

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
ARTICLE 1. DEFINITIONS
ARTICLE 2. GENERAL PROVISIONS
ARTICLE 5. VIOLATIONS AND PENALTIES**

**(Notice Published November 4th, 2022)
NOTICE OF PROPOSED RULEMAKING**

NOTICE IS HEREBY GIVEN that the Department of Food and Agriculture (Department) proposes to adopt and amend regulations as described below within the California Code of Regulations, Title 3 (3 CCR), Division 5, Chapter 1, Articles 1, 2, and 5, Sections 5000, 5001, 5001.1, and 5005. The Department is issuing this notice to meet requirements set forth in Government Code Section 11346.4.

PUBLIC HEARING

Any interested person or his or her duly authorized representative may request a public hearing on this proposed action by submitting a written request no later than 15 days before the close of the written comment period noted below.

WRITTEN COMMENT PERIOD

Any interested person, or his or her authorized representative, may submit written comments relevant to the proposed regulatory action to the Department by mail, fax, or email. The written comment period will close on December 27th, 2022. The Department will only consider comments received by that date. Submit written comments to:

Ashley James, Research Data Analyst II
California Department of Food and Agriculture
Feed, Fertilizer, and Livestock Drugs Regulatory Services Branch
1220 N Street
Sacramento, CA 95814
(916) 900-5022
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Following the written comment period or public hearing, if one is requested, and after considering all comments, objections, and recommendations regarding the proposed actions, the Department, at its own motion or at the request of any interested person, may adopt the proposal substantially as set forth without further notice.

AUTHORITY AND REFERENCE

Notice is hereby given that the California Department of Food and Agriculture, pursuant to the authority vested by Sections 407 and 14231 of the Food and Agricultural Code (FAC), proposes to make changes to Title 3, Division 5, Chapter 1 of the CCR to implement, interpret, or make specific FAC Sections 14203, 14205, 14281, 14285, 14290, 14294, 14296, 14321, 14326, 14327, 14328, 14329, 14351, 14354, 14356, 14357, and 14362.

INFORMATIVE DIGEST / POLICY STATEMENT

The Department's Livestock Drugs Program is responsible for enforcing the Livestock Drug Law (FAC Division 7, Chapter 4) by maintaining the registration of over-the-counter livestock drugs and retailer licenses for the sale of restricted livestock drugs. Inspectors and investigators located throughout the state conduct inspections at retailers and distributors, respond to consumer complaints, and enforce the laws and regulations that govern the manufacturing, distribution, and labeling of livestock drugs in California. The work of the Livestock Drugs Program helps ensure products reviewed for safety and efficacy are available for their appropriate use in treating the livestock population of the state. This helps ensure a clean and wholesome supply of food and fiber, as well as providing assurance that the product received by the consumer is the quality purported by the manufacturer.

The Department is proposing the adoptions and revisions to 3 CCR, Division 5, Chapter 1 described below.

The proposed amendment of Chapter 1 removes the language "sales of restricted" from the chapter title.

The proposed adoption of Section 5000(g) defines the term "sell."

The proposed amendment of Section 5001 removes the language "of restricted livestock drugs" from the section title.

The proposed amendment of Section 5001(a) removes subsections (1) and (2) that define types of sales.

The proposed amendment of Section 5001(c) replaces the phrase "kept for sale" with the term "sold."

The proposed amendment of Section 5001(d) removes the phrase "by restricted livestock drug licensees" and adds the phrase "within or into this state."

The proposed adoption of Section 5001.1 defines adulteration and clarifies what the Department will consider to be an adulterated livestock drug for enforcement purposes.

The proposed revision of Section 5005(c) adds the phrase “within or into this state.”

The proposed amendment to Section 5005(i) removes the term “restricted.”

The proposed amendment to Section 5005(j) removes the term “restricted.”

Anticipated Benefits of the Proposed Regulations:

The Department anticipates the proposed regulatory changes will be consistent with the intent of the Livestock Drug Law, prevent potentially unsafe unregistered livestock drug products from being sold to California consumers from out of state, and enable the Department to pursue consistent enforcement action against all unregistered and/or adulterated livestock drug products.

Determination of Inconsistency/Incompatibility with Existing Regulations:

The Department evaluated the proposed regulations and made several determinations required by Government Code Section 11346.5(a)(3)(A) to 11346.5(a)(3)(D). The Department determined that there are no existing state laws or regulations related directly to the proposed action and the effect of the proposed action; the proposed regulations are not inconsistent or incompatible with existing state regulations.

PLAIN ENGLISH REQUIREMENT

The Department prepared the proposed regulations pursuant to the standard of clarity provided in Government Code Section 11349 and the plain English requirements of Government Code Sections 11342.580 and 11346.2, subdivision (a)(1). The proposed regulations are written to be easily understood by the individuals that will use them.

DISCLOSURES REGARDING THE PROPOSED ACTION

The Department has made the following initial determinations:

Mandate on local agencies and school districts: None.

Cost or savings to any state agency: None.

Cost to any local agency or school district which must be reimbursed in accordance with Government Code sections 17500 through 17630: None.

Other nondiscretionary cost or savings imposed upon local agencies: None.

Cost or savings in federal funding to the state: None.

Significant, statewide adverse economic impact directly affecting business including the ability of California businesses to compete with businesses in other states: None.

Cost impacts on a representative person or business: The Department is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Significant effect on housing costs: None.

RESULTS OF THE ECONOMIC IMPACT ASSESSMENT/ANALYSIS

California Government Code Section 11346.3 requires state agencies to assess the potential economic impacts on California businesses and individuals when proposing to adopt or amend any administrative regulation. The Department has initially determined that the proposed regulatory action will not have a broad economic or fiscal impact to the Livestock Drug industry.

These proposed regulatory actions will not:

- 1) Create or eliminate jobs within the state
- 2) Create new businesses or eliminate existing businesses within the State of California
- 3) Affect the expansion of businesses currently operating within the State of California
- 4) Affect worker safety or the state's environment. The proposed regulatory action will benefit the health and welfare of California residents by enabling the Department to prevent potentially unsafe unregistered livestock drug products from being sold to California consumers by firms based out of state, ultimately enhancing consumer protections.

The proposed regulatory action will not require any additional ongoing expenses to individuals or businesses in California. However, the Department does anticipate additional ongoing expenses for out of state manufacturers whose unregistered livestock drug products are sold to California consumers. To date, the Department has discovered a total of 678 unregistered livestock drug products made by 102 out of state manufacturers being sold to California consumers. The fee for a two-year livestock drug registration is \$180 per product; an average of seven unregistered products per out of state manufacturer totals to an average cost of \$1,260 per out of state manufacturer every other year.

SMALL BUSINESS DETERMINATION

The Department has initially determined that the proposed regulations will not impact small businesses. The proposed revisions will not have any associated economic impact for California businesses because these are existing statutory requirements.

However, the Department does anticipate a small economic impact for out of state manufacturers whose unregistered livestock drug products are sold to California consumers.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code Section 11346.5(a)(13), the Department must determine that no reasonable alternative it has considered or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Department invites interested persons to present statements or arguments with respect to alternatives to the proposed regulations at the scheduled hearing or during the written comment period.

CONTACT PERSONS

Written comments and inquiries concerning the substance of the proposed regulation, initial statement of reasons, proposed actions, location of the rulemaking file, or a request for a public hearing should be directed to:

Ashley James, Research Data Analyst II
California Department of Food and Agriculture
Feed, Fertilizer, and Livestock Drugs Regulatory Services Branch
1220 N Street
Sacramento, CA 95814
Email: feed_lvstk@cdfa.ca.gov
Phone: 916-900-5022

The backup contact person for these inquiries is:

Erika Lewis, Research Data Specialist II
California Department of Food and Agriculture
Feed, Fertilizer, and Livestock Drugs Regulatory Services Branch
1220 N Street
Sacramento, CA 95814
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Phone: 916-900-5022

AVAILABILITY OF STATEMENT OF REASONS, TEXT OF PROPOSED REGULATIONS, AND RULEMAKING FILE

The Department will have the entire rulemaking file available for inspection and copying throughout the rulemaking process. A copy of this notice, the proposed regulation text, and the initial statement of reasons may be obtained by contacting Ashley James at the address provided in the "Contact Persons" section.

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the notice of proposed action, the initial statement of reasons, and the proposed regulation text in underline and strikethrough can be accessed through the Department's website: <https://www.cdfa.ca.gov/is/Regulations.html>.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After considering all timely and relevant comments received during the written comment period, the Department may adopt the proposed regulations substantially as described in this notice. If the Department makes modifications which differ, but are sufficiently related to the originally proposed text, it will make the modified text (with the changes clearly indicated) available to the public for at least 15 days prior to amendment. Please send requests for copies of any modified regulations to the attention of Ashley James at the address provided in the "Contact Persons" section. The Department will accept written comments on the modified regulations for 15 days after the date on which they are made available.

AVAILABILITY OF THE FINAL STATEMENT OF REASONS

Upon its completion, copies of the final statement of reasons may be obtained by contacting Ashley James at the address provided in the "Contact Persons" section.