

OTC → PRESCRIPTION

What you need to know about the FDA Guidance for Industry #263 change from over-the-counter to prescription-only antibiotics



Beginning June 11, 2023, all remaining over-the-counter medically important antibiotic and antimicrobial drugs will now require a prescription from a veterinarian in order to obtain them. **These drugs are not being removed from the market and will still be available** with a prescription from a licensed veterinarian.

WHICH DRUGS WILL BE AFFECTED?

The most commonly used drugs that will be impacted by this change are:

- Cephapirin
- Dihydrostreptomycin
- Erythromycin
- Gentamicin
- Lincomycin
- Oxytetracycline
- Penicillin
- Spectinomycin
- Sulfabromomethazine
- Sulfachlorpyridazine
- Sulfadimethoxine
- Sulfamethazine
- Sulfisoxazole
- Sulfomyxin
- Tetracycline
- Tylosin

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WHY IS THIS HAPPENING?

On September 14, 2018, FDA unveiled a **5-year action plan** ([fda.gov/media/115776/download](https://www.fda.gov/media/115776/download)) for supporting antimicrobial stewardship in veterinary settings. This plan builds upon the important steps the FDA Center for Veterinary Medicine has already taken to support the judicious use of antimicrobials in animals. One action item included in this plan is to ensure that any medically important antimicrobial new animal drugs that continue to remain available as OTC products are brought under the oversight of licensed veterinarians. Under Guidance for Industry #263, the FDA has provided sponsors with specific recommendations on how to facilitate voluntary changes to the approved conditions of use of these drugs to prescription marketing status. The voluntary process outlined in this guidance will help to ensure new animal drugs containing antimicrobials of human importance are administered only under veterinary oversight and only for therapeutic uses.

WHO DECIDED THIS AND WHEN WAS IT DECIDED?

In June 2021, FDA began to work with affected drug sponsors to help them to voluntarily change the marketing status of their medically important antimicrobial new animal drug products from OTC to Rx with the expectation that the Rx-labeled product begin to be introduced to the market June 11, 2023. Based on the positive feedback received regarding the approach taken to successfully implement the recommendations outlined in **FDA Guidance for Industry #209** and **#213**, FDA believes a voluntary approach, partnering with the affected drug sponsors, is an effective and efficient way to achieve the common goal of judicious use of medically important antimicrobials in animals.

FDA RESOURCES



FDA Guidance for Industry #263



FDA Frequently Asked Questions



FDA Antibiotic Stewardship
Beef and Dairy Cattle



FDA Antibiotic Stewardship
Beef and Dairy Cattle (Spanish)

[fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-209-judicious-use-medically-important-antimicrobial-drugs-food-producing-animals](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-209-judicious-use-medically-important-antimicrobial-drugs-food-producing-animals)

[fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-213-new-animal-drugs-and-new-animal-drug-combination-products-administered-or-medicated-feed](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-213-new-animal-drugs-and-new-animal-drug-combination-products-administered-or-medicated-feed)

[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)

[fda.gov/animal-veterinary/antimicrobial-resistance/gfi-263-frequently-asked-questions-farmers-and-ranchers](https://www.fda.gov/animal-veterinary/antimicrobial-resistance/gfi-263-frequently-asked-questions-farmers-and-ranchers)