RESTRICTED LIVESTOCK DRUG RETAILER FREQUENTLY ASKED QUESTIONS (FAQS)

1. What is a restricted livestock drug (RLD)?

California Food and Agricultural Code defines a restricted livestock drug (RLD) as any livestock drug sold in a form that could be used by humans or any livestock drug which, if improperly administered to livestock, is dangerous to the health of those livestock or to humans who consume products from those livestock (Division 7, Chapter 4, Section 14203). RLDs must be registered with CDFA to be sold in California and must have a product label indicating, "Restricted Drug (CA)-Use only as directed." Please note that drugs federally labeled as prescription-only are not considered RLDs.

2. What are the requirements to sell RLDs?

California law requires retailers selling RLDs to be licensed by CDFA. According to existing law and regulation, a licensed RLD retailer is required to:

Apply for and annually renew their RLD retailer license.

Pay an annual license fee of \$50 to CDFA.

Receive approval and license number from CDFA.

Maintain a record of each RLD sold for three (3) years.

Permit CDFA staff to enter and inspect any facility where RLDs are stored or sold.

Provide a copy of RLD sales records when requested by CDFA staff.

3. Is a company required to obtain a separate RLD license for each location where RLDs are sold? Is a separate license required to sell RLDs online?

Yes, each location where RLDs are sold is required to obtain a separate RLD license from CDFA. In addition, if a company sells RLDs online, the company must obtain a separate RLD license for online sales. This requirement also applies to online retailers based out of state that sell RLDs to customers in California.

4. What information is required to be maintained in the record for each RLD sold?

A licensed RLD retailer is required to maintain a record of the following information for three (3) years for each RLD sold:

Purchaser name, address, phone number, and signature

Product name (drug or trade name)

Route of administration

Quantity and lot number

Date of sale

Intended species (recommended)

Purchaser email (recommended)

5. What drugs are considered RLDs?

RLDs include:

Medically important antimicrobial drugs, known as California prescription drugs (Examples: LA-200, Duramycin, Penicillin, etc.)

Non-medically important antimicrobial drugs (Example: Monensin, Salinmycin, Tialmulin, Bacitracin, etc.)

Coccidostats (Example: Amprolium, etc.)

Certain wormers (Example: Livestock Ivermectin, Fenbandazole, etc.)

Hormones (Example: Estradiol, Progesterone, etc.)

Certain feed additives, known as Type A Medicated Articles (Example: Ractopamine Hydrochloride, etc.)

Please see question 6 below for more information about California prescription drugs and a list of products that require a prescription. All other RLDs may be sold by licensed retailers without a prescription; a complete list of products is available on the RLD website at: https://www.cdfa.ca.gov/is/ffldrs/pdfs/RLD_Only_List-no_MIADs.pdf

6. What is a California prescription drug?

California law requires a prescription to purchase or use medically important antimicrobial drugs that are federally labeled for over the counter sale. These products are known as California prescription drugs and have additional requirements for retailers that choose to sell them. Because they are federally labeled for over the counter sale, California prescription drugs are considered a type of RLD; their product labels must be registered with CDFA (see question 1) and they may only be sold by licensed retailers (see questions 7 and 8 below). Examples include LA-200, Duramycin, and Penicillin; a full list of these products is available on the AUS website at: https://www.cdfa.ca.gov/ahfss/AUS/docs/MIADs_Changing_Jan2018.pdf.

7. What types of retailers can sell California prescription drugs?

To sell California prescription drugs, a retailer must be licensed by either: California Board of Pharmacy as a veterinary food-animal drug retailer or pharmacy; or CDFA as a RLD retailer (additional requirements apply, see question 8 below).

8. What are the additional requirements for licensed RLD retailers to sell California prescription drugs?

According to existing law and regulation, a licensed RLD retailer that wishes to sell California prescription drugs is required to:

Employ a Qualified Individual and submit proof of the individual's credentials to CDFA. Employ a pharmacist on staff or on a quarterly consulting basis and submit an annual certification to CDFA.

Develop store specific written operating procedures.

Maintain the following additional information for each sale of a California prescription drug:

- Indication that the drug sold is a California prescription drug.
- Qualified Individual who sold the product.
- Unique transaction number.
- o Copy of the prescription with the unique transaction number recorded on it.

9. Does CDFA charge an additional fee for licensed RLD retailers who wish to sell California prescription drugs?

No, CDFA does not charge a fee in addition to the annual \$50 license see for RLD retailers who wish to sell California prescription drugs. However, retailers who wish to sell California prescription drugs must submit the following information to the AUS email at AUS_Regulations@cdfa.ca.gov and receive approval from CDFA prior to selling any California prescription drug:

California Department of Food and Agriculture, Antimicrobial Use and Stewardship Telephone: 916-900-5022 • aus_regulations@cdfa.ca.gov • www.cdfa.ca.gov/ahfss/AUS

Identification of one or more Qualified Individuals and proof of credentials; and Identification of a staff pharmacist, <u>or</u> a signed a written certification from a consulting pharmacist, dated within the previous three months.

10. Are licensed RLD retailers required to sell California prescription drugs?

No, licensed RLD retailers are not required to sell California prescription drugs. Whether or not to sell California prescription drugs is a business decision at the discretion of each licensed RLD retailer and may depend on a number of factors, such as business size, staffing, demand, sales volume, etc.

11. What are federal prescription drugs and how are they different from California prescription drugs?

The US Food and Drug Administration (FDA) is responsible for determining the marketing status of animal drug products. A federal prescription drug is any product that the FDA has determined is only safe to be dispensed by or upon the lawful written order of a licensed veterinarian. These products are labeled with the statement: "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian." A California prescription drug is a medically important antimicrobial drug that the FDA has determined is safe for over the counter sale, but requires a prescription for sale or use in California according to California Food and Agricultural Code Division 7, Chapter 4.5.

12. Can licensed RLD retailers sell federal prescription drugs?

No, licensed RLD retailers <u>cannot</u> sell any drug federally labeled as prescription-only. Federal prescription drugs are not registered with CDFA and may only be sold by retailers licensed by the California Board of Pharmacy. For information on how to become licensed to sell federal prescription drugs, please visit the California Board of Pharmacy's website, https://www.pharmacy.ca.gov/.

For additional information, please contact AUS:

Email AUS_Regulations@cdfa.ca.gov Call 916-900-5022