
Guidance for Industry No. 263: Transition of Remaining Over-the-Counter Antibiotics to Prescription Status

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()Background

In December of 2013, the Food and Drug Administration’s (FDA) Guidance for Industry (GFI) #213 was published in the federal register. This led to two significant changes regarding the use of medically important antibiotics (see sidebar) in the feed and water of livestock beginning Jan. 1, 2017. One change that occurred was medically important antibiotics could no longer be used for production purposes such as growth promotion or increased feed efficiency. The other change was many of these antibiotics, which had been available over the counter (OTC), now required either a Veterinary Feed Directive if used in feed or a prescription if used in drinking water. This action brought the majority of antibiotic use in the livestock industry under veterinary supervision. However, a small percentage remained available OTC in the form of injectables, intramammary tubes, boluses, etc.

The term “medically important antibiotics” refers to a list of antibiotics found in Appendix A of GFI #152 that are important for treating human disease. Some of these antibiotics are also used in veterinary medicine to treat, prevent or control disease.

In September of 2018 the FDA Center for Veterinary Medicine released a five-year plan titled, “Supporting antimicrobial stewardship in veterinary settings: Goals for fiscal years 2019–2023.” The plan contained three goals, with each goal having three objectives and multiple action items were associated with each objective.

Two of the action items in the plan specifically focused on the remaining OTC antibiotics:

Action 1.1.3: **Issue a draft strategy** (e.g., GFI) to bring all dosage forms (including injectable, intramammary, etc.) of medically important antimicrobial drugs approved for use in food-producing animals under the oversight of a licensed veterinarian.

Action 1.1.4: **Issue and implement a final strategy** (e.g., GFI) to bring all dosage forms (including, injectable, intramammary, etc.) of medically important antimicrobial drugs approved for use in food-producing animals under the oversight of a licensed veterinarian.

In September of 2019, the FDA announced the availability of draft GFI #263 which was 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.” This provided a strategy and timeframe for transitioning the remaining medically important antibiotics from OTC availability to requiring veterinary oversight. The public comment period for the draft ended on Dec. 24, 2019, and the final publication of GFI #263 appeared in the federal register on June 11, 2021.

()Impact

So, what changes will occur with the implementation of GFI #263? By June 11, 2023, the FDA expects all medically important antibiotics that are currently available OTC to display the following statement on the label, “Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.” Once this label change occurs, an antibiotic can only be sold or dispensed on the prescription of a licensed veterinarian thereby ending OTC sales of that antibiotic. A few examples of antibiotics that will be affected are listed in Table 1 and access to the complete list can be found under [Resources \(#resources\)](#) at the end of this article.

()Frequently asked questions

Considering the implementation of GFI #263 will end OTC sales of all medically important antibiotics, animal owners have raised questions and concerns. The FDA provides answers to frequently asked questions by farmers and ranchers (see [Resources \(#resources\)](#)) however, the following are common questions received from animal owners in Missouri and are answered from that perspective.

When will antibiotics with the new labeling first appear at retail locations?

The expectation is that antibiotics affected by GFI #263 will transition to prescription status by June 11, 2023, at the latest. Therefore, product with revised labeling will begin to appear around that time but it will depend on when manufacturers begin printing labels and inventory turnover in the supply chain. Keep in mind,

product displaying the revised label can only be sold or dispensed on a veterinary prescription, even if the transaction takes place before the June 11, 2023 deadline.

I don't own livestock, such as cattle or pigs, but I do use some of the antibiotics affected by GFI #263 in other species. Will I still need a prescription?

A prescription will be required regardless of the species the antibiotics are used in.

I don't use a veterinarian. How do I ensure I have access to antibiotics once the changes occur?

You will need to work with a veterinarian to ensure continued access. For a veterinarian to issue a prescription, a veterinarian-client-patient-relationship (VCPR) must be established. In Missouri, this means a veterinarian is acquainted with the keeping and care of your animal(s) either by examination or timely visits to the operation where the animal(s) is kept. You will need to contact a local veterinarian for further details about requirements of a VCPR.

Will these changes lead to additional expenses?

It is not known if the changes will affect antibiotic prices. However, there are veterinary expenses associated with establishing and maintaining a VCPR. Someone that already has a VCPR established should expect little to no additional expenses associated with these changes.

My local farm store currently sells some of the antibiotics listed in Table 1. Will they be able to sell these antibiotics once they require a prescription?

In Missouri, selling, dispensing or filling orders for animal prescription drugs is regulated by state statutes and rules. Any entity within the state engaged in these practices, with the exception of a veterinarian, is required to have a pharmacy permit and must comply with the rules and requirements associated with that permit. If the farm store intends to sell prescription antibiotics, they will need a pharmacy permit to do so.

Will I be able purchase these antibiotics from online vendors that are not located in Missouri?

Online pharmacies that conduct interstate business must follow federal and state requirements when distributing, dispensing or delivering prescription drugs. Many of the popular online vendors already comply with these requirements and currently offer prescription drugs for sale. Contact the vendor with any additional questions you may have.

Table 1. Example of antibiotics affected by GFI #263.

Antibiotic	Product examples
Cephapirin, Cephapirin Benzathine	Intramammary tubes: ToDAY and ToMORROW
Lincomycin	Injectables: Lincomix 100, Lincomix 300, LincoMed 100, LincoMed 300
Oxytetracycline	Injectables: Liquamycin LA-200, Noromycin 300 LA, Bio-Mycin 200, Agrimycin 200, etc. Boluses: Terramycin Scours Tablets, OXY 500 Calf Boluses
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
Sulfadimethoxine, Sulfamethazine	Injectables: Di-Methox 40%, SulfMed 40% Boluses: Albon, Sustain III Cattle & Calf Boluses, Supra Sulfa III Cattle and Calf Boluses
Tylosin	Injectables: Tylan 50, Tylan 200

()Resources

- [Complete list of antibiotics affected by GFI #263](https://extension.missouri.edu/media/wysiwyg/Extensiondata/Pub/docs/g02112-Antibiotics-impacted-by-GFI263.pdf) (<https://extension.missouri.edu/media/wysiwyg/Extensiondata/Pub/docs/g02112-Antibiotics-impacted-by-GFI263.pdf>)
- [FDA's Frequently Asked Questions for Farmers and Ranchers](https://www.fda.gov/animal-veterinary/judicious-use-antimicrobials/gfi-263-frequently-asked-questions-farmers-and-ranchers) (<https://www.fda.gov/animal-veterinary/judicious-use-antimicrobials/gfi-263-frequently-asked-questions-farmers-and-ranchers>)
- [Guidance for Industry #263](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-263-recommendations-sponsors-medically-important-antimicrobial-drugs-approved-use-animals) (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-263-recommendations-sponsors-medically-important-antimicrobial-drugs-approved-use-animals>)