Frequently Asked Questions

Antimicrobial Transition: Over–the–counter to Prescription

What is the FDA label directive related to antimicrobial drugs transitioning from OTC to Rx?

In 2021, the U.S. Food and Drug Administration (FDA) announced Guidance for Industry (GFI) #263 that requires animal drug manufacturers to change medically important antimicrobial drugs from over-the-counter (OTC) to prescription (Rx) status by June 11, 2023.

Why was this guidance given?

The FDA is completing the last phase of the transition from OTC status to requiring veterinary oversight. This action ensures the remaining 4%* of medically important antimicrobials will be used under the supervision of a licensed veterinarian.

Which Zoetis products does this impact?

Zoetis has six commercially available products that will change from OTC to Rx to comply with the new guidance from the FDA:

- Albadry Plus® (*penicillin G procaine and novobiocin sodium intramammary infusion*) Suspension for cattle
- Albon® (*sulfadimethoxine*) Boluses for cattle
- Lincomix® (*brand of lincomycin injection*) for swine
- Liquamycin® LA-200® (*oxytetracycline injection*) for cattle and swine
- Terramycin® (*oxytetracycline hydrochloride and polymyxin B sulfate ophthalmic ointment*) for sheep, cattle and horses
- Terramycin (*oxytetracycline HCl*) Scours Tablets for cattle

How will these products be available after June 11, 2023?

Once the transition is implemented, producers will need a prescription from a licensed veterinarian to purchase the products listed. This means the products will no longer be available for purchase from a retailer via e-commerce or at a brick-and-mortar retailer without a prescription from a veterinarian.

Once a producer has a veterinarian's prescription, they have the following options to purchase through these channels:

- Veterinarian: Buy directly from a veterinarian and pick up at a veterinary office
- Retailer: Buy from e-commerce or a brick-and-mortar retailer that fills prescriptions from a veterinarian
- Distributor: Obtain a veterinary prescription and have the product delivered or shipped from a distributor partner

After June 11, 2023, how can producers obtain a veterinarian prescription for previously OTC antimicrobials?

According to Center for Veterinary Medicine guidance, a valid veterinarian-client-patient relationship (VCPR) is required to obtain a prescription product with specific directions for use. Producers should work with their local veterinarian to establish a VCPR and identify disease management strategies for their operations. Under a valid VCPR, veterinarians will revisit animal health protocols and issue prescriptions as needed.

*4% by weight as estimated by the FDA 2020 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals. Full report available at: https://www.fda.gov/media/154820/download

zoetis

Frequently Asked Questions

Helpful reference links

Learn more about FDA regulation of animal drugs

VCPR overview from the American Veterinary Medical Association

IMPORTANT SAFETY INFORMATION:

Do not use Albadry Plus 30 days prior to calving. Milk from treated cows must not be used for food during the first 72 hours after calving. Treated animals must not be slaughtered for food for 30 days following udder infusion.

Albon Bolus has a 60 hour milk withhold period, and a pre-slaughter withdrawal time of seven days. Do not use in calves to be processed for veal. Treatment should not be continued beyond five days.

Do not use Lincomix Injectable in animals with a history of hypersensitivity to lincomycin. Withdraw 48 hours prior to slaughter.

Discontinue treatment with Liquamycin LA-200 at least 28 days prior to slaughter. Discard milk for 96 hours after the last treatment. Do not exceed the highest recommended level of drug per pound of body weight per day. Withdraw Liquamycin LA-200 at least 28 days prior to slaughter.

Discontinue treatment with Terramycin Ophthalmic Ointment (oxytetracycline hydrochloride/ polymyxin B sulfate) if severe allergic reactions occur.

Terramycin has a pre-slaughter withdrawal time of 7 days. Do not use in lactating dairy cattle. Do not use in calves to be processed for veal.

All trademarks are the property of Zoetis Services LLC or a related company or a licensor unless otherwise noted.
© 2023 Zoetis Services LLC. All rights reserved. LIQ-00006

zoetis