CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE

TITLE 3 OF THE CALIFORNIA CODE OF REGULATIONS

NOTICE OF PROPOSED RULEMAKING ACTION

Notice is hereby given that the Department of Food and Agriculture (Department) intends to adopt Division 5, Livestock Drugs and create Chapter 1, Sales of Restricted Livestock Drugs (Sections 5000-5004) and Chapter 2, Sales of Medically Important Antimicrobial Drugs (Sections 5005-5012) described below. With this rulemaking, the Department will propose permanent regulations, after the consideration of all comments, objections, and recommendations. The Department is issuing this notice to meet requirements set forth in Government Code Section 11346.4.

PUBLIC HEARING

Any interested person, or their authorized representative, may present, either orally or in writing, comments regarding the proposed action at one of the public hearings, to be held at the following times and locations:

Tuesday, August 15, 2017 from 1 PM to 2 PM
California Department of Food and Agriculture Office
1910 S Archibald Ave, Ste Y
Ontario, CA 91761

Tuesday, August 22, 2017 from 10 AM to 11 AM
California Department of Food and Agriculture Office
2800 Gateway Oaks Dr, Room 101
Sacramento, CA 95833

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. Comments may be submitted by mail to the address provided below, by facsimile (FAX) to (916) 900−5349, or by email to aus_regulations@cdfa.ca.gov. The written comment period closes at 5:00 p.m. on August 22, 2017. The Department will only consider comments received at the Department by that time.

Submit comments to:
Rachelle Kennedy, Senior Environmental Scientist (Specialist)
Feed, Fertilizer, and Livestock Drugs Regulatory Services Branch
California Department of Food and Agriculture
1220 N Street, Sacramento, CA 95814

AUTHORITY AND REFERENCE

The Department is proposing changes to Title 3 of the California Code of Regulations as follows: adoption of Sections 5000 – 5012. Food and Agricultural Code Sections 407, 14231, 14403, and 14405 authorize the Department to adopt these proposed regulations. The proposed regulations implement, interpret, and make specific Sections 14203, 14205, 14262, 14295, 14321, 14322, 14323, 14324, 14325, 14326, 14327, 14328, 14329, 14330, 14382,

14400, 14403, 14405, 14406, 14408 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 and Division 3, Part 1, Chapter 5 of Title 2 of the Government Code.

INFORMATIVE DIGEST / POLICY STATEMENT

California Senate Bill 27 (Hill) was signed by Governor Brown on October 10, 2015 with the intent to preserve the efficacy and ensure current and future availability of medically important antimicrobial drugs for use in livestock to maintain animal health and welfare while minimizing potential public health impacts. The bill resulted in additions to the California Food and Agricultural Code (Division 7, Chapter 4.5, Sections 14400-14408) that address the use of medically important antimicrobial drugs in livestock, development of antimicrobial drug stewardship programs and best management practices, and surveillance of antimicrobial use and practices as well as antimicrobial resistance patterns in bacteria.

To implement the new provisions of Division 7, Chapter 4.5, the California Department of Food and Agriculture (hereafter referred to as “the Department”) created the Antimicrobial Use and Stewardship (AUS) program. The AUS program spans two divisions within the Department, the Division of Inspection Services and the Animal Health and Food Safety Services Division. Within the Division of Inspection Services, the Livestock Drug Program is responsible for enforcing the current Livestock Drug Law (Division 7, Chapter 4 of the Food and Agricultural Code) by maintaining the registration of over-the-counter livestock drugs and licenses for the sale of restricted livestock drugs. There are two sections of Division 7, Chapter 4.5 that are subject to the current Livestock Drug Law. For this reason, the Division of Inspection Services has proposed regulations to provide improved clarity on portions of Food and Agricultural Code Division 7, Chapters 4 and 4.5 in an effort to help industry and consumers to better understand the law, while also helping the Department implement the mandates of Senate Bill 27.

Food and Agricultural Code (FAC) Section 14401 states that beginning January 1, 2018, a medically important antimicrobial drug shall not be administered to livestock unless ordered by a licensed veterinarian through a prescription or veterinary feed directive, pursuant to a veterinarian-client-patient relationship that meets the requirements of Section 2032.1 of Title 16 of the California Code of Regulations (CCR). However, to ensure that these drugs remain available to livestock producers for their appropriate use in protecting the health of the livestock population of the state, FAC Section 14403 goes on to state that medically important antimicrobial drugs may be sold by retailers licensed pursuant to FAC Division 7, Chapter 4, Article 5. This means that businesses licensed by the Division of Inspection Services to sell restricted livestock drugs under the current Livestock Drugs Law may continue to sell medically important antimicrobial drugs after FAC Section 14401 goes into effect on January 1, 2018. However, once the law goes into effect, restricted livestock drug licensees may only sell medically important antimicrobial drugs at retail when presented with a valid prescription or veterinary feed directive from a licensed veterinarian.

The existing Livestock Drug Law (FAC Division 7, Chapter 4) would benefit from additional clarity on which types of businesses are required to have a restricted livestock drug license, how to apply for and renew a license, what information is required on the license application, and what records must be kept and for how long. The new law on livestock use of antimicrobial drugs (FAC Division 7, Chapter 4.5) lacks clarity on what restricted livestock drug licensees

must do before selling medically important antimicrobial drugs at retail to ensure compliance with the law, what records must be kept and for how long, how medically important antimicrobial drugs must be stored, and how medically important antimicrobial drugs must be labeled prior to retail sale.

The proposed regulations for FAC Division 7, Chapter 4, will clarify the existing statutory requirement that all businesses selling restricted livestock drugs into California are required to have a restricted livestock drug license, will explain how to apply for and renew a license, as well as what records must be kept and how long the records must be kept. The proposed regulations for FAC Division 7, Chapter 4.5, will clarify the additional requirements associated with sales of medically important antimicrobial drugs, including what restricted livestock drug licensees are responsible for verifying prior to selling medically important antimicrobial drugs, additional recordkeeping requirements specific to retail sales of medically important antimicrobial drugs, provisions for the proper storage and inventory of medically important antimicrobial livestock drugs, and instructions for how medically important antimicrobial livestock drugs must be labeled prior to retail sale.

Anticipated benefits of the proposed regulations:
Clarifying that the existing livestock drug law requires all businesses, regardless of location (in state or out of state) or sales method (online, catalog, etc.), to have a restricted livestock drug license prior to selling restricted livestock drugs in California will help ensure that all restricted livestock drugs, including medically important antimicrobial drugs, are sold appropriately and in accordance with California law.

Specifying how to apply for and renew a restricted livestock drug license will provide improved clarity and uniformity for businesses and will help ensure that businesses become and remain licensed.

Explaining what records must be kept by restricted livestock drug licensees and how long the records must be kept will ensure that records of sale remain available for an adequate period of time for the Department to inspect in order to verify compliance with the requirements of the law.

Clarifying that medically important antimicrobial drugs are considered restricted livestock drugs will help ensure that businesses selling medically important antimicrobial drugs are aware that they must have a restricted livestock drug license and that they are required to comply with the laws and regulations applicable to sales of restricted livestock drugs in addition to medically important antimicrobial drugs.

Explaining what restricted livestock drug licensees are responsible for verifying prior to selling medically important antimicrobial drugs at retail will help ensure that medically important antimicrobial drugs are only sold with a valid prescription or veterinary feed directive from a licensed veterinarian.

Specifying the additional recordkeeping requirements for retail sales of medically important antimicrobial drugs will ensure that Department investigators are able to verify that restricted livestock drug licensees are complying with FAC Division 7, Chapter 4.5, by only selling medically important antimicrobial drugs when presented with a prescription or veterinary feed directive from a licensed veterinarian. The maintenance of adequate sales records will also help

the Department monitor the sales and usage of medically important antimicrobial drugs and prepare a report on their use for the Legislature, as required by FAC Division 7, Chapter 4.5.

Clarifying the proper storage and inventory of medically important antimicrobial drugs will minimize the risk of theft, loss, or illegal sale and will help ensure that medically important antimicrobial drugs are only available at retail with a valid prescription or veterinary feed directive from a licensed veterinarian.

Specifying how medically important antimicrobial livestock drugs must be labeled prior to retail sale will help ensure they are administered in accordance with veterinarian guidance and will minimize the risk of improper use that may contribute to antibiotic resistance.

Overall, the broad goal of these regulations is to help ensure that medically important antimicrobial livestock drugs remain available to livestock producers for their appropriate use in protecting the health of the livestock population of the state, and that such use will in turn benefit the general public by maintaining an abundant supply of wholesome food and fiber.

Inconsistency with federal or state statute or regulation: There is no existing, comparable federal statute or regulation regarding the licensing of retailers selling livestock drugs that are federally labeled for over the counter use, including medically important antimicrobial drugs, or any associated recordkeeping provisions. Title 21, Chapter I, Subchapter E: Part 558 of the Code of Federal Regulations describes restrictions on medicated animal feed and mandates the use of a veterinary feed directive. However, the proposed regulations supplement rather than conflict with federal regulations on the veterinary feed directive. The proposed regulations only seek to clarify how businesses licensed by the Department to sell restricted livestock drugs can comply with state-mandated provisions for the retail sale of medically important antimicrobial drugs. The regulations do not impact the sale of medicated animal feed by feed mills.

The Department is the only agency which can implement regulations pertaining to restricted livestock drug licensees. As required by Government Code Section 11346.5(a)(3)(D), the Department has conducted an evaluation of this regulation and has determined that it is not inconsistent or incompatible with existing state regulations. It is important to clarify that restricted livestock drug licensees may only dispense drugs that are federally labeled as over the counter; licensees may not sell drugs that are federally labeled as prescription only. Because only over the counter drugs are sold, restricted livestock drug licensees are therefore not subject to requirements governing prescription drugs. In addition, Section 14403 expressly exempts restricted livestock drug licensees from the requirements applicable to veterinary food-animal drug retailers found in Business and Professions Code Section 4196.

Documents incorporated by reference: None.

DISCLOSURES REGARDING THE PROPOSED ACTION

Mandate on local agencies and school districts: None.

Cost or savings to any state agency: The Department has anticipated costs resulting from the adoption of the regulations on sales of medically important antimicrobial drugs. The additional expenditures for the implementation of the proposed regulations have been included on 2017-2018 Budget Request Name 8570-007-BCP-CP-2017-GB. The cost for the Inspection Services

portion of the Antimicrobial Use and Stewardship program for the 2017/2018 fiscal year is budgeted at $827,000. The ongoing cost for the next two fiscal years is budgeted at $827,000 per year; this cost is expected to be permanent.

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.

Cost impacts on a representative person or business: Based on investigator observations in the field, the Department anticipates that compliance with the proposed regulations will only require use of existing facilities and basic office equipment for the majority of restricted livestock drug licensees and has concluded that cost impacts will not be significant. The Department has prepared an estimate of possible costs for small and typical businesses; please reference the Initial Statement of Reasons for additional information.

Persons/businesses affected by this proposal: This proposal affects businesses selling restricted livestock drugs in the state of California. In addition, some provisions of this proposal impose requirements specifically on those restricted livestock drug licensees that sell medically important antimicrobial drugs at retail.

Anticipated compliance requirements as a result of this proposal: The proposed regulations clarify the existing requirement that any businesses selling restricted livestock drugs into California, including alternative methods of sale (e.g., online) and businesses based out of state, must have a restricted livestock drug license issued by the Department. In addition, the proposed regulations clarify that all restricted livestock drug licensees are responsible for complying with the recordkeeping provisions for sales of restricted livestock drugs, as well as the additional verification, recordkeeping, storage, and labeling provisions for retail sales of medically important antimicrobial drugs.

Business reporting requirement: The proposed regulation clarifies that records relating to sales of restricted livestock drugs and medically important antimicrobial drugs must be maintained for three years and are subject to audit by the Secretary of the Department. However, the regulations do not impose a mandatory reporting requirement.

RESULTS OF THE ECONOMIC IMPACT ASSESSMENT/ANALYSIS

The Department has initially determined that the proposed regulatory action will not: (1) create or eliminate jobs within the State of California; (2) create new businesses or eliminate existing businesses within the State of California; or (3) affect the expansion of businesses currently doing business within the State of California.

Benefits of the proposed action: The Department believes that the proposed regulations will benefit the health and welfare of California residents. The proposed regulations will bring clarity to the existing law and will reduce the likelihood of unlawful sales. The lawful sale of restricted livestock drugs, including medically important antimicrobial drugs, will help ensure that a safe supply of livestock drugs remain available to producers for their appropriate use in protecting

the health of the livestock population of the state, thereby maintaining an abundant supply of wholesome food and fiber. This will also help to preserve the efficacy and ensure current and future availability of medically important antimicrobial drugs while minimizing potential public health impacts.

Significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states: Although the proposed action will directly affect businesses statewide, including small businesses, the Department concludes that the adverse economic impact, including the ability of California businesses to compete with businesses in other states, will not be significant.

Significant effect on housing costs: None.

SMALL BUSINESS DETERMINATION

The Department has determined that the proposed action will affect small business.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code Section 11346.5, subdivision (a)(13), the Department must determine that no reasonable alternative it has considered or that has otherwise been identified and brought to the attention of the agency would be more effective in carrying out the purpose for which the action is proposed, or 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

Mail and telephone inquiries concerning the proposed administrative action may be directed to:
Rachelle Kennedy, Senior Environmental Scientist (Specialist)
Feed, Fertilizer, and Livestock Drugs Regulatory Services Branch
California Department of Food and Agriculture
1220 N Street, Sacramento, CA 95814
Telephone: 916-900-5022

The backup contact person for these inquiries is:
Erika Lewis, Associate Governmental Program Analyst
Feed, Fertilizer, and Livestock Drugs Regulatory Services Branch
California Department of Food and Agriculture
1220 N Street, Sacramento, CA 95814
Telephone: 916-900-5022

Please direct requests for copies of the proposed text (the “express terms”) of the regulations, the Initial Statement of Reasons, the modified text of the regulations, if any, or other information upon which the rulemaking is based, to Rachelle Kennedy at the above address.

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 at its office located at 2800 Gateway Oaks Drive, Sacramento, CA 95833. As of the date this notice is published in the Notice Register, the rulemaking file consists of this notice, the proposed text of the regulations, and the Initial Statement of Reasons. Copies may be obtained by contacting Rachelle Kennedy.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After considering all timely and relevant comments received, the Department may adopt the proposed regulations substantially as described in this notice. If the Department makes modifications which 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 before the Department adopts the regulations as revised. Please send requests for copies of any modified regulations to the attention of Rachelle Kennedy. 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 Rachelle Kennedy.

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Action, the Initial Statement of Reasons, and the text of the regulations in underline and strikeout can be accessed through the Department’s website: https://www.cdfa.ca.gov/is/Regulations.html.