

## **New Rules are Coming for Medically Important Antibiotics**

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Many livestock producers were impacted in 2017 by FDA Guidance for the Industry #213, also known as the Veterinary Feed Directive. Guidance #213 impacted the antimicrobials used in livestock feed and/or water that were considered medically important. Medically important antimicrobials are those that may be used in human medicine as well as animal medicine. Guidance #213 required a veterinary-client-patient-relationship and a prescription from the veterinarian to purchase and use feed and/or water antimicrobials in animals. The new FDA Guidance for the Industry #263, published on June 11, 2021, will now require purchase and use of current and future medically important antimicrobials to have a veterinary prescription and will no longer be available over-the-counter (OTC).

The FDA is allowing a two-year phase-in of the guidance, so by June 11, 2023, all current and future medically important antimicrobials will require a veterinary prescription and must contain the prescription statement: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian." The main restriction noted by most livestock producers will be the need for a veterinary prescription for injectable medically important antimicrobials. Some stores, just as with the feed and/or water antimicrobials, may stop selling the newly encompassed products, but they still may be purchased at other stores or your veterinarian.

Some examples of the drug classes that will be impacted are oxytetracyclines (Liquamycin LA-200, Noromycin 300 LA), penicillins, sulfa-based antimicrobials, and Tylosin. The new Guidance #263 not only impacts injectables but boluses as well. These products are not being removed from the market and will be readily available for purchase with a veterinary prescription.

Additionally, it is not recommended to stock up on these products prior to Guidance #263 implementation. Purchasing these products in large quantities also can lead to a large amount of product expiring prior to use. All of these products have expiration dates and are impacted by storage time and temperature. Utilizing any drug after the expiration date reduces its efficacy and may lead to additional treatments needed.

Guidance #263 only impacts medically important antimicrobials; it does not impact antimicrobials that are not considered medically important. Being prepared for Guidance #263 will help minimize complications as it comes into effect. If you don't currently have a veterinary-client-patient-relationship (VCPR), now is a great time to begin establishing it. This relationship will help both the veterinary and producer provide the best care for the livestock.

More information regarding Guidance for Industry #263 can be found at:

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-263-recommendations-sponsors-medically-important-antimicrobial-drugs-approved-use-animals>