

CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE

CALIFORNIA CODE OF REGULATIONS

TITLE 3. FOOD AND AGRICULTURE

DIVISION 5. LIVESTOCK DRUGS

CHAPTER 1. SALES OF RESTRICTED LIVESTOCK DRUGS

PROPOSED REGULATION TEXT

ARTICLE 1. DEFINITIONS

§5000. Definitions.

For purposes of this chapter, the following definitions apply:

(a) "Designated individual" means an individual representing a restricted livestock drug licensee that is assigned to perform the duties required to maintain a restricted livestock drug licensee's compliance with California livestock drug laws and regulations.

(b) "Livestock" includes all animals in a species typically raised, kept, or used for profit and includes bees, mammals, avian, aquatic, and amphibian species. It does not include those species which are usually kept as pets, such as dogs, cats, and pet birds. "Species that are raised, kept, or used for profit" means:

(1) Livestock that are typically used for financial gain, commercial use, breeding, competition, or show; or

(2) Livestock whose owners are engaged in business using animals for financial gain, commercial use, breeding, competition, or show.

(c) "Restricted livestock drug" means any livestock drug which is sold in such form that it might be administered to humans and if so administered would be dangerous to the health of such humans or any livestock drug which if improperly administered to livestock is dangerous to the health of such livestock or to humans who consume products from such livestock. Restricted drugs include all of the following:

(1) Arsenic compounds and preparations.

(2) Diethylstilbestrol and other substances which have a hormonelike action.

(3) Sulfanilamide or substitute sulfanilamides.

(4) Antibiotic preparations, including medically important antimicrobial drugs as defined in Section 14400(a) of Chapter 4.5 of Division 7 of the Food and Agricultural Code.

(5) Such other drugs and their preparations which the Secretary determines are hazardous to the health of livestock or the public safety.

(d) "Restricted livestock drug licensee" is a person that has obtained a restricted livestock drug license pursuant to Article 5 (commencing with Section 14321) of Chapter 4 of Division 7 of the Food and Agricultural Code.

Note: Authority Cited: Sections 407 and 14231 of the Food and Agricultural Code. Reference: Section 14203, 14205, 14321 of the Food and Agricultural Code.

ARTICLE 2. GENERAL PROVISIONS

§5001. Sales of Restricted Livestock Drugs.

(a) A person shall not sell any restricted livestock drug in this state at retail unless he or she holds a restricted livestock drug license issued pursuant to Article 5 of Chapter 4 of Division 7 of the Food and Agricultural Code.

(1) The term sell includes in-person sales at a physical place of business, including mobile units, as well as all sales conducted using the internet, electronic mail, telephone, facsimile, mail order, or catalog.

(2) A person whose business is located outside of the state of California who makes any sale of a restricted livestock drug into California must obtain a restricted livestock drug license prior to any such sale.

(3) A separate restricted livestock drug license is required for each place of business at which any restricted livestock drug is kept for sale, and for each mobile unit in which any such drug is kept for sale.

(b) A copy of the laws and regulations relating to livestock drugs shall be provided to each restricted livestock drug licensee upon issuance of the license. The failure of any restricted livestock drug licensee to receive a copy of the regulations is not a defense to a violation of the regulations.

(c) Each restricted livestock drug licensee shall be supervised or managed by a designated individual named on the restricted livestock drug license application that shall be responsible for maintaining the restricted livestock drug licensee's compliance with state laws and regulations.

(d) All livestock drugs sold by restricted livestock drug licensees must be registered pursuant to Article 4 of Chapter 4 of Division 7 of the Food and Agricultural Code.

Note: Authority Cited: Sections 407 and 14231 of the Food and Agricultural Code. Reference: Sections 14281, 14321 and 14326 of the Food and Agricultural Code.

ARTICLE 3. LICENSING

§5002. License Application.

(a) Any person may file with the Secretary an application for a restricted livestock drug license pursuant to Article 5 of Chapter 4 of Division 7 of the Food and Agricultural Code. The application shall be on a form which is supplied by the Secretary and shall contain:

(1) The legal business name, Federal Tax ID number, and telephone number of the firm.

(2) The full name of the owner or owners of the firm.

(3) The mailing address of the firm, including street number, city, county, state, and ZIP code.

(4) The location of business to be licensed, including street number, city, county, state, and ZIP code. If the business to be licensed is conducting online sales, the website where sales are conducted shall be provided.

(5) A designated individual for the business to be licensed who shall be responsible for compliance with the livestock drugs law and shall serve as the primary emergency contact. The following information shall be provided for the designated individual: name, title, email address, and telephone number.

(6) A secondary emergency contact for the business to be licensed. The following information shall be provided for the secondary emergency contact: name, title, email address, and telephone number.

(7) A disclosure of whether the business to be licensed is a mobile unit. If the location to be licensed is a mobile unit, the license plate number shall be provided.

(8) A disclosure of the company type (corporation, partnership, individual, limited liability company, co-partnership, or other). If other, the type shall be specified.

(9) A disclosure of the type of sales conducted by the business to be licensed (sales directly to the end user for the purpose of administration to livestock and/or sales to other businesses for the purpose of resale).

(10) A disclosure of whether the business to be licensed will sell medically important antimicrobial drugs as defined in Section 14400(a) of Chapter 4.5 of Division 7 of the Food and Agricultural Code.

(11) A certification that the information provided on the application is complete, true, and accurate. The certification shall be made by the owner of the firm or designated individual for the business to be licensed and shall contain the following information: name, title, signature, and date signed.

(b) The application shall be accompanied by an application fee of fifty dollars (\$50).

(1) The fee is not refundable if the license is refused.

(2) If the license is issued, the application fee covers the license for the remainder of the current calendar year in which it is issued.

(3) The fee shall not be reduced to cover a fraction of a year.

(c) The application described in Section 5002(a) and accompanying fee described in Section 5002(b) shall be submitted in one of two ways:

(1) Electronically using the Feed, Fertilizer, and Livestock Drugs Regulatory Services online registration database.

(2) By mail using a form available on the Feed, Fertilizer, and Livestock Drugs Regulatory Services website.

(d) A restricted livestock drug licensee shall notify the Department within thirty (30) calendar days if any of the information provided on the license application changes after the license is issued.

Note: Authority Cited: Sections 407 and 14231 of the Food and Agricultural Code. Reference: Sections 14322, 14323, and 14324 of the Food and Agricultural Code.

§5003. License Renewal.

(a) Applications for restricted livestock drug license renewal shall be submitted on or before January 31 of each year on a form supplied by the Secretary which shall be limited to the information described in Section 5002(a) of this chapter.

(b) The fee for the renewal application for a license is fifty dollars (\$50) per year, payable on or before January 31 of each year. If the fee is not paid by that date, a penalty of fifty dollars (\$50) shall be added to the fee.

(c) Renewal applications and accompanying fees shall be submitted in the manner specified in Section 5002(c) of this chapter.

(d) A restricted livestock drug licensee shall notify the Department in a timely manner if any of the information provided on the license renewal changes after the license is renewed.

Note: Authority Cited: Sections 407 and 14231 of the Food and Agricultural Code. Reference: Section 14325 of the Food and Agricultural Code.

ARTICLE 4. RECORDKEEPING

§5004. Sales Records.

(a) Each restricted livestock drug licensee shall maintain in this state, or with the Secretary's permission, at another location, an accurate record of each sale of a restricted livestock drug by the licensee.

(b) The record of each sale of a restricted livestock drug shall include all of the following:

(1) The established drug name or trade name, route of administration, quantity, and lot number(s) of the restricted livestock drug sold.

(2) Date of sale.

(3) Name, address, telephone number, and email address (optional) of the purchaser.

(4) Signature of the purchaser.

(5) Any additional information as required under Section 5008 of the California Code of Regulations regarding retail sales of medically important antimicrobial drugs.

(c) The record of each sale of a restricted livestock drug shall be kept by a restricted livestock drug licensee for a period of not less than three years following the transaction.

(d) The record of each sale of a restricted livestock drug is subject to audit by the Secretary and shall be made available to the Secretary upon request.

Note: Authority Cited: Sections 407 and 14231 and of the Food and Agricultural Code.
Reference: Sections 14295, 14328, 14329, and 14330 of the Food and Agricultural Code.

CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE

**CALIFORNIA CODE OF REGULATIONS
TITLE 3. FOOD AND AGRICULTURE
DIVISION 5. LIVESTOCK DRUGS
CHAPTER 2. SALES OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS**

PROPOSED REGULATION TEXT

ARTICLE 1. DEFINITIONS

§5005. Definitions.

For purposes of this chapter, the following definitions apply:

(a) "Dispense" means to deliver a medically important antimicrobial drug to a purchaser under a lawful veterinary prescription or veterinary feed directive.

(b) "Extra label use" has the same definition as in Section 530.3(a) of Title 21 of the Code of Federal Regulations.

(c) "Inventory" means a record of accountability for all medically important antimicrobial drugs.

(d) "Livestock" includes all animals in a species typically raised, kept, or used for profit and includes mammals, avian, aquatic, and amphibian species. It does not include bees or those species which are usually kept as pets, such as dogs, cats, and pet birds. "Species that are raised, kept, or used for profit" means:

(1) Livestock that are typically used for financial gain, commercial use, breeding, competition, or show; or

(2) Livestock whose owners are engaged in business using animals for financial gain, commercial use, breeding, competition, or show.

(e) "Medically important antimicrobial drug" means a restricted livestock drug as defined in Section 14400(a) of Chapter 4.5 of Division 7 of the Food and Agricultural Code.

(f) "Restricted livestock drug" means any livestock drug which is sold in such form that it might be administered to humans and if so administered would be dangerous to the health of such humans or any livestock drug which if improperly administered to livestock is dangerous to the health of such livestock or to humans who consume products from such livestock. Restricted drugs include all of the following:

(1) Arsenic compounds and preparations.

(2) Diethylstilbestrol and other substances which have a hormonelike action.

(3) Sulfanilamide or substitute sulfanilamides.

(4) Antibiotic preparations, including medically important antimicrobial drugs as defined in Section 14400(a) of Chapter 4.5 of Division 7 of the Food and Agricultural Code.

(5) Such other drugs and their preparations which the Secretary determines are hazardous to the health of livestock or the public safety.

(g) "Restricted livestock drug licensee" is a person that has obtained a restricted livestock drug license pursuant to Article 5 (commencing with Section 14321) of Chapter 4 of Division 7 of the Food and Agricultural Code.

(h) "Veterinary feed directive" has the same definition as in Section 558.3 of Title 21 of the Code of Federal Regulations.

(i) "Veterinary prescription" means a lawful non-verbal order, given by a licensed veterinarian, for use of a medically important antimicrobial drug.

Note: Authority Cited: Sections 407, 14231, 14403, and 14405 of the Food and Agricultural Code. Reference: Section 14203, 14400, 14403 and 14405 of the Food and Agricultural Code.

ARTICLE 2. GENERAL PROVISIONS

§5006. Sales of Medically Important Antimicrobial Drugs.

(a) Notwithstanding Sections 14401 and 14402 of the Food and Agricultural Code and Article 15 (commencing with Section 4196) of Chapter 9 of Division 2 of the Business and Professions Code, medically important antimicrobial drugs may be sold by retailers licensed pursuant to Article 5 (commencing with Section 14321) of Chapter 4 of Division 7 of the Food and Agricultural Code with a prescription or veterinary feed directive from a licensed veterinarian.

(b) Medically important antimicrobial drugs are a subset of the broader classification of restricted livestock drugs under Section 14203(d) of the Food and Agricultural Code and are therefore subject to Chapter 4 of Division 7 of the Food and Agricultural Code and Chapter 1 of Division 5 of Title 3 of the of the California Code of Regulations, in addition to Chapter 4.5 of Division 7 of the Food and Agricultural Code and the provisions of this chapter.

(c) Pursuant to Food and Agricultural Code Section 14262(d), a restricted livestock drug licensee shall not sell any drug that is required by federal law to be sold on prescription only unless they also hold a valid license under Chapter 9 of Division 2 of the Business and Professions Code allowing them to do so.

(d) The provisions of this chapter apply only to medically important antimicrobial drugs sold by restricted livestock drug licensees to the end user for the purpose of administration to livestock, rather than sales made to other businesses for the purpose of resale.

Note: Authority Cited: Sections 407, 14231, 14403, and 14405 of the Food and Agricultural Code. Reference: Sections 14203, 14262, 14321, and 14403 of the Food and Agricultural Code.

ARTICLE 3. ADDITIONAL REQUIREMENTS FOR RETAIL SALES OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS

§5007. Verification.

(a) A restricted livestock drug licensee shall not sell a medically important antimicrobial drug at retail without the purchaser first providing a valid veterinary prescription or veterinary feed directive.

(b) A restricted livestock drug licensee shall verify that the veterinarian listed on a veterinary prescription or veterinary feed directive is currently licensed by the California Veterinary Medical Board prior to completing the retail sale of any medically important antimicrobial drug.

(1) For the purpose of veterinarian license verification, a restricted livestock drug licensee shall rely upon the information on the Department of Consumer Affairs' licensing and enforcement website.

(c) No medically important antimicrobial drug may be sold at retail by a restricted livestock drug licensee more than six months after the issuance date of a veterinary prescription or veterinary feed directive or after the expiration date listed on a veterinary prescription or veterinary feed directive, whichever comes first.

Note: Authority Cited: Sections 407, 14231, 14403, and 14405 of the Food and Agricultural Code. Reference: Section 14403 of the Food and Agricultural Code, Section 4830 of the Business and Professions Code, Section 558.6(b)(3)(v) of Title 21 of the Code of Federal Regulations, Section 1780.1(g)(2) of Title 16 of the California Code of Regulations.

§5008. Sales Records.

(a) In addition to the recordkeeping requirements for sales of restricted livestock drugs listed in Chapter 4 of Division 7 of the Food and Agricultural Code and Section 5004 of the California Code of Regulations, each restricted livestock drug licensee shall include the following additional information in the record for each retail sale of a medically important antimicrobial drug:

(1) The name and California Veterinary Medical Board license number of the prescribing veterinarian.

(2) A unique transaction identification number. This number must be listed on the record of sale as well as on the corresponding copy of the veterinary prescription or veterinary feed directive maintained on file.

(3) A copy of the veterinary prescription or veterinary feed directive labeled with the corresponding unique transaction identification number.

(b) The record of each retail sale of a medically important antimicrobial drug and accompanying copy of the veterinary prescription or veterinary feed directive shall be kept by a restricted livestock drug licensee for a period of not less than three years following the retail transaction.

(c) The record of each retail sale of a medically important antimicrobial drug and accompanying copy of the veterinary prescription or veterinary feed directive is subject to audit by the Secretary and shall be made available to the Secretary upon request.

Note: Authority Cited: Sections 407, 14231, 14403, and 14405 of the Food and Agricultural Code. Reference: Sections 14295, 14328, 14329, 14330, 14403, 14405, and 14406 of the Food and Agricultural Code.

§5009. Storage and Inventory.

(a) Each restricted livestock drug licensee shall store medically important antimicrobial drugs in a secure, lockable area.

(b) Entry into areas where medically important antimicrobial drugs are held shall be limited to authorized personnel.

(c) Restricted livestock drug licensees shall establish, maintain, and adhere to written policies and training procedures for all employees that handle and dispense medically important antimicrobial drugs for retail sale and shall include the following:

(1) The receipt, security, storage, inventory, labeling, and dispensing of medically important antimicrobial drugs.

(2) Identifying, recording, and internally reporting losses or thefts of medically important antimicrobial drugs.

(3) Maintaining a correct inventory of medically important antimicrobial drugs and verifying that inventory records are free from errors and inaccuracies.

(4) Maintaining records to document proper storage conditions for medically important antimicrobial drugs as recommended by the manufacturer and required by regulation.

(d) All invoices and records of shipment for medically important antimicrobial drugs shall be kept on file and maintained for at least three years from the date of shipment.

(e) All invoices and records of shipment for medically important antimicrobial drugs are subject to audit by the Secretary and shall be made available to the Secretary upon request.

Note: Authority Cited: Sections 407, 14231, 14403, and 14405 of the Food and Agricultural Code. Reference: Sections 14295, 14327, 14330, 14403, and 14405 of the Food and Agricultural Code.

§5010. Labeling.

(a) A prescription for a medically important antimicrobial drug shall be dispensed in accordance with its federally approved label. If a medically important antimicrobial drug is to be administered off-label in accordance with a veterinarian prescription, it shall be dispensed by a restricted livestock drug licensee with an added label including all of the following:

(1) Date dispensed.

(2) Name and address of the prescribing veterinarian.

(3) Name of the client who was issued the veterinary prescription or veterinary feed directive.

(4) Established name of the medically important antimicrobial drug or, if formulated from more than one active ingredient, the established name of each ingredient.

(5) Class/species or identification of the animal or the herd, flock, pen, lot, or other group of animals being treated.

(6) Condition for which the medically important antimicrobial drug was prescribed.

(7) Directions for use, including dosage, frequency, route of administration, duration of treatment, and withdrawal time.

(8) Date of expiration.

(b) Upon receipt of a veterinary prescription or veterinary feed directive lacking sufficient information to fulfill the labeling requirements described in Section 5010(a), the restricted livestock drug licensee shall contact the prescribing veterinarian to obtain the required information prior to dispensing the medically important antimicrobial drug and shall document any such request for clarification.

Note: Authority Cited: Sections 407, 14231, 14403, and 14405 of the Food and Agricultural Code. Reference: Section 14330 and 14403 of the Food and Agricultural Code.

ARTICLE 4. VIOLATIONS AND PENALTIES

§5011. Violations.

(a) It is unlawful for any restricted livestock drug licensee to sell any medically important antimicrobial drug that is required by federal law to be sold on prescription only unless they also hold a valid license under Chapter 9 of Division 2 of the Business and Professions Code allowing them to do so.

(b) It is unlawful for any restricted livestock drug licensee to sell any medically important antimicrobial drug at retail unless the purchaser provides a valid veterinary prescription or veterinary feed directive.

(c) It is unlawful for any restricted livestock drug licensee to sell any medically important antimicrobial drug at retail if the veterinary prescription or veterinary feed directive provided by the purchaser is not issued by a veterinarian licensed by the California Veterinary Medical Board.

(d) It is unlawful for any restricted livestock drug licensee to sell any medically important antimicrobial drug at retail beyond the expiration date listed on the veterinary prescription or veterinary feed directive or if the date of issuance of the veterinary prescription or veterinary feed directive is more than six months prior to the date of purchase.

(e) It is unlawful for any restricted livestock drug licensee to prevent the entry into and inspection of any premises where medically important antimicrobial drugs are stored or sold.

(f) It is unlawful for any restricted livestock drug licensee to fail to keep adequate retail sales records of medically important antimicrobial drugs or to fail to make the required records available to the Secretary upon request as required by Section 5008 of this chapter.

(g) It is unlawful for any restricted livestock drug licensee to fail to comply with the minimum standards for storage and inventory of medically important antimicrobial drugs as required by Section 5009 of this chapter.

(h) It is unlawful for any restricted livestock drug licensee to fail to comply with the minimum standards for labeling medically important antimicrobial drugs sold at retail as required by Section 5010 of this chapter.

Authority Cited: Sections 407, 14231, 14403, and 14405 of the Food and Agricultural Code. Reference: Sections 14203, 14262, 14295, 14321, 14327, 14328, 14329, 14330, 14403, 14405, and 14406 of the Food and Agricultural Code, Section 4830 of the Business and Professions Code, Section 558.6(b)(3)(v) of Title 21 of the Code of Federal Regulations, Section 1780.1(g)(2) of Title 16 of the California Code of Regulations.

§5012. Penalties.

(a) Upon finding a violation, the Secretary shall issue a notice of warning.

(b) A person who violates this chapter shall be liable for a civil penalty of two hundred and fifty dollars (\$250) for each day a violation occurs if at least one notice of warning has been issued by the Secretary for a prior violation within the preceding 12-month period.

(c) For a second or subsequent violation, a person who violates this chapter shall be punishable by an administrative fine, levied by the Secretary, in the amount of five hundred dollars (\$500) for each day a violation occurs.

(d) A person may contest a penalty or fine for any violation specified in Section 5011 by requesting a hearing before the Secretary. At the hearing, the person shall be given the right to present evidence on his or her own behalf.

(1) Requests must be submitted by written correspondence to the Secretary of the Department of Food and Agriculture, 1220 "N" Street, Room A-107, Sacramento, California 95814.

(2) Requests must be submitted within 30 days from the date of the notice of penalty or fine.

(3) Requests must be accompanied by a written statement supporting the need for the hearing.

(4) A formal or informal hearing may be requested. The hearing officer shall determine whether to proceed with an informal hearing or whether a formal hearing or other appropriate administrative proceeding may be required by statute pursuant to Chapter 5 (commencing with section 11500), Part 1, Division 3, Title 2 of the Government Code.

(5) If a hearing is not requested, the penalty or fine shall constitute a final and nonreviewable order.

(e) The Secretary may, after a hearing, refuse to issue or renew, or may suspend or revoke a restricted livestock drug license for any violation of this chapter, pursuant to the procedural requirements outlined in Section 14382 of the Food and Agricultural Code and Government Code Title 2, Division 3, Part 1, Chapter 5.

Note: Authority Cited: Sections 407, 14231, 14403, and 14405 of the Food and Agricultural Code. Reference: Sections 14382 and 14408 of the Food and Agricultural Code, Division 3 Part 1 Chapter 5 of Title 2 of the Government Code.