Key Medical Antibiotics in Veterinary Medicine to Become “Prescription Only” in 2023

In June 2023, the Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) will implement their Guidance for Industry (GFI) #263 which instructs animal drug companies to voluntarily change labels so that antibiotics, which are medically important for human medicine and currently available over-the-counter for animals, will require a prescription from a licensed veterinarian for legal use.

GFI #263 builds upon FDA’s previous GFI #213, which brought 96% of all medically important antibiotic drugs used in water and feed for animals under veterinary oversight and limited their use to treatment, control, and prevention of specific diseases. GFI #263 addresses the remaining 4% of the medically important antimicrobial drugs not covered by GFI #213 and includes other dosage forms such as injectable and topical products.

Antibiotics are a powerful tool for both animal and human health. They can be used to prevent and treat infections caused by bacteria. However, when antibiotics are not used properly and responsibly, bacteria can become resistant or unresponsive. Antibiotics can continue to be effective for prevention, control, and treatment of disease through good stewardship and responsible use. GFI #263 is consistent with FDA, CVM’s five-year action plan for supporting antimicrobial stewardship in veterinary settings, as published in 2018.

What do these changes mean for cattle producers in the United States? After June 2023, producers will need a valid veterinarian-client-patient relationship (VCPR) to obtain medically important antibiotics. All medically important antibiotics previously available over-the-counter will require a prescription from a veterinarian licensed in the state where the cattle reside.

Producers should identify a veterinarian as a partner in supporting the health of their cattle. By having a veterinarian who is familiar with you and your cattle, the veterinarian can be prepared to provide appropriate care in case of an illness or infection. Before illness occurs, set protocols for common conditions with your veterinarian so that you have access to the antibiotics needed to take swift action on your own and recognize when you need to involve your veterinarian. Illness and infections are never convenient. The best time to talk to your veterinarian is before animals are sick. Planning with your veterinarian ensures you can care for your cattle herd in a timely manner and when it matters most.

Please look for additional information concerning these marketing changes for medically important antibiotics in animals in future issues of National Cattlemen.

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Some of the Commonly Used Medically Important Antibiotics for Cattle with Label Changes to Veterinary Prescription Only Status by June 2023:

- **Oxytetracyclines**
  - **Injectables:** Liquamycin LA-200, Noromycin 300 LA, Bio-Mycin 200, Agrimycin 200, etc.
  - **Boluses:** Terramycin Scours Tablets, OXY 500 Calf Boluses

- **Penicillins (Penicillin G procaine, penicillin G benzathine)**
  - **Injectables:** Penicillin Injectable, Dura-Pen, Pro-Pen-G, Combi-Pen 48, etc.
  - **Intramammary tubes:** Masti-Clear, Go-dry, Albadry Plus

- **Sulfa-based antibiotics (Sulfadimethoxine, sulfamethazine)**
  - **Injectables:** Di-Methox 40%, SulfMed 40%
  - **Boluses:** Albon, Sustain III Cattle & Calf Boluses, Supra Sulfa III Cattle & Calf Boluses

- **Tylosin**
  - **Injectables:** Tylan 50, Tylan 200

- **Cephapirin, cephapirin benzathine**
  - **Intramammary tubes:** ToDAY and ToMORROW