



# GUIDANCE FOR INDUSTRY 263

## FREQUENTLY ASKED QUESTIONS

### OVER THE COUNTER ANIMAL MICROBIAL DRUGS SOON TO REQUIRE PRESCRIPTIONS

[Guidance for industry \(GFI\) #263](#) is an effort to combat antimicrobial resistance (AMR), which is a serious threat to animal and public health, according to the U.S. Food & Drug Administration (FDA). Because antimicrobial use in humans, animals and horticulture can contribute to the development of AMR, using antimicrobials carefully can slow the rate at which AMR develops.

#### WHICH ANTIMICROBIAL ACTIVE INGREDIENTS ARE AFFECTED BY THE CHANGE?

The following is a list of ingredients that are affected by this change:

- Sulfisoxazole
- Oxytetracycline, Polymyxin B
- Oxytetracycline
- Sulfamethazine
- Sulfabromomethazine
- Erythromycin
- Tylosin
- Sulfadimethoxine
- Sulfomyxin
- Sulfachlorpyridazine
- Spectinomycin
- Lincomycin
- Chlortetracycline
- Penicillin G Procaine, Novobiocin
- Dihydrostreptomycin, Penicillin G Procaine
- Tetracycline
- Penicillin G Procaine
- Dihydrostreptomycin
- Penicillin G Benzathine, Penicillin G Procaine
- Gentamicin
- Cephapirin
- Cephapirin Benzathine

#### WHO IS AFFECTED BY GFI 263?

Anyone who currently purchases antimicrobials without a prescription and retailers selling antimicrobials without an authorized prescription resell license.

#### WHEN WILL THESE PRODUCTS CHANGE FROM OVER THE COUNTER (OTC) TO PRESCRIPTION (RX)?

June 11, 2023 is the FDA's target date to introduce new Rx labeled products into the marketplace. FDA intends to allow existing inventory of OTC-labeled product that may already be in distribution channels to deplete.

#### WILL ANTIMICROBIALS STILL BE AVAILABLE TO PRODUCERS?

Yes, however producers will need to consult with their licensed veterinarian, whom they have an established valid veterinarian-client-patient relationship with, to access appropriate antimicrobials designed to address animal health issues.

For more information, visit <https://www.fda.gov/animal-veterinary/unpublished-judicious-use-antimicrobials/gfi-263-frequently-asked-questions-farmers-and-ranchers>.

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