

Frequently Asked Questions About GFI #263

The U.S. Food and Drug Administration (FDA) has been taking steps to improve the judicious use of antibiotics in human and veterinary medicine. The FDA is completing its goal of bringing all medically important antibiotics (MIA) under the supervision of veterinarians with its Guidance for Industry #263. The majority (96%) of the MIA used by animal owners are already prescription or veterinary feed directive drugs. The remaining 4% that are currently over-the-counter (OTC) will transition to prescription by June 11, 2023, when GFI #263 takes effect.

When does GFI #263 take effect?

All labels will be changed from OTC to prescription by June 2023. Some labels will have changed before then, depending on the drug manufacturer.

What drugs are affected by GFI #263?

Only medically important antibiotics that are currently over-the-counter. Examples include:

Penicillin	Tetracycline	Oxytetracycline
Gentamicin	Cephapirin	Tylosin
Lincomycin	Sulfa drugs	Spectinomycin

Not affected products include dewormers, probiotics, aspirin, electrolytes, and some coccidiostats.

Does this rule only affect food-producing animals?

No. This rule affects MIA labeled for food-producing and companion animals.

Can I share prescription antibiotics with my neighbor?

No. This is illegal. They need to contact a local veterinarian for a prescription.

Should I stock up on OTCs now, for future use?

No. These medications will expire.

Can I still buy medications at farm supply stores?

Yes. You may still buy antibiotics at feed supply stores, online, or through drug supply companies, but only with a prescription.

Will a DVM be required to examine each animal before prescribing an Rx drug?

No. Veterinarians are generally not required to examine each animal for which a prescription is issued under a veterinary-client-patient relationship (VCPR). The final decision will be up to the private veterinarian.



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What is a VCPR?

Veterinary-Client-Patient-Relationship. The FDA says, “Such a relationship can only exist when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animals by virtue of examination of the animals and/or by medically appropriate and timely visits to the premises where the animals are kept.”

How do I know if I have a VCPR?

If you have a regular veterinarian who sees your animals at least once a year and who comes out for emergencies, then you probably have a VCPR. If you are not sure, call your veterinarian’s office to confirm.

What should I do if I don’t have a VCPR?

Contact a local veterinarian now. Veterinarians are not required to respond to emergencies for owners who are not clients. They shouldn’t write prescriptions if you do not have a VCPR or they haven’t seen the sick animal.