that promotes judicious and appropriate antimicrobial use to minimize the risk of antimicrobial resistance, maintain the long-term effectiveness of antimicrobials currently available, and protect future antimicrobial availability.



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