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

INITIAL STATEMENT OF REASONS

Within the California Department of Food and Agriculture (Department), the Livestock Drug Program is responsible for enforcing the Livestock Drug Law (Food and Agricultural Code (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 Drug 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 proposed adoptions and amendments described below will provide enhanced clarity of the livestock drug law.

SECTIONS AFFECTED

California Code of Regulations (CCR), Title 3, Division 5, Chapter 1, Articles 1, 2, and 5, Sections 5000, 5001, 5001.1, and 5005.

PROBLEM STATEMENT

The Department originally adopted CCR Title 3 (3 CCR), Division 5, Chapter 1 for the purpose of implementing California State Senate Bill 27 (Hill, 2016) concerning medically important antimicrobial drugs, a type of restricted livestock drug. For this reason, 3 CCR Division 5, Chapter 1 focuses exclusively on restricted livestock drugs. In the years since the regulations were adopted, it has become apparent that revisions are needed to broaden the scope of 3 CCR Division 5, Chapter 1 to ensure further clarity for all livestock drugs, not just restricted livestock drugs.

Part of the purpose of 3 CCR Division 5, Chapter 1 is to prevent livestock drugs from being sold into California by unlicensed retailers based out of state. Because the Livestock Drug Law was enacted in 1967, it does not address alternate methods of sale such as online and catalog sales. Section 5000 was adopted in 2018 to clarify that the

requirements apply to all methods of sale in an effort to ensure the law remains effective. However, existing Section 5001(d) inadvertently includes limiting language that is inconsistent with statute. As currently written, Section 5001(d) only requires livestock drugs sold by restricted livestock drug licensees to be registered pursuant to Section 14281 of the FAC. In actuality, all livestock drugs must be registered, not just livestock drugs sold by restricted livestock drug licensed retailers. Under FAC Sections 14281 and 14282, manufacturers are responsible for registering their livestock drug products with the Department before they can be sold into California. Since 3 CCR Division 5, Chapter 1 was implemented, the Department has conducted virtual inspections of online retailers and discovered a total of 678 unregistered livestock drug products made by 102 out of state manufacturers being sold to purchasers in California.

Additionally, existing Section 5005(j) states it is unlawful to sell an adulterated livestock drug, but 3 CCR Division 5, Chapter 1 does not currently contain any provisions for what constitutes an adulterated livestock drug. Adulteration is a commonly used term in the feed and livestock drug industry that refers to a product that is unsafe or inconsistent with its labeling. An explanation of adulteration is needed to ensure the Department can pursue consistent enforcement action.

BENEFITS

The proposed adoptions and revisions will ensure the regulations are 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 unregistered and/or adulterated livestock drug products.

SPECIFIC PURPOSE AND NECESSITY

The following paragraphs provide the specific purpose, rationale, and summaries of these proposed changes to the CCR related to livestock drugs.

CHAPTER 1. SALES OF RESTRICTED LIVESTOCK DRUGS is being amended to remove the language “sales of restricted.” The purpose of this change is to broaden the scope of Chapter 1. This is necessary to clarify that the provisions apply to all livestock drugs, not just restricted livestock drugs, as appropriate.

ARTICLE 1. DEFINITIONS

Section 5000. Definitions.

Section 5000(g) is being adopted to define the term “sell.” The purpose of this change is to clarify that the term “sell” includes alternative methods of sales, such as online and catalog sales, in addition to traditional in-person sales made at physical stores and

mobile units in California. The Department maintains that the intent of FAC Division 7, Chapter 4, is to apply to all sales of livestock drugs within or into California. However, the law was enacted in 1967; alternate methods of sale have emerged since that time and the proposed change is necessary to ensure the law remains effective. Similar clarifying language is already included under current Section 5001(a); however, the Department is proposing to strike the language in its current location and add a definition for sell under Section 5000 instead. This is necessary to ensure that the term "sell" is defined for the purposes of the entire chapter, rather than just for Section 5001. This language is based on the definition of sell in the commercial feed regulations under 3 CCR Section 2675(f).

The **Note** section is being amended to include FAC Section 14281 to the References to establish where the authority and reference stem from. The purpose of this addition is to add consistency within the regulation text and add clarity as to where the Department has authority to regulate adulterated products. This is necessary to avoid any confusion on definitions in this section.

Section 5001. Sales of Restricted Livestock Drugs is being amended to remove the phrase "of restricted livestock drugs" from the section title. The purpose of this change is to broaden the scope of Section 5001. This is necessary to clarify that the provisions apply to all livestock drugs, not just restricted livestock drugs, as appropriate.

Section 5001(a) is being amended to remove subsections (1) and (2). The purpose of this change is to remove duplicative language defining types of sales because the Department is proposing to define the term "sell" under section 5000(g). This is necessary to ensure that the term "sell" is defined for the purposes of the entire chapter, rather than just for Section 5001.

Section 5001(c) is being amended to replace the phrase "kept for sale" with the term "sold." This is necessary for clarity and continuity with term "sell" as defined in proposed section 5000(g).

Section 5001(d) is being amended to remove the phrase "by restricted livestock drug licensees" and add the phrase "within or into this state." The purpose of removing the phrase "by restricted livestock drug licensees" is to ensure this section is consistent with the intent of FAC Section 14281. As currently written, section 5001(d) only requires livestock drugs sold by restricted livestock drug licensees to be registered pursuant to FAC Section 14281. In actuality, all livestock drugs must be registered pursuant to FAC Section 14281, not just livestock drugs sold by restricted livestock drug licensed retailers. Removing the phrase "restricted livestock drug licensees," is necessary to clarify that livestock drugs sold by any firm, regardless of license status, must be registered pursuant to FAC Section 14281. The purpose of adding the phrase "within or into this state" is to clarify that this provision also applies to livestock drugs sold to purchasers in California by firms based in another state. The Department maintains that

the intent of FAC Division 7, Chapter 4, is to apply to all sales of livestock drugs within or into California. However, the law was enacted in 1967; since that time, alternate methods of sale have allowed firms based out of state to sell livestock drugs to purchasers in California. The proposed revision is necessary to prevent California consumers from purchasing unregistered livestock drug products from out of state firms that may not meet the Department's standards for safety and efficacy. Similar clarifying language is already included under current Section 5001(a).

Section 5001.1. Adulteration is being adopted to define adulteration. This is consistent with the Department's commercial feed regulations, which include a section for adulteration under 3 CCR Section 2734.

Section 5001.1(a) is being adopted to clarify what constitutes an adulterated livestock drug. The purpose of this change is to clearly define the circumstances in which a livestock drug will be subject to enforcement action under Section 5005(j). This is necessary to ensure the Department can take consistent enforcement action to remove potentially unsafe adulterated livestock drug products from sale. This language is based on the Federal Food, Drug, and Cosmetic Act's definition of "Adulteration" as it pertains to livestock drugs.

Section 5001.1(a)(1) is being adopted to clarify that a livestock drug containing any filthy, putrid, or decomposed substance shall be considered adulterated. The purpose of this adoption is to ensure the Department can deny registration of livestock drugs containing filthy, putrid, or decomposed substances and to take enforcement action to remove any products containing filthy, putrid, or decomposed substances from sale. This is necessary to ensure the safety of drugs being administered to livestock, as well as mitigating health risks to individuals administering drugs and the animals being treated.

Section 5001.1(a)(2) is being adopted to clarify that a livestock drug containing any poisonous, deleterious, or nonnutritive substance injurious to health when used in accordance with the label shall be considered adulterated. FAC Section 14288(b) allows the Department to deny registration of any livestock drug that is dangerous when used in accordance with instructions. The purpose of this adoption is to clarify that the term "adulterated" shall be used to refer to livestock drugs as described in FAC Section 14288(b) and ensures all instances of adulteration are listed in one section for ease of reference for the regulated public. This will also ensure the Department can deny registration of livestock drugs containing poisonous, deleterious, or nonnutritive substances in amounts harmful to human or animal health when used in accordance with the label, and to ensure the Department can take enforcement action to remove unsafe products from sale. This is necessary to ensure the safety of drugs being administered to livestock, as well as mitigating health risks to individuals administering

drugs and the animals being treated. This provision is based on the description of adulteration under FAC Section 15041(a) pertaining to commercial feed.

Section 5001.1(a)(3) is being adopted to clarify that a livestock drug which differs in composition, quality, or does not conform in all respects with its registration shall be considered adulterated. FAC Sections 14281 and 14282 require manufacturers to register livestock drugs with the Department prior to sale in California; FAC Section 14294 allows the Department to remove any drug which does not conform with its registration from sale. The purpose of this adoption is to clarify that the term "adulterated" shall be used to refer to nonconforming livestock drugs as described in FAC Section 14294 and ensures all instances of adulteration are listed in one section for ease of reference for the regulated public. This is necessary to ensure the safety of drugs being administered to livestock, to mitigate the health risks to individuals administering drugs and the animals being treated, and to provide assurance that livestock drugs purchased by consumers are of the quality and quantity purported by the manufacturer. This provision is based on the description of adulteration under FAC Section 15041(c) pertaining to commercial feed.

Section 5001.1(a)(4) is being adopted to clarify that a livestock drug which is manufactured, processed, or packaged in a manner that does not conform to current good manufacturing practices shall be considered adulterated. The purpose of this adoption is to ensure the Department can deny registration of, or take enforcement action against, a livestock drug if the controls within the facility do not provide adequate assurance of preventing adulteration as described in subparagraphs (1), (2), (3), and (6) of this section. This is necessary to ensure the safety of drugs being administered to livestock, to mitigate the health risks to individuals administering drugs and the animals being treated, and to provide assurance that livestock drugs purchased by consumers are of the quality and quantity purported by the manufacturer. This provision is based on the description of adulteration under FAC Section 15041(d) pertaining to commercial feed.

Section 5001.1(a)(5) is being adopted to further clarify that a livestock drug containing an ingredient that lacks sufficient information to ensure safety and efficacy shall be considered adulterated. FAC Section 14288 allows the Department to deny registration of any livestock drug that is of little or no value for the purpose for which it is intended to be used, that is dangerous when used in accordance with instructions, that lacks adequate warnings for unsafe use, that does not otherwise comply with the requirements of FAC Division 7, Chapter 4, or that does not provide sufficient information for the Department to be able to make the aforementioned determinations. The purpose of this adoption is to clarify that the term "adulterated" shall be used to refer to livestock drugs as described in FAC Section 14288 and ensures all instances of adulteration are listed in one section for ease of reference for the regulated public. This is necessary to ensure the safety and efficacy of drugs being administered to livestock,

to mitigate the health risks to individuals administering drugs and the animals being treated, and to provide assurance that livestock drugs purchased by consumers possess the quality, quantity, and therapeutic benefits purported by the manufacturer.

Section 5001.1(a)(6) is being adopted to clarify that a livestock drug intended for ruminants which contains proteins derived from prohibited mammalian tissue shall be considered adulterated. Code of Federal Regulations Title 21 (21 CFR), Part 589.2000 describes restrictions on the use of animal proteins to prevent transmission of bovine spongiform encephalopathy, 3 CCR Section 2681 requires the manufacture, distribution, and use of commercial feed to comply with 21 CFR 589.2000, and 3 CCR Section 2734(b) further states that commercial feed containing protein derived from prohibited mammalian tissues shall be considered adulterated. The purpose of this adoption is to ensure that federal and state restrictions regarding proteins derived from prohibited mammalian tissues are applicable to livestock drugs as well as commercial feed, and to enable the Department to deny registration of, or take enforcement action against, livestock drugs which do not comply. This is necessary to ensure the safety of drugs being administered to livestock, as well as mitigating health risks to individuals administering drugs and the animals being treated.

The **Note** section is being adopted to establish where the authority and reference for the new section stem from. The purpose of this addition is to add consistency within the regulation text and add clarity as to where the Department has authority to regulate adulterated products. This is necessary to avoid any confusion on enforcement actions taken against products that fit the definition of “Adulteration”.

ARTICLE 5. VIOLATIONS AND PENALTIES

Section 5005. Violations.

Section 5005(c) is being amended to add the phrase “within or into this state.” The purpose of this change is to clarify that all livestock drugs sold to purchasers in California must have an approved product registration from the Department, even if the manufacturer, retailer, or distributor is based out of state. This is necessary to prevent California consumers from purchasing unregistered livestock drug products from out of state firms that may not meet the Department’s standards for safety and efficacy.

Section 5005(i) is being amended to remove the term “restricted”. The purpose of this change is to ensure the Department can inspect any premises where livestock drugs are stored or sold to verify product registration. This is necessary to ensure the Department can verify the registration status and prevent California consumers from purchasing unregistered livestock drug products that may not meet the Department’s standards for safety and efficacy.

Section 5005(j) is being amended to remove the term “restricted”. The purpose of this change is to clarify that it is unlawful to sell any livestock drug that is outdated, damaged, misbranded, or adulterated. Clarifying that the prohibition on sales of outdated, damaged, misbranded, or adulterated products applies to all livestock drugs, not just restricted livestock drugs, will ensure all products sold are safe for livestock.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR OTHER DOCUMENTS RELIED UPON

The Department relied upon the following documents in establishing the proposed regulatory action:

- Federal Food, Drug, and Cosmetic Act; 21 USC 351: Adulterated drugs and devices

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 proposed revisions seek to clarify existing regulation and ensure consistency with what is already required by statute. The Department anticipates these clarifying changes will not have an economic impact on the California livestock drug industry, related businesses, or the general public. Clarifying that the term “sell” includes alternate methods of sale and that all livestock drugs sold within or into this state must be registered will only impact livestock drug manufacturers based out of state whose unregistered livestock drug products are sold to California consumers. In addition, the proposed definition of adulteration would not impact any compliant firm.

The Department concludes that the proposed regulations will not:

(1) Create or eliminate jobs within California.

(2) Create new businesses or eliminate existing businesses within the State of California.

(3) Affect the expansion of businesses currently doing business within the State of California.

(4) Affect the health and welfare of California residents, worker safety, and the state’s environment.

EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS

Sections 5000(g), 5001, and 5005. The Department anticipates there will be no significant statewide adverse economic impact directly affecting California businesses as a result of defining the term "sell" and requiring product registration for all livestock drugs sold within or into this state. 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. 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.

Section 5001.1. The Department anticipates there will be no significant statewide adverse economic impact directly affecting California businesses as a result of defining the term "adulteration." The proposed revisions will have no economic impact on firms that are compliant with the FAC and CCR and would only impact firms selling livestock drugs that are harmful or inconsistent with label claims.

REASONABLE ALTERNATIVES TO THE REGULATIONS AND THE DEPARTMENT'S REASONS FOR REJECTING THOSE ALTERNATIVES

The Department considered not defining the term "sell" under Section 5000(g). This alternative was rejected because current regulation defines alternate methods of sale under Section 5001(a), which pertains only to restricted livestock drugs. Defining sell for the purposes of the entire chapter will ensure alternate methods of sale are covered for both restricted and non-restricted livestock drugs.

The Department considered not specifying that product registration is required for all livestock drugs sold within or into this state under Section 5001(d) and 5005(c). This alternative was rejected because it is inconsistent with the intent of FAC Section 14281. The Department maintains that the intent of FAC Division 7, Chapter 4, is to apply to all sales of livestock drugs within or into California. However, the law was enacted in 1967; since that time, alternate methods of sale have allowed firms based out of state to sell livestock drugs to purchasers in California. The proposed revision is necessary to prevent California consumers from purchasing unregistered livestock drug products from out of state that may not meet the Department's standards for safety and efficacy.

The Department considered not removing the term "restricted" from Section 5001(d). This alternative was rejected because it is inconsistent with the intent of FAC Section 14281, which requires all livestock drugs to be registered prior to sale. It is the

manufacturer's responsibility to register any livestock drug product sold under FAC Section 14282, regardless of whether the manufacturer has a restricted livestock drug license.

The Department considered not removing the term "restricted" from Section 5005(i). This alternative was rejected because it is inconsistent with the intent of FAC Section 14295, which grants the Department authority to access all premises used in the manufacture, sale, or storage of any livestock drug, not just restricted livestock drugs.

The Department considered not removing the term "restricted" from Section 5005(j). This alternative was rejected because it is inconsistent with the intent of FAC Section 14352, which states it is unlawful to sell any livestock drug which does not conform with its registration, not just restricted livestock drugs.

The Department considered not adding Section 5001.1 to define adulteration. This alternative was rejected because current regulation lacks clarity on what constitutes adulteration for the purposes of enforcement. Section 5005(j) says it is unlawful to sell an adulterated livestock drug but does not define what adulteration means.

The Department considered adding Chapter 3 to 3 CCR Division 5 instead of broadening Chapter 1 to cover provisions applicable to livestock drugs. This alternative was rejected because most of the requirements are applicable to both livestock drugs and restricted livestock drugs. It would be duplicative to adopt another Chapter restating much of the language already included under Chapter 1.

DUPLICATION OR CONFLICT WITH FEDERAL REGULATIONS

The proposed regulations do not duplicate or conflict with federal regulations.