

FREQUENTLY ASKED QUESTIONS ABOUT GUIDANCE #263

The Food and Drug Administration (FDA) has updated antimicrobial drug guidelines to include additional oversight by licensed veterinarians. **The change will take effect June 11, 2023**, and requires livestock owners to obtain a veterinarian's prescription to access antimicrobials considered medically important to human health for their animals.

Learn more about Guidance #263 in this Frequently Asked Questions document.

Q: *What antimicrobial drugs are moving to prescription-only status in 2023?*

A: Only products considered medically important to human health will be removed from Over the Counter status and changed to prescription only. The following are some products that will have label changes:

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

Additionally, several swine medications fall under the new guidance:

LINCOMYCIN

- Injectables: Lincomix 100, Lincomix 300, LincoMed 100, LincoMed 300
- Gentamicin
- Injectables: Garasol, Gentamicin Piglet Injection



[For a full list of affected drugs, visit FDA's website.](#)



Q: *Guidance #263 requires farmers to have a valid veterinary-client-patient relationship (VCPR) in place before requesting medically important antimicrobial drugs intended for food animals. What is a VCPR?*

A: **Under the Veterinary Medicine and Surgery Practice Act of 2004, Illinois defines VCPRs as relationships in which all of the following conditions have been met (taken directly from the Illinois General Assembly's website):**

1. The veterinarian has assumed the responsibility for making clinical judgments regarding the health of an animal and the need for medical treatment and the client, owner, or other caretaker has agreed to follow the instructions of the veterinarian;
2. There is sufficient knowledge of an animal by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal. This means that 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 by medically appropriate and timely visits to the premises where the animal is kept, or the veterinarian has access to the animal patient's records and has been designated by the veterinarian with the prior relationship to provide reasonable and appropriate medical care if he or she is unavailable; and
3. The practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the treatment regimen or, if unavailable, has designated another available veterinarian who has access to the animal patient's records to provide reasonable and appropriate medical care.

VCPR does not mean a relationship solely based on telephonic or other electronic communications.

Q: *What is the background on Guidance #263?*

A: **In response to concerns over antimicrobial resistance, the Food and Drug Administration (FDA) developed a plan for judicious use of antimicrobials in food animal production. The plan included bringing all dosage forms under the oversight of a licensed veterinarian.**

First in 2013, FDA issued Guidance for Industry (GFI) #213, which led to significant changes regarding the use of medically important antibiotics in feed and water.

Then in 2021, FDA published GFI #263 titled, "Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to Be Available as Over-the-Counter."

Guidance #263 recommends producers of medically important antimicrobial drugs halt sales OTC and voluntarily bring these products under veterinary oversight or prescription marketing status. Product labels on these drugs will now contain the prescription (Rx) statement, "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

Q: *Where else can I find information?*

A: **For information regarding Guidance #263, visit the following websites.**

- [Guidance for Industry #263](#)
- Full list of antibiotics affected: <chrome-extension://efaidnbnmnib-pcajpcglclefindmkaj/https://extension.missouri.edu/media/wysiwyg/Extension-data/Pub/docs/g02112-Antibiotics-impacted-by-GFI263.pdf>
- Illinois Definition of veterinary-client-patient relationship <https://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=1326&ChapterID=24>

