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DEPARTMENT OF CONSUMER AFFAIRS • VETERINARY MEDICAL BOARD
1747 North Market Blvd., Suite 230, Sacramento, CA 95834-2978
P (916) 515-5220 | Toll-Free (866) 229-0170 | www.vmb.ca.gov

MEMORANDUM

DATE	July 17, 2019
TO	Veterinary Medical Board
FROM	Jessica Sieferman, Executive Officer
SUBJECT	**Agenda Item 7. Discussion and Possible Action on California Department of Food and Agriculture (CDFA) Guidelines for Veterinarians: Judicious Use of Antimicrobials in Livestock**

The California Department of Food and Agriculture (CDFA) Antimicrobial Use and Stewardship (AUS) developed *Guidelines for Veterinarians: Judicious Use of Antimicrobials in Livestock* and requests Board feedback prior to finalizing. For more detailed information, please refer to the attached documents.

Attachments:

1. CDFA Background Memo
2. Original SB 27 bill analysis
3. California's Livestock: Use of Antimicrobial Drugs law
4. Revised Judicious Use Guidelines (Producer)
5. Revised Judicious Use Guidelines (Veterinarian)
6. A similar bill proposed in New York
7. CDFA Presentation to the VMB

June 24, 2019

Dear member of the California Veterinary Medical Board,

California Senate Bill 27 (Hill), signed by Governor Brown on October 10, 2015, resulted in additions to the California Food and Agricultural Code (Division 7, Chapter 4.5, Sections 14400-14408; attached PDF pg. 14-16) that address the sales and use of medically important antimicrobial drugs for livestock, development of voluntary antimicrobial stewardship guidelines and best management practices, and monitoring of antimicrobial use as well as antimicrobial resistance patterns in bacteria. The California Department of Food and Agriculture (CDFA), responsible for the implementation of 4.5 FAC § 14400-14408, requested funding for the development of the Antimicrobial Use and Stewardship (AUS) program. Funding was made available on July 1, 2016, and initial positions were filled between November of 2016 and March of 2017.

Specific conditions of the law became effective January 1, 2018, requiring all previously over the counter medically important antimicrobial drugs (MIADs) to be administered with a prescription or veterinary feed directive ordered by a California licensed veterinarian under a valid veterinarian-client-patient relationship (FAC 14401). Additionally, veterinarians may decide to use MIADs in livestock to treat, control the spread of, and, in some cases, prevent disease or infection (FAC 14402). The law prohibits the administration of MIADs in a regular pattern to prevent disease unless they are necessary in relation to surgery or a medical procedure (FAC 14402(d)). Although the FDA had requested the removal of growth promotion indications from all MIADs, which went into effect on January 1, 2017, 14402(d) was added to address concerns that MIADs would be used for continuous durations at lower than therapeutic doses for growth promotion under the guise of disease prevention. The attached transcript of the Assembly Floor Analysis (PDF pg. 1-3), dated one month prior to the signing of SB 27, provides documentation of this concern.

CDFA AUS maintains a transparent process of implementation and openly receives feedback from all stakeholders. Upon the development of the program, several stakeholder groups, especially consumer and environmental advocacy groups, requested clarification of “regular pattern” (FAC 14402(d)). In response, CDFA AUS released an educational statement for veterinarians and livestock producers regarding the meaning of “regular pattern” in August of 2017. The statement was removed from the website in October 2017 after concerns were raised by a number of stakeholder groups. At that time, some stakeholder groups recommended that the Department promulgate regulations to clarify what specific regular pattern practices are prohibited by law; example regulations were suggested. CDFA AUS determined that the suggested language did not define “regular pattern” as intended, but instead described specific scenarios to be prohibited. A set of example scenarios cannot account for the complexity and nuance that goes into the medical decision-making process performed by a licensed veterinarian. Further, CDFA does not have the authority to regulate the practice of veterinary medicine, only gather on-farm and voluntarily submitted information from livestock producers, as well as provide recommendations for antimicrobial stewardship.

The standard of veterinary medical practice evolves in California and is solely enforceable through the Veterinary Medicine Practice Act by the Veterinary Medical Board (FAC 14408). An alternative regulatory approach is being considered in a New York bill that requires the VMB to enforce a similar type of law, with additional prohibitions and requirements (PDF pg. 33-38). In California, the Department has advised that clarification be communicated through guidelines, as the professional judgment of a veterinarian is essential to justifying the use of MIADs.

The *Guidelines for Veterinarians: Judicious Use of Antimicrobials in Livestock*, developed by AUS, are based on sound scientific principles and highlight relevant laws that must be considered in the decision-making process for antimicrobial therapy in livestock medicine. The guidelines have been in a revision process for two years in an effort to gain consensus from all stakeholder groups. AUS program intends to promote effective antimicrobial stewardship by encouraging engagement in antimicrobial use and resistance monitoring and education for both veterinarians and producers.

We look forward to discussing the implementation of SB 27 (specifically 4.5 FAC § 14402) further at your Board meeting on July 17, where we hope you might contribute the Board's large body of expertise to the concluding edits of this document.

Thank you for your careful review of this matter.

CDFA Antimicrobial Use and Stewardship

(Without Reference to File)

SENATE THIRD READING
SB 27 (Hill)
As Amended September 10, 2015
Majority vote

SENATE VOTE: 25-10

Committee	Votes	Ayes	Noes
Agriculture	7-1	Perea, Gallagher, Cooper, Dodd, Eggman, Irwin, Salas	Grove
Appropriations	15-0	Gomez, Bloom, Bonta, Calderon, Chang, Nazarian, Eggman, Gallagher, Eduardo Garcia, Holden, Jones, Rendon, Wagner, Weber, Wood	
Agriculture	7-0	Perea, Gallagher, Dodd, Irwin, Jones-Sawyer, Mathis, Quirk	

SUMMARY: Prohibits, beginning January 1, 2018, the use of medically important anti-microbial drugs (MIAMs) for the treatment of livestock animals, except pursuant to a prescription or feed directive from a licensed veterinarian and when, in the professional judgment of a licensed veterinarian, the MIAMs are necessary: 1) to treat a disease or infection; 2) to control the spread of disease or infection; or 3) in relation to surgery or a medical procedure. This bill allows for prophylaxis to prevent the elevated risk of disease transmission or infection and forbids the use of MIAMs for growth promotion and feed efficiency. Specifically, **this bill**:

1) In order to implement and monitor compliance with the MIAM rules, the bill requires the California Department of Food and Agriculture (CDFA) to:

   a) Coordinate with the federal Food and Drug Administration (FDA) to develop a program to track antimicrobial drug sales, use, resistance, and management practices; and,

   b) Develop antimicrobial stewardship guidelines on good management practices in consultation with the Veterinary Medical Board (VMB), the California Department of Public Health (DPH), universities, and cooperative extensions; and,

   c) Conduct outreach and training, and report to the Legislature by January 1, 2019, the results of outreach and monitoring activities.

FISCAL EFFECT: According to the Assembly Appropriations Committee, this bill has:

1) Estimated General (GF) and Special Fund (SF) costs of approximately $864,000 in 2015-16 and $4.8 million in 2016-17 to develop programs, stewardship guidelines, monitoring systems and procedures, and regulations, as well as begin training, inspections, and MIAMs use tracking. Annual GF and SF costs of approximately $4.3 million thereafter to continue

training, inspections, and tracking. Some of these costs may be funded from federal and local sources, and potentially offset in part with civil fine revenue.

2) Potentially significant costs to VMB and DPH to help develop stewardship guidelines and training materials.

COMMENTS: Antimicrobial drugs have been widely used in human medicine since the 1940s. Antimicrobial drugs have significant health benefits in both human and animal medicine, and are important and valuable tools used to treat and prevent illness and infection. Incidences of antimicrobial resistance have been recorded over time and, if left unchecked, pose a threat to public health.

The Centers for Disease Control and Prevention (CDC) estimates that in the United States, more than two million people are sickened every year with antibiotic-resistant infections, with at least 23,000 infections resulting in death. CDC notes that the use of antibiotics is the single most important factor leading to antibiotic resistance around the world. Up to 50% of all antibiotics prescribed for people are either not needed or not optimally effective as prescribed. Antibiotics are also used in food-producing animals for the purpose of promoting growth, which CDC recommends phasing out.

The FDA has issued several industry recommendations regarding the use of MIAMs in the feed and drinking water of food-producing animals. The recommendations contained in Guidance for Industry #152, #213, and #219 establish lists of antibiotics important to human health, promote judicious use of those drugs in food production, and encourage veterinary oversight to ensure compliance with industry best practices.

In March 2015, President Obama issued a national action plan on combating antibiotic-resistant bacteria. The five-year action plan articulated goals of slowing the emergence of resistant bacteria, strengthening surveillance efforts, advancing the development and use of rapid diagnostics to identify resistant bacteria, accelerate development of new antibiotics, treatments, and vaccines, and improve collaboration among stakeholders. For antimicrobial use in food animals, the plan seeks to implement FDA guidance.

According to the author, overuse and misuse of antibiotics in livestock animals, especially antibiotics important in human medicine, contributes to antibiotic resistance. To address the overuse and misuse, this bill is intended to ensure veterinary oversight; encourage judicious use of MIAMS and prohibit use for growth promotion and other nontherapeutic purposes; and, monitor MIAM sales, usage, management practices, and resistance.

According to supporters, many antimicrobials used in food production are currently available at feed stores and online, without any veterinary prescription or oversight and this bill will stop this practice along with making all use of MIAMs require a prescription. Furthermore, supporters argue the prophylactic use exception has been carefully crafted for judicious use of MIAMs, and the bill explicitly forbids MIAM use for growth promotion and feed efficiency.

While recent amendments removed much of the opposition, those still opposed argue this bill explicitly authorizes the routine use of antibiotics on animals that are not sick through the exception for prophylactic use to prevent disease transmission or infection. Opponents fear prophylactic use will allow back door use for nontherapeutic purposes, and is precisely the low-

dose use that contributes most to resistant bacteria. Furthermore, opponents assert that surveillance of MIAM use in food animal production needs to be mandatory.

Analysis Prepared by: Victor Francovich / AGRI. / (916) 319-2084 FN: 0002319

FOOD AND AGRICULTURAL CODE - FAC

DIVISION 7. AGRICULTURAL CHEMICALS, LIVESTOCK REMEDIES, AND COMMERCIAL FEEDS [12500 - 15340] *(Division 7 enacted by Stats. 1967, Ch. 15.)*

CHAPTER 4.5. Livestock: Use of Antimicrobial Drugs [14400 - 14408] *(Chapter 4.5 added by Stats. 2015, Ch. 758, Sec. 1.)*

14400. For purposes of this chapter, the following definitions apply:

(a) "Medically important antimicrobial drug" means an antimicrobial drug listed in Appendix A of the federal Food and Drug Administration's Guidance for Industry #152, including critically important, highly important, and important antimicrobial drugs, as that appendix may be amended.

(b) "Livestock" means all animals and poultry, including aquatic and amphibian species, that are raised, kept, or used for profit. Livestock does not include bees or those species that are usually kept as pets, such as dogs, cats, and pet birds.

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

(Added by Stats. 2015, Ch. 758, Sec. 1. (SB 27) Effective January 1, 2016.)

14401. 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.

(Added by Stats. 2015, Ch. 758, Sec. 1. (SB 27) Effective January 1, 2016.)

14402. (a) Beginning January 1, 2018, a medically important antimicrobial drug may be used when, in the professional judgment of a licensed veterinarian, the medically important antimicrobial drug is any of the following:

(1) Necessary to treat a disease or infection.

(2) Necessary to control the spread of a disease or infection.

(3) Necessary in relation to surgery or a medical procedure.

(b) A medically important antimicrobial drug may also be used when, in the professional judgment of a licensed veterinarian, it is needed for prophylaxis to address an elevated risk of contraction of a particular disease or infection.

(c) A person shall not administer a medically important antimicrobial drug to livestock solely for purposes of promoting weight gain or improving feed efficiency.

(d) Unless the administration is consistent with subdivision (a), a person shall not administer a medically important antimicrobial drug in a regular pattern.

(Added by Stats. 2015, Ch. 758, Sec. 1. (SB 27) Effective January 1, 2016.)

14403. (a) Notwithstanding Sections 14401 and 14402 of this 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 with a prescription or veterinary feed directive from a licensed veterinarian.

(b) This section shall not be construed to invalidate the requirement to obtain a prescription or veterinary feed directive to administer a medically important antimicrobial drug as required by Section 14401.

(c) The department may promulgate regulations to implement this section.

(Added by Stats. 2015, Ch. 758, Sec. 1. (SB 27) Effective January 1, 2016.)

14404. (a) The department, in consultation with the Veterinary Medical Board, the State Department of Public Health, universities, and cooperative extensions, shall develop antimicrobial stewardship guidelines and best management practices for veterinarians, as well as livestock owners and their employees who are involved with administering medically important antimicrobial drugs, on the proper use of medically important antimicrobial drugs for disease treatment, control, and prevention. The guidelines shall include scientifically validated practical alternatives to the use of medically important antimicrobial drugs, including, but not limited to, the introduction of effective vaccines and good hygiene and management practices.

(b) The department shall consult with livestock producers, licensed veterinarians, and any other relevant stakeholders on ensuring livestock timely access to treatment for producers in rural areas with limited access to veterinary care.

(c) For purposes of this section, "antimicrobial stewardship" is a commitment to do all of the following:

(1) To use medically important antimicrobial drugs only when necessary to treat, control, and, in some cases, prevent, disease.

(2) To select the appropriate medically important antimicrobial drug and the appropriate dose, duration, and route of administration.

(3) To use medically important antimicrobial drugs for the shortest duration necessary and to administer them to the fewest animals necessary.

(Added by Stats. 2015, Ch. 758, Sec. 1. (SB 27) Effective January 1, 2016.)

14405. (a) It is the intent of the Legislature that the department coordinate with the United States Department of Agriculture, the federal Food and Drug Administration, and the federal Centers for Disease Control and Prevention to implement the expanded antimicrobial resistance surveillance efforts included in the National Action Plan for Combating Antibiotic-Resistant Bacteria, and that the information gathered through this effort will help lead to a better understanding of the links between antimicrobial use patterns in livestock and the development of antimicrobial resistant bacterial infections.

(b) (1) The department shall gather information on medically important antimicrobial drug sales and usage, as well as antimicrobial resistant bacteria and livestock management practice data. Monitoring efforts shall not be duplicative of the National Animal Health Monitoring System and the National Antimicrobial Resistance Monitoring System, and, to the extent feasible, the department shall coordinate with the United States Department of Agriculture, the federal Centers for Disease Control and Prevention, and the federal Food and Drug Administration in the development of these efforts.

(2) In coordinating with the National Animal Health Monitoring System and the National Antimicrobial Resistant Monitoring System, the department shall gather representative samples from all of the following:

(A) California's major livestock segments.

(B) Regions with considerable livestock production.

(C) Representative segments of the food production chain.

(c) The department shall work with willing participants to gather samples and shall consult with, and conduct outreach to, livestock producers, licensed veterinarians, and any other relevant stakeholders on the implementation of the monitoring efforts. Participation in this effort shall be done in a manner that does not breach veterinary-client-patient confidentiality laws.

(d) (1) The department shall report to the Legislature by January 1, 2019, the results of its outreach activities and monitoring efforts. The department shall advise the Legislature as to whether or not participation is sufficient to provide statistically relevant data. The report shall be submitted in compliance with Section 9795 of the Government Code.

(2) This subdivision is inoperative on January 1, 2023, pursuant to Section 10231.5 of the Government Code.

(e) The department shall seek funds from federal, state, and other sources to implement this section.

(f) The department may promulgate regulations to implement this section.

(Added by Stats. 2015, Ch. 758, Sec. 1. (SB 27) Effective January 1, 2016.)

14406. The department has the authority to request and receive copies of veterinary feed directives from the livestock owner, veterinarian, or distributor to fully implement the provisions of this chapter.

(Added by Stats. 2015, Ch. 758, Sec. 1. (SB 27) Effective January 1, 2016.)

14407. Notwithstanding the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code), any information provided pursuant to this chapter and Section 14902.5, if that section is added by Senate Bill 770 of the 2015–16 Regular Session of the Legislature, shall be held confidential, and shall not be disclosed to any person or governmental agency, other than the department or the Veterinary Medical Board, for the purposes of enforcing the Veterinary Medicine Practice Act (Chapter 11 (commencing with Section 4800) of Division 2 of the Business and Professions Code), unless the data is aggregated to prevent the identification of an individual farm or business. Information may be shared with federal agencies so long as it is protected by the federal Confidential Information Protection and Statistical Efficiency Act of 2002 (Public Law 107-347).

(Added by Stats. 2015, Ch. 758, Sec. 1. (SB 27) Effective January 1, 2016.)

14408. (a) A person who violates this chapter shall be liable for a civil penalty of not more than two hundred and fifty dollars ($250) for each day a violation occurs.

(b) (1) 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.

(2) In addition to the administrative fine, the violator shall attend an educational program on the judicious use of medically important antimicrobial drugs that has been approved by the secretary. The violator shall successfully complete the program and provide proof to the secretary within 90 days from the occurrence of the violation.

(c) Subdivisions (a) and (b) do not apply to licensed veterinarians. If the Veterinary Medical Board determines that a veterinarian is in violation of the Veterinary Medicine Practice Act (Chapter 11 (commencing with Section 4800) of Division 2 of the Business and Professions Code), the veterinarian may be subject to disciplinary sanctions pursuant to the act.

(d) The moneys collected pursuant to this article shall be deposited into the Department of Food and Agriculture Fund and shall be available for expenditure upon appropriation by the Legislature.

(Added by Stats. 2015, Ch. 758, Sec. 1. (SB 27) Effective January 1, 2016.)

Guidelines for Judicious Use of Antimicrobials in Livestock

The core foundation for antimicrobial stewardship and judicious use of antibiotics in livestock is an effective relationship between a veterinarian and livestock owners. Biosecurity and herd health plans developed and revised under the guidance of a veterinarian are vital to maintain productivity, animal health and welfare, as well as a safe and secure food supply. Livestock owners, and their employees responsible for animal care, play a critical role in the success of a herd health plan. Recognizing early signs of illness in animals, such as slight changes in behavior, requires skill and experience, and it demonstrates a dedication to animal care and stockmanship. Various tools and/or scoring systems (e.g., monitoring feed and water consumption, calf health scores, the California Mastitis Test, and automated animal health trackers) may assist with the training and day-to-day activities of those responsible for animal care.

In California, the potential use of medically important antimicrobial drugs (hereafter referred to as antibiotics) in livestock must be deemed necessary under the professional judgment of a California licensed veterinarian, within the context of a valid veterinarian-client-patient relationship (VCPR) and in accordance with current veterinary medical practice and legal parameters.[a] To use antibiotics effectively and responsibly, a veterinarian must first develop a preliminary or general diagnosis, or have an indication of elevated risk of disease or infection.[b,c] The diagnostic process includes consideration of the history, clinical judgement, and epidemiological knowledge of the veterinarian.

Once the need for antibiotic therapy has been established, the following are essential to practice the judicious use of antibiotics:

These guidelines are intended to aid livestock owners and their employees responsible for animal care in responsible antibiotic use under the guidance of a veterinarian in compliance with state and federal laws.

1) The decision to use antibiotics for sick or at-risk animals should be made promptly and, when appropriate, antibiotic therapy should be initiated in a timely manner to minimize the infectious burden, improve therapeutic outcomes, and reduce the development of antibiotic resistance.

2) In deciding to implement the use of an antibiotic, a veterinarian may consider the expected benefit from therapy.
   a) Antibiotic therapy may be indicated for treatment in animals with an infectious disease or evidence of an infectious disease before a final diagnosis can be made. The veterinarian may assess the likelihood the illness is a result of a bacterial infection, the expected outcome of starting antibiotic therapy, and potential adverse effects of antibiotic therapy.
   b) Antibiotic therapy may be required for control to decrease the severity of disease, reduce shedding of infectious bacteria, and minimize chances for spreading the disease to additional animals.
   c) Antibiotic therapy may be necessary for prevention to address an elevated risk of contracting a particular disease or infection when the ability to predict outcomes to infectious exposure is not possible, but infection is anticipated based on the veterinarian's professional judgment regarding animal-specific risk factors.
   d) Medically important antibiotics shall not be administered to livestock solely for purposes of promoting weight gain or improving feed efficiency.
   e) Keeping accurate treatment and production records that include health outcomes of treated animals may aid the veterinarian in monitoring the effectiveness of animal health and disease prevention plans, reviewing treatment

[a] Medically important antimicrobial drugs and are defined as those listed in Appendix A of the U.S. Food and Drug Administration's Guidance for Industry #152.
[b] Defined in the Veterinary Medicine Practice Act, Title 16 of the California Code of Regulations, Section 2032.1.
[c] Allowable and prohibited uses of medically important antimicrobial drugs in livestock are described in 4.5 FAC § 14402. Attached in Appendix D.

plans and procedures, and identifying optimal management practices and judicious on-farm use of antibiotics that promote antibiotic stewardship.

3) General supportive care (e.g., quality feed and water, shelter, and ventilation) provided for ill animals may reduce the need or duration of antibiotic therapy or improve treatment outcomes.
   a) The use of alternatives to antibiotic therapy may be considered when recognized by scientific studies to improve animal welfare with no negative effects on treatment outcome.

4) Choosing appropriate antibiotic(s) and course of therapy for the treatment, control, or prevention of a disease must be under the oversight of a licensed veterinarian. The veterinarian's recommendation is based on a working diagnosis, relevant scientific information, standard of care consistent with current veterinary medical practice in this state, the animal owner's values and expectations – while in compliance with state and federal laws.
   a) Veterinarians may not use antibiotics to prevent disease in a regular pattern, unless in relation to surgery or to a medical procedure. Examples of antibiotics used in a regular pattern to prevent disease include, but are not limited to:
      i) Antibiotics given to prevent disease beyond the period of elevated risk determined in the professional judgment of the licensed veterinarian.
      ii) Antibiotics given to prevent disease out of habit in a recurrent manner solely based on the animal's age or weight, the calendar date, or a life stage event of the animal(s) without the presence of an elevated risk of a particular disease or infection determined in the professional judgment of the licensed veterinarian.
   b) Antibiotics may be used in an extra-label manner only when authorized by a California licensed veterinarian within the context of a valid VCPR and when the health of an animal is threatened, or suffering or death may result from failure to treat. The circumstances of use must comply with federal regulatory requirements.[d]
   c) Livestock owners and their employees responsible for animal care should carefully follow treatment protocols as they are written and have been communicated. Before altering the case definition or course of treatment, consult the veterinarian of record.
   d) Livestock owners and their employees responsible for animal care should follow all instructions printed on the label or otherwise provided by the veterinarian.

5) Antibiotics kept on-farm for the existing or anticipated needs to treat livestock should be accompanied by a veterinarian's clear instructions for use. Responsible practices include the following:
   a) Avoid stockpiling antibiotics beyond anticipated needs.
   b) Take care to ensure stored antibiotics are not expired.
   c) Store antibiotics according to the approved product label.
   d) Antibiotics should be stored in a secure location that allows for timely access by authorized persons.
   e) Dispose of expired or unusable antibiotics and contaminated animal products appropriately to avoid environmental contamination. To find locations to dispose of unwanted pharmaceuticals, needles, and syringes, visit: https://search.earth911.com/; type "medications" or "medical sharps" in the search field; type in your zip code; call any of the listed locations to confirm this service is currently provided.

[d] Extra-label drug use (ELDU) in food-animal species is permitted under the Animal Medicinal Drug Use Clarification Act of 1994 if criteria are met as defined in Title 21 in the Code of Federal Regulations, Part 530. ELDU ("Off-Label Use") is any use of an FDA-approved drug that differs from instructions on the approved product label (species, animal production class, dose, volume per injection site, route, frequency, duration, or indication).

Guidelines for Veterinarians: Judicious Use of Antimicrobials in Livestock

The practices and protocols developed and implemented by veterinarians, livestock owners, and personnel responsible for animal care are critical to the promotion and maintenance of animal health and welfare, the conservation of animal resources, and the protection of public health.[1-3] Established biosecurity and therapeutic recommendations, including treatment protocols, are vital to limiting the severity and the spread of disease or infection in livestock.[4] In the event of a disease occurrence, timing is everything.[5,6] The ability to recognize early signs of disease or infection in animals, and to identify those animals with an elevated risk of contracting a particular disease or infection, are vital to the successes of infectious disease prevention, control, and treatment.[2,7] Various tools and/or scoring systems may facilitate the training and day-to-day activities of those responsible for animal care.[2,7]

In California, the use of medically important antimicrobial drugs (MIADs) in livestock must be deemed necessary under the professional judgement of a licensed veterinarian, within the context of a valid veterinarian-client-patient relationship and in accordance with current veterinary medical practice and legal parameters.[a] To effectively and appropriately employ the use of MIADs, a veterinarian must first initiate a general or preliminary diagnosis of disease or infection, or have indication of an elevated risk of contracting a particular disease or infection, in an individual animal or group of animals.[8,b,c] The diagnostic process may incorporate relevant history, production performance, clinical signs, physical examination, and/or diagnostic test results.[9]

Once a veterinarian has identified a possible indication to use medically important antimicrobial drugs (MIADs), judicious use includes careful consideration of the following practices:

These guidelines are intended to serve as an adjunct to professional judgement. The following are based on current scientific principles and state and federal laws regarding MIADs.

1) Antimicrobial therapy should be initiated in a timely manner, often before a definitive diagnosis can be made, in order to minimize the infectious burden to the animal(s) and the environment, reduce the amount of MIADs necessary to affect clinical outcome, improve clinical response to therapy, and diminish the development of antimicrobial resistance.[4,6,10,11]

2) Antimicrobials should be reserved for cases that would be expected to provide a measurable benefit to the clinical outcome.[12] The following indications may be considered when determining the benefit of therapy:

    a) Antimicrobial therapy may be indicated for treatment in animals with evidence of infectious disease before a final diagnosis can be made. Prudently consider the use of MIADs in chronic or moribund cases or those cases that may have no anticipated recovery for production purposes.[12,13]
    b) Antimicrobial therapy may be necessary for control to decrease the risk of a subclinical infection resulting in clinical signs of disease, reduce shedding of infectious bacteria, and minimize chances of disease transmission.
    c) Antimicrobial therapy may be necessary for prevention to address an elevated risk of contracting a particular disease or infection when the ability to predict outcomes to infectious exposure is not possible, but infection is anticipated based on a licensed veterinarian's professional judgment regarding animal-specific risk factors.

[a] Medically important antimicrobial drugs (MIADs) are defined as those listed in Appendix A of the U.S. Food and Drug Administration's Guidance for Industry #152, including critically important, highly important, and important.
[b] As defined in the Veterinary Medicine Practice Act, 16 CCR § 2032.1. Attached in Appendix A.
[c] Allowable and prohibited uses of medically important antimicrobial drugs in livestock are described in 4.5 FAC § 14402. Attached in Appendix D.

d) MIADs shall not be administered to livestock solely for purposes of promoting weight gain or improving feed efficiency.[6,d]

3) Veterinarians are encouraged to work with clients to maintain accurate drug inventory, measures of production performance, and treatment records that include clinical outcomes. Assembly and analysis of this information may aid in monitoring treatment efficacy, reviewing treatment protocols and management procedures, providing objectives for communication and training of those responsible for livestock care on improving disease detection, and optimize identification of animals at risk of an unfavorable outcome and allow for appropriate management. [1,2,7,14]

   a) Veterinarians maintain medical records in compliance with state and federal regulations.[e] Except where disclosure is allowed per California and federal laws, veterinary medical records are considered confidential and are prohibited from disclosure without client consent.[f]

4) Ancillary treatments and supportive care may be used when shown to reduce the need for MIADs, improve clinical response to therapy, or to improve animal welfare with no deleterious effect on treatment outcome.[2,15]

5) Appropriate antimicrobial selection should be made based on knowledge of the identified or suspected pathogen(s), compliance with federal regulatory requirements, and the expected efficacy of the drug as determined by available scientific medical evidence, the clinical experience of the veterinarian, results of initial treatment, and/or antimicrobial susceptibility.[9,16,19,g]

   a) Carefully consider the use of combination antimicrobial therapy for cases with impaired host defenses, polymicrobial infections, or emergence of resistance is shown to be reduced. Limit combinations to those with predictable synergistic effects, where effective, broad spectrum antimicrobials are not available.[5,8,10,18]
   b) Antimicrobial susceptibility testing should be performed by laboratories using current and validated methods approved by the Clinical and Laboratory Standards Institute.[13,17]
   c) Interpretation and application of antimicrobial susceptibility test results to the individual animal or the herd requires the knowledge and expertise of a licensed veterinary medical professional.[17] Consults with veterinary specialists may be useful on a case-by-case basis.

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[e] 16 CCR 2032.3, 16 CCR 2032.2, and 21 CFR Part 558

[f] BPC 4857

[g] The Animal Medicinal Drug Use Clarification Act (AMDUCA) permits Extralabel Drug Use (ELDU) in food-producing animals, by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship, if criteria are met as defined in Title 21 in the Code of Federal Regulations, Part 530. Attached in Appendix B. A veterinarian must select a drug that is labeled for its intended use and that contains the same active ingredient which is in the required dosage form and concentration, except where a veterinarian finds that the approved drug is clinically ineffective for its intended use. See www.FARAD.org for more informative resources on ELDU.

5) Establish optimal antimicrobial therapy regimens for the treatment, control, or prevention of disease or infection as supported by relevant clinical trials and principles of veterinary medicine.[9,13] Use must comply with federal and state legal requirements.[h,i]

   a) Utilize an adequate dose, route of administration, and appropriate dosing frequency, to achieve and maintain steady-state drug concentration above the known or predictable minimum inhibitory concentration of the identified or likely pathogen(s).[6,8,19,20]
   b) Target methods of drug delivery, such as local or regional therapy, when feasible and likely to achieve the desired drug concentration at the site of infection.[10,13]
   c) Duration of therapy should be long enough to achieve the desired clinical response but short enough to minimize the risk of adverse effects and selection of resistant bacteria.[6,8,13,19-21,j]
   e) In circumstances when multiple animals are affected or at risk of contracting a disease or infection, antimicrobials should be administered to the fewest number of animals necessary.
   f) MIADs may not be used to prevent disease in a regular pattern, unless in relation to surgery or to a medical procedure.[k] Examples of MIADs used in a regular pattern to prevent disease include, but are not limited to:
      i) MIADs given to prevent disease beyond the period of elevated risk[l] determined in the professional judgement of the licensed veterinarian.
      i) MIADs given to prevent disease out of habit in a recurrent manner solely based on the animal's age or weight, the calendar date, or a life stage event of the animal(s) without the presence of an elevated risk of a particular disease or infection determined in the professional judgment of the licensed veterinarian.

6) Avoid oversupplying MIADs beyond the anticipated needs of therapy for ill or at-risk animals.[1]

[h] AMDUCA permits ELDU in food-producing animals, by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship, if criteria are met as defined in Title 21 in the Code of Federal Regulations, Part 530. Attached in Appendix B. ELDU ("Off-Label Use") is any use of an FDA-approved drug that differs from instructions on the approved product label (species, animal production class, dose, volume per injection site, route, frequency, duration, or indication). See www.FARAD.org for more informative resources on ELDU.

[i] Allowable and prohibited uses of medically important antimicrobial drugs in livestock are described in 4.5 FAC § 14402. Attached in Appendix D.

[j] Currently, there is a dearth of scientific literature to support evidence-based decisions on effective duration of antimicrobial therapies in the practice of veterinary medicine on livestock animals.

[k] Allowable and prohibited uses of medically important antimicrobial drugs in livestock are described in 4.5 FAC § 14402. Attached in Appendix D.

Appendix A

Title 16, California Code of Regulations, Section 2032.1 – Veterinarian-Client-Patient Relationship

(a) It is unprofessional conduct for a veterinarian to administer, prescribe, dispense or furnish a drug, medicine, appliance, or treatment of whatever nature for the prevention, cure, or relief of a wound, fracture or bodily injury or disease of an animal without having first established a veterinarian-client-patient relationship with the animal patient or patients and the client, except where the patient is a wild animal or the owner is unknown.

(b) A veterinarian-client-patient relationship shall be established by the following:

(1) The client has authorized the veterinarian to assume responsibility for making medical judgments regarding the health of the animal, including the need for medical treatment,

(2) The veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian is personally acquainted with the care of the animal(s) by virtue of an examination of the animal or by medically appropriate and timely visits to the premises where the animals are kept, and

(3) The veterinarian has assumed responsibility for making medical judgments regarding the health of the animal and has communicated with the client a course of treatment appropriate to the circumstance.

(c) A drug shall not be prescribed for a duration inconsistent with the medical condition of the animal(s) or type of drug prescribed. The veterinarian shall not prescribe a drug for a duration longer than one year from the date the veterinarian examined the animal(s) and prescribed the drug.

(d) As used herein, “drug” shall mean any controlled substance, as defined by Section 4021 of Business and Professions code, and any dangerous drug, as defined by Section 4022 of Business and Professions code.

Note: Authority cited: Sections 4808, Business and Professions Code. Reference: Section 4883, Business and Professions Code.

Appendix B

Title 21, Code of Federal Regulations, Part 530 – Extralabel Drug Use in Animals

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 351, 352, 353, 355, 357, 360b, 371, 379e.

Source: 61 FR 57743, Nov. 7, 1996, unless otherwise noted.

Subpart A—General Provisions

§530.1 Scope.

This part applies to the extralabel use in an animal of any approved new animal drug or approved new human drug by or on the lawful order of a licensed veterinarian within the context of a valid veterinary-client-patient relationship.

§530.2 Purpose.

The purpose of this part is to establish conditions for extralabel use or intended extralabel use in animals by or on the lawful order of licensed veterinarians of Food and Drug Administration approved new animal drugs and approved new human drugs. Such use is limited to treatment modalities when the health of an animal is threatened or suffering or death may result from failure to treat. This section implements the Animal Medicinal Drug Use Clarification Act of 1994 (the AMDUCA) (Pub. L. 103-396).

§530.3 Definitions.

(a) *Extralabel use* means actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. This includes, but is not limited to, use in species not listed in the labeling, use for indications (disease or other conditions) not listed in the labeling, use at dosage levels, frequencies, or routes of administration other than those stated in the labeling, and deviation from the labeled withdrawal time based on these different uses.

(b) *FDA* means the U.S. Food and Drug Administration.

(c) The phrase *a reasonable probability that a drug's use may present a risk to the public health* means that FDA has reason to believe that use of a drug may be likely to cause a potential adverse event.

(d) The phrase *use of a drug may present a risk to the public health* means that FDA has information that indicates that use of a drug may cause an adverse event.

(e) The phrase *use of a drug presents a risk to the public health* means that FDA has evidence that demonstrates that the use of a drug has caused or likely will cause an adverse event.

(f) A *residue* means any compound present in edible tissues that results from the use of a drug, and includes the drug, its metabolites, and any other substance formed in or on food because of the drug's use.

(g) A *safe level* is a conservative estimate of a drug residue level in edible animal tissue derived from food safety data or other scientific information. Concentrations of residues in tissue below the safe level will not raise human food safety concerns. A safe level is not a safe concentration or a tolerance and does not indicate that an approval exists for the drug in that species or category of animal from which the food is derived.

(h) *Veterinarian* means a person licensed by a State or Territory to practice veterinary medicine.

(i) A *valid veterinarian-client-patient relationship* is one in which:

(1) A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian;

(2) There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and

(3) The practicing veterinarian is readily available for followup in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

§530.4 Advertising and promotion.
Nothing in this part shall be construed as permitting the advertising or promotion of extralabel uses in animals of approved new animal drugs or approved human drugs.

§530.5 Veterinary records.
(a) As a condition of extralabel use permitted under this part, to permit FDA to ascertain any extralabel use or intended extralabel use of drugs that the agency has determined may present a risk to the public health, veterinarians shall maintain the following records of extralabel uses. Such records shall be legible, documented in an accurate and timely manner, and be readily accessible to permit prompt retrieval of information. Such records shall be adequate to substantiate the identification of the animals and shall be maintained either as individual records or, in food animal practices, on a group, herd, flock, or per-client basis. Records shall be adequate to provide the following information:

(1) The established name of the drug and its active ingredient, or if formulated from more than one ingredient, the established name of each ingredient;

(2) The condition treated;

(3) The species of the treated animal(s);

(4) The dosage administered;

(5) The duration of treatment;

(6) The numbers of animals treated; and

(7) The specified withdrawal, withholding, or discard time(s), if applicable, for meat, milk, eggs, or any food which might be derived from any food animals treated.

(b) A veterinarian shall keep all required records for 2 years or as otherwise required by Federal or State law, whichever is greater.

(c) Any person who is in charge, control, or custody of such records shall, upon request of a person designated by FDA, permit such person designated by FDA to, at all reasonable times, have access to, permit copying, and verify such records.

Subpart B—Rules and Provisions for Extralabel Uses of Drugs in Animals

§530.10 Provision permitting extralabel use of animal drugs.
An approved new animal drug or human drug intended to be used for an extralabel purpose in an animal is not unsafe under section 512 of the act and is exempt from the labeling requirements of section 502(f) of the act if such use is:

(a) By or on the lawful written or oral order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship; and

(b) In compliance with this part.

§530.11 Limitations.
In addition to uses which do not comply with the provision set forth in §530.10, the following specific extralabel uses are not permitted and result in the drug being deemed unsafe within the meaning of section 512 of the act:

(a) Extralabel use in an animal of an approved new animal drug or human drug by a lay person (except when under the supervision of a licensed veterinarian);

(b) Extralabel use of an approved new animal drug or human drug in or on an animal feed;

(c) Extralabel use resulting in any residue which may present a risk to the public health; and

(d) Extralabel use resulting in any residue above an established safe level, safe concentration or tolerance.

§530.12 Labeling.
Any human or animal drug prescribed and dispensed for extralabel use by a veterinarian or dispensed by a pharmacist on the order of a veterinarian shall bear or be accompanied by labeling information adequate to assure the safe and proper use of the product. Such information shall include the following:

(a) The name and address of the prescribing veterinarian. If the drug is dispensed by a pharmacy on the order of a veterinarian, the labeling shall include the name of the prescribing veterinarian and the name and address of the dispensing pharmacy, and may include the address of the prescribing veterinarian;

(b) The established name of the drug or, if formulated from more than one active ingredient, the established name of each ingredient;

(c) Any directions for use specified by the veterinarian, including the class/species or identification of the animal or herd, flock, pen, lot, or other group of animals being treated, in which the drug is intended to be used; the dosage, frequency, and route of administration; and the duration of therapy;

(d) Any cautionary statements; and

(e) The veterinarian's specified withdrawal, withholding, or discard time for meat, milk, eggs, or any other food which might be derived from the treated animal or animals.

§530.13 Extralabel use from compounding of approved new animal and approved human drugs.
(a) This part applies to compounding of a product from approved animal or human drugs by a veterinarian or a pharmacist on the order of a veterinarian within the practice of veterinary medicine. Nothing in this part shall be construed as permitting compounding from bulk drugs.

(b) Extralabel use from compounding of approved new animal or human drugs is permitted if:

(1) All relevant portions of this part have been complied with;

(2) There is no approved new animal or approved new human drug that, when used as labeled or in conformity with criteria established in this part, will, in the available dosage form and concentration, appropriately treat the condition diagnosed. Compounding from a human drug for use in food-producing animals will not be permitted if an approved animal drug can be used for the compounding;

(3) The compounding is performed by a licensed pharmacist or veterinarian within the scope of a professional practice;

(4) Adequate procedures and processes are followed that ensure the safety and effectiveness of the compounded product;

(5) The scale of the compounding operation is commensurate with the established need for compounded products (e.g., similar to that of comparable practices); and

(6) All relevant State laws relating to the compounding of drugs for use in animals are followed.

(c) Guidance on the subject of compounding may be found in guidance documents issued by FDA.

Subpart C—Specific Provisions Relating to Extralabel Use of Animal and Human Drugs in Food-Producing Animals

§530.20 Conditions for permitted extralabel animal and human drug use in food-producing animals.
(a) The following conditions must be met for a permitted extralabel use in food-producing animals of approved new animal and human drugs:

(1) There is no approved new animal drug that is labeled for such use and that contains the same active ingredient which is in the required dosage form and concentration, except where a veterinarian finds, within the context of a valid veterinarian-client-patient relationship, that the approved new animal drug is clinically ineffective for its intended use.

(2) Prior to prescribing or dispensing an approved new animal or human drug for an extralabel use in food animals, the veterinarian must:

(i) Make a careful diagnosis and evaluation of the conditions for which the drug is to be used;

(ii) Establish a substantially extended withdrawal period prior to marketing of milk, meat, eggs, or other edible products supported by appropriate scientific information, if applicable;

(iii) Institute procedures to assure that the identity of the treated animal or animals is carefully maintained; and

(iv) Take appropriate measures to assure that assigned timeframes for withdrawal are met and no illegal drug residues occur in any food-producing animal subjected to extralabel treatment.

(b) The following additional conditions must be met for a permitted extralabel use of in food-producing animals an approved human drug, or of an animal drug approved only for use in animals not intended for human consumption:

(1) Such use must be accomplished in accordance with an appropriate medical rationale; and

(2) If scientific information on the human food safety aspect of the use of the drug in food-producing animals is not available, the veterinarian must take appropriate measures to assure that the animal and its food products will not enter the human food supply.

(c) Extralabel use of an approved human drug in a food-producing animal is not permitted under this part if an animal drug approved for use in food-producing animals can be used in an extralabel manner for the particular use.

§530.21 Prohibitions for food-producing animals.
(a) FDA may prohibit the extralabel use of an approved new animal or human drug or class of drugs in food-producing animals if FDA determines that:

(1) An acceptable analytical method needs to be established and such method has not been established or cannot be established; or

(2) The extralabel use of the drug or class of drugs presents a risk to the public health.

(b) A prohibition may be a general ban on the extralabel use of the drug or class of drugs or may be limited to a specific species, indication, dosage form, route of administration, or combination of factors.

§530.22 Safe levels and analytical methods for food-producing animals.
(a) FDA may establish a safe level for extralabel use of an approved human drug or an approved new animal drug when the agency finds that there is a reasonable probability that an extralabel use may present a risk to the public health. FDA may:

(1) Establish a finite safe level based on residue and metabolism information from available sources;

(2) Establish a safe level based on the lowest level that can be measured by a practical analytical method; or

(3) Establish a safe level based on other appropriate scientific, technical, or regulatory criteria.

(b) FDA may require the development of an acceptable analytical method for the quantification of residues above any safe level established under this part. If FDA requires the development of such an acceptable analytical method, the agency will publish notice of that requirement in the Federal Register.

(c) The extralabel use of an animal drug or human drug that results in residues exceeding a safe level established under this part is an unsafe use of such drug.

(d) If the agency establishes a safe level for a particular species or category of animals and a tolerance or safe concentration is later established through an approval for that particular species or category of animals, for that species or category of animals, the safe level is superseded by the tolerance or safe concentration for that species or category of animals.

§530.23 Procedure for setting and announcing safe levels.
(a) FDA may issue an order establishing a safe level for a residue of an extralabel use of an approved human drug or an approved animal drug. The agency will publish in the Federal Register a notice of the order. The notice will include:

(1) A statement setting forth the agency's finding that there is a reasonable probability that extralabel use in animals of the human drug or animal drug may present a risk to the public health;

(2) A statement of the basis for that finding; and

(3) A request for public comments.

(b) A current listing of those drugs for which a safe level for extralabel drug use in food-producing animals has been established, the specific safe levels, and the availability, if any, of a specific analytical method or methods for drug residue detection will be codified in §530.40.

§530.24 Procedure for announcing analytical methods for drug residue quantification.
(a) FDA may issue an order announcing a specific analytical method or methods for the quantification of extralabel use drug residues above the safe levels established under §530.22 for extralabel use of an approved human drug or an approved animal drug. The agency will publish in the Federal Register a notice of the order, including the name of the specific analytical method or methods and the drug or drugs for which the method is applicable.

(b) Copies of analytical methods for the quantification of extralabel use drug residues above the safe levels established under §530.22 will be available upon request from the Communications and Education Branch (HFV-12), Division of Program Communication and Administrative Management, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855. When an analytical method for the detection of extralabel use drug residues above the safe levels established under §530.22 is developed, and that method is acceptable to the agency, FDA will incorporate that method by reference.

§530.25 Orders prohibiting extralabel uses for drugs in food-producing animals.
(a) FDA may issue an order prohibiting extralabel use of an approved new animal or human drug in food-producing animals if the agency finds, after providing an opportunity for public comment, that:

(1) An acceptable analytical method required under §530.22 has not been developed, submitted, and found to be acceptable by FDA or that such method cannot be established; or

(2) The extralabel use in animals presents a risk to the public health.

(b) After making a determination that the analytical method required under §530.22 has not been developed and submitted, or that such method cannot be established, or that an extralabel use in animals of a particular human drug or animal drug presents a risk to the public health, FDA will publish in the Federal Register, with a 90-day delayed effective date, an order of prohibition for an extralabel use of a drug in food-producing animals. Such order shall state that an acceptable analytical method required under §530.22 has not been developed, submitted, and found to be acceptable by FDA; that such method cannot be established; or that the extralabel use in animals presents a risk to the public health; and shall:

(1) Specify the nature and extent of the order of prohibition and the reasons for the prohibition;

(2) Request public comments; and

(3) Provide a period of not less than 60 days for comments.

(c) The order of prohibition will become effective 90 days after date of publication of the order unless FDA publishes a notice in the Federal Register prior to that date, that revokes the order of prohibition, modifies it, or extends the period of public comment.

(d) The agency may publish an order of prohibition with a shorter comment period and/or delayed effective date than specified in paragraph (b) of this section in exceptional circumstances (e.g., where there is immediate risk to the public health), provided that the order of prohibition states that the comment period and/or effective date have been abbreviated because there are exceptional circumstances, and the order of prohibition sets forth the agency's rationale for taking such action.

(e) If FDA publishes a notice in the Federal Register modifying an order of prohibition, the agency will specify in the modified order of prohibition the nature and extent of the modified prohibition, the reasons for it, and the agency's response to any comments on the original order of prohibition.

(f) A current listing of drugs prohibited for extralabel use in animals will be codified in §530.41.

(g) After the submission of appropriate information (i.e., adequate data, an acceptable method, approval of a new animal drug application for the prohibited extralabel use, or information demonstrating that the prohibition was based on incorrect data), FDA may, by publication of an appropriate notice in the Federal Register, remove a drug from the list of human and animal drugs prohibited for extralabel use in animals, or may modify a prohibition.

(h) FDA may prohibit extralabel use of a drug in food-producing animals without establishing a safe level.

Subpart D—Extralabel Use of Human and Animal Drugs in Animals Not Intended for Human Consumption

§530.30 Extralabel drug use in nonfood animals.

(a) Because extralabel use of animal and human drugs in nonfood-producing animals does not ordinarily pose a threat to the public health, extralabel use of animal and human drugs is permitted in nonfood-producing animal practice except when the public health is threatened. In addition, the provisions of §530.20(a)(1) will apply to the use of an approved animal drug.

(b) If FDA determines that an extralabel drug use in animals not intended for human consumption presents a risk to the public health, the agency may publish in the Federal Register a notice prohibiting such use following the procedures in §530.25. The prohibited extralabel drug use will be codified in §530.41.

Subpart E—Safe Levels for Extralabel Use of Drugs in Animals and Drugs Prohibited From Extralabel Use in Animals

§530.40 Safe levels and availability of analytical methods.

(a) In accordance with §530.22, the following safe levels for extralabel use of an approved animal drug or human drug have been established: [Reserved]

(b) In accordance with §530.22, the following analytical methods have been accepted by FDA: [Reserved]

§530.41 Drugs prohibited for extralabel use in animals.

(a) The following drugs, families of drugs, and substances are prohibited for extralabel animal and human drug uses in food-producing animals.

(1) Chloramphenicol;

(2) Clenbuterol;

(3) Diethylstilbestrol (DES);

(4) Dimetridazole;

(5) Ipronidazole;

(6) Other nitroimidazoles;

(7) Furazolidone.

(8) Nitrofurazone.

(9) Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxypyridazine);

(10) Fluoroquinolones; and

(11) Glycopeptides.

(12) Phenylbutazone in female dairy cattle 20 months of age or older.

(13) Cephalosporins (not including cephapirin) in cattle, swine, chickens, or turkeys:

(i) For disease prevention purposes;

(ii) At unapproved doses, frequencies, durations, or routes of administration; or

(iii) If the drug is not approved for that species and production class.

(b) The following drugs, families of drugs, and substances are prohibited for extralabel animal and human drug uses in nonfood-producing animals: [Reserved]

(c) [Reserved]

(d) The following drugs, or classes of drugs, that are approved for treating or preventing influenza A, are prohibited from extralabel use in chickens, turkeys, and ducks:

(1) Adamantanes.

(2) Neuraminidase inhibitors.

[62 FR 27947, May 22, 1997, as amended at 67 FR 5471, Feb. 6, 2002; 68 FR 9530, Feb. 28, 2003; 68 FR 14134, Mar. 24, 2003; 71 FR 14377, Mar. 22, 2006; 77 FR 745, Jan. 6, 2012]

The most current version may be found on the Electronic Code of Federal Regulations website: https://www.ecfr.gov/cgi-bin/text-idx?SID=3fba2570d1166f25cadaa2e0065b7e95&mc=true&node=pt21.6.530&rgn=div5

Compliance Policy Guide 615.115 – Extralabel Use of Medicated Feeds for Minor Species

Prior to 1994, the Federal Food, Drug, and Cosmetic Act (the FD&C Act) did not permit the extralabel use of animal drugs, but the Agency exercised enforcement discretion regarding extralabel use of animal drugs provided certain criteria were met. These criteria were published in Compliance Policy Guide 7125.06 and were largely incorporated into the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA). AMDUCA amended the FD&C Act to permit extralabel uses under certain conditions. The regulations promulgated pursuant to AMDUCA are codified at 21 CFR part 530.

AMDUCA does not permit extralabel use of medicated feeds. However, when there are no approved treatment options available and the health of animals is threatened, and suffering or death would result from failure to treat the affected animals, extralabel use of medicated feed may be considered for treatment of minor species. Because of the need to have therapeutic options available for treatment of minor species, and to help ensure animal safety and human food safety, FDA is issuing this revised CPG to provide guidance to FDA staff with respect to factors to consider when determining whether to take enforcement action against a veterinarian, animal producer, feed manufacturer, and/or feed distributor for the extralabel use of OTC and VFD medicated feeds in minor species. In general, the Agency will not recommend or initiate enforcement action against the veterinarian, animal producer, feed mill, or other distributor when extralabel use is consistent with this document.

Appendix C

Definitions of Antimicrobial Use for Treatment, Control and Prevention:

The American Veterinary Medical Association (AVMA) professional policies provide guidance on the practice of veterinary medicine. The AVMA encourages its members to voluntarily adhere to policies impacting the practice of veterinary medicine, as these policies are developed by peers on behalf of the profession. AVMA policies are not, and do not supersede, law or regulation. AVMA's concise definitions[m] of treatment, control and prevention of individual animals and animal populations alleviate confusion and assist veterinarians in clearly communicating their intentions when prescribing or recommending antimicrobial use.[n]

Antimicrobial prevention of disease (synonym: prophylaxis):
1) Prevention is the administration of an antimicrobial to an individual animal to mitigate the risk for acquiring disease or infection that is anticipated based on history, clinical judgement, or epidemiological knowledge.
2) On a population basis, prevention is the administration of an antimicrobial to a group of animals, none of which have evidence of disease or infection, when transmission of existing undiagnosed infections, or the introduction of pathogens, is anticipated based on history, clinical judgement or epidemiological knowledge.

Antimicrobial control of disease (synonym: metaphylaxis):
1) Control is the administration of an antimicrobial to an individual animal with a subclinical infection to reduce the risk of the infection becoming clinically apparent, spreading to other tissues or organs, or being transmitted to other individuals.
2) On a population basis, control is the use of antimicrobials to reduce the incidence of infectious disease in a group of animals that already has some individuals with evidence of infectious disease or evidence of infection.

Antimicrobial treatment of disease:
1) Treatment is the administration of an antimicrobial as a remedy for an individual animal with evidence of infectious disease.
2) On a population basis, treatment is the administration of an antimicrobial to those animals within the group with evidence of infectious disease.

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[m] AVMA Definitions of Antimicrobial Use for Treatment, Control and Prevention can be found at https://www.avma.org/KB/Policies/Pages/AVMA-Definitions-of-Antimicrobial-Use-for-Treatment-Control-and-Prevention.aspx

[n] Smith, D.R., et al. The AVMA's definitions of antimicrobial uses for prevention, control, and treatment of disease. *J Am Vet Med Assoc.* 2019 Apr 1;254(7):792-797. doi: 10.2460/javma.254.7.792

Appendix D

Division 7, Food and Agriculture Code, Chapter 4.5 – Livestock: Use of Antimicrobial Drugs

§14402.

(a) Beginning January 1, 2018, a medically important antimicrobial drug may be used when, in the professional judgment of a licensed veterinarian, the medically important antimicrobial drug is any of the following:

(1) Necessary to treat a disease or infection.

(2) Necessary to control the spread of a disease or infection.

(3) Necessary in relation to surgery or a medical procedure.

(b) A medically important antimicrobial drug may also be used when, in the professional judgment of a licensed veterinarian, it is needed for prophylaxis to address an elevated risk of contraction of a particular disease or infection.

(c) A person shall not administer a medically important antimicrobial drug to livestock solely for purposes of promoting weight gain or improving feed efficiency.

(d) Unless the administration is consistent with subdivision (a), a person shall not administer a medically important antimicrobial drug in a regular pattern.

(Added by Stats. 2015, Ch. 758, Sec. 1. (SB 27) Effective January 1, 2016.)

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IN SENATE

May 14, 2019

Introduced by Sens. KAVANAGH, HOYLMAN -- read twice and ordered printed, and when printed to be committed to the Committee on Higher Education -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

AN ACT to amend the education law and the state finance law, in relation to protecting medically important antimicrobials for human public health

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. Legislative findings. The legislature declares that the overuse and misuse of medically important antimicrobials poses a serious public health threat.

The World Health Organization has stated that "without urgent, coordinated action by many stakeholders, the world is headed for a post-antibiotic era, in which common infections and minor injuries which have been treatable for decades can once again kill." In 2016, members of the UN General Assembly adopted a political declaration acknowledging that "the resistance of bacterial, viral, parasitic and fungal microorganisms to antimicrobial medicines that were previously effective for treatment of infections is mainly due to: the inappropriate use of antimicrobial medicines in public health, animal, food, agriculture and aquaculture sectors; ... resistance to antibiotics, which are not like other medicines ... is the greatest and most urgent global risk, requiring increased attention and coherence at the international, national and regional levels."

The legislature further finds that overuse and misuse of medically important antimicrobials in livestock production is a significant component of the threat posed. The United States Food and Drug Administration and the Centers for Disease Control and Prevention have stated that there is a definitive link between the routine use of medically impor-

EXPLANATION--Matter in *italics* (underscored) is new; matter in brackets [-] is old law to be omitted.

LBD11330-08-9

tant antimicrobials on industrial farms and the crisis of antimicrobial-resistant infections in humans.

The issue of antimicrobial misuse and overuse, whether in people or animals, is a significant and urgent public health matter.

It has been estimated that seventy percent of all antimicrobials sold in the United States are for use in food-producing animals, often to compensate for the effects of unsanitary and overcrowded conditions on farms.

Many of the antimicrobials provided to food-producing animals are identical to, or from the same class as, drugs used in human medicine to treat serious conditions (i.e., medically important drugs). Thus, antimicrobial-resistant bacteria that emerge and spread from food-producing animals in farm settings to infect humans can be very dangerous because the antibiotics usually used to treat the infections in humans may no longer be effective against them.

The legislature further finds that, as with any use of medically important antimicrobials in animals, such use must be closely supervised by a New York state licensed veterinarian or those veterinarians authorized to practice within the state. Moreover, that it is the licensed veterinarian who must ensure that the use of medically important antimicrobials is appropriate and necessary.

The legislature therefore intends to place appropriate restrictions on the misuse and overuse of medically important antimicrobials in food-producing animals by ensuring that veterinarians have the clear authority to control the use of medically important antimicrobials in food-producing animals in New York state and that their practices are following the best scientific evidence.

The purpose of this act is to protect public health by preserving the effectiveness of medically important antimicrobials now and for future generations by eliminating the use of those medicines in food-producing animals for disease prevention, resulting in a reduction in the rise and spread of antimicrobial-resistant bacteria and antimicrobial-resistant infections in humans.

§ 2. The education law is amended by adding a new article 135-A to read as follows:

ARTICLE 135-A

COMBATING ANTIMICROBIAL RESISTANCE ACT

§ 6720. Short title. This act shall be known and may be cited as the "combating antimicrobial resistance act of 2019."

§ 6721. Definitions. As used in this section:

1. "Antimicrobial" means any substance of natural, semi-synthetic, or synthetic origin that at in vivo concentrations kills or inhibits the growth of microorganisms by interacting with a specific target. The term antimicrobial is a collective for antiviral, antibacterial, antifungal, antiparasitic, and antiprotozoal agents.

2. "Antimicrobial class" means antimicrobial agents with related molecular structures, often with a similar mode of action because of

interaction with a similar target and thus subject to a similar mechanism of resistance.

3. "Antimicrobial resistance (AMR)" means the ability of a microorganism to multiply or persist in the presence of an increased level of an antimicrobial relative to the susceptible counterpart of the same species.

4. "Disease control" means administration of antimicrobial agents to a group of animals containing sick and healthy individuals (presumed to be infected), to minimize or resolve clinical signs of infectious disease and to prevent further spread of the disease.

5. "Disease prevention" means administration of antimicrobial agents to an individual or a group of animals at risk of acquiring a specific infection or in a specific situation where infectious disease is likely to occur if the antimicrobial agent is not administered.

6. "Disease treatment" means administration of antimicrobial agents to an individual or group of animals showing clinical signs of infectious disease or that test positive for a disease.

7. "Food-producing animal" means:

(a) All cattle, swine, or poultry, regardless of whether the specific animal is raised for the purpose of producing food for human consumption; or

(b) Any animal of a type that the department of agriculture and markets identifies by rule as livestock typically used to produce food for human consumption, including aquatic and amphibian species.

8. "Livestock producer" means a person raising a food-producing animal for commercial purposes.

9. "Medically important antimicrobial" means a drug that is composed in whole or in part of:

(a) A form of the antibiotic classes of penicillin, tetracyline, macrolide, lincosamide, streptogramin, aminoglycoside, sulfonamide, or cephalosporin; or

(b) A drug from an antimicrobial class that is categorized as critically important, highly important, or important in the World Health Organization list of Critically Important Antimicrobials for Human Medicine (5th Revision, 2016), or a subsequent revision or successor document issued by the World Health Organization that is recognized by rule by the department of health.

10. "Veterinary Feed Directive" has the same definition as in section 558.3 of title 21 of the code of federal regulations.

§ 6722. Prohibition of certain antimicrobial administration. Beginning January first, two thousand twenty, medically important antimicrobials shall not be administered to a food-producing animal unless ordered by a licensed veterinarian who has visited the farm operation within the previous six months, through a prescription or Veterinary Feed Directive, pursuant to a veterinarian-client-patient relationship that meets the requirements as defined by the New York state office of professions.

§ 6723. Authorization of certain antimicrobial administration. 1. Beginning January first, two thousand twenty, a livestock producer may provide a medically important antimicrobial to a food-producing animal only if a licensed veterinarian, in the exercise of professional judgment, determines that the provision of the medically important antimicrobial to the animal is necessary:

(a) To control the spread of a disease or infection;

(b) To treat a disease or infection; or

(c) In relation to surgical or other medical procedures.

2. Medically important antimicrobials shall not be administered by any person to food-producing animals solely for the purposes of promoting weight gain, improving feed efficiency, or disease prevention.

3. A veterinarian who determines that the provision of a medically important antimicrobial to a food-producing animal is necessary for a purpose described in this section shall specify an end date for the provision of the antimicrobial to the animal.

4. A livestock producer may administer a medically important antimicrobial to a food-producing animal only for the purpose as determined by a licensed veterinarian under this article. The livestock producer may provide the antimicrobial only for the duration specified by the veterinarian.

§ 6724. Annual reports. 1. Veterinarians licensed to practice in New York state, or who are licensed in a bordering state and practice in the state, and who prescribe medically important antimicrobials or write a Veterinary Feed Directive for one or more sets of food-producing animals must file an annual report under this section in a form and manner required by the department by rule. This report will be submitted to the commissioner, the commissioner of health, the commissioner of agriculture and markets, the temporary president of the senate, the senate minority leader, the speaker of the assembly, and the minority leader of the assembly. If any medically important antimicrobials were prescribed to, provided to, or administered to food-producing animals during the reporting period, the annual report must contain the following information:

(a) The total number of food-producing animals provided with medically important antimicrobials;

(b) The name of each medically important antimicrobial provided;

(c) The species of food-producing animals that were provided with each medically important antimicrobial;

(d) The quantity of each medically important antimicrobial prescribed to each species of food-producing animal;

(e) The number of days that each medically important antimicrobial was intended to be provided to a food-producing animal;

(f) The dosage of each medically important antimicrobial that was intended to be provided to a food-producing animal;

(g) The method for providing each medically important antimicrobial to a food-producing animal;

(h) The purpose for providing each medically important antimicrobial to a food-producing animal; and

(i) The disease or infection, if any, that was intended to be controlled due to the provision of each medically important antimicrobial.

2. For the purposes of paragraph (h) of subdivision one of this section, the purpose for providing a medically important antimicrobial to a food-producing animal must be reported as:

(a) Disease control; or

(b) Disease treatment; or

(c) Necessary for surgical or other medical procedures.

3. Information reported under this section should be made publicly available by the department of health annually in an online searchable database of aggregated data. Such database shall protect the identity of a licensed veterinarian, an individual farm or business.

4. Information reported under this section is a public record and is not subject to exemption from public disclosure as required under the New York state freedom of information law.

5. The state board of veterinary medicine, the department of health and the department of agriculture and markets will consult as necessary to fulfill the requirements of this section.

§ 6725. Antimicrobial stewardship guidelines. 1. The state board of veterinary medicine, in consultation with the department of agriculture and markets, the department of health, universities, and cooperative extensions, shall develop antimicrobial stewardship guidelines and best management practices for veterinarians, livestock owners, and their employees who are involved with the administering of medically important antimicrobials on the proper use of medically important antimicrobials for disease treatment and control. The guidelines shall include scientifically validated practical alternatives to the use of medically important antimicrobials, including, but not limited to, good hygiene and management practices. The guidelines shall be reviewed and updated periodically, as necessary.

2. The state board of veterinary medicine shall consult with livestock producers, licensed veterinarians, and other relevant stakeholders on ensuring that livestock grown in rural areas with limited access to veterinary care have timely access to treatment.

3. For the purposes of this section, "antimicrobial stewardship" is a commitment to do all of the following:

(a) To use medically important microbials only when necessary to treat or control disease;

(b) To select the appropriate medically important microbial and the appropriate dose, duration, and route of administration; and

(c) To use medically important microbials for the shortest duration necessary and allowable, and to administer them to the fewest animals necessary.

§ 6726. Implementation. 1. The state board of veterinary medicine, the department of health, and the department of agriculture and markets shall coordinate with the United States Department of Agriculture, the United States Food and Drug Administration, and the Centers for Disease Control and Prevention to implement the expanded antimicrobial resistance surveillance efforts included in the National Action Plan for Combating Antibiotic-Resistant Bacteria, and that the information gathered through this effort will help lead to a better understanding of the links between antimicrobial use patterns in livestock and the development of antimicrobial-resistant bacterial infections.

2. (a) The department of health, the state board of veterinary medicine, the department of agriculture and markets, veterinarians, and livestock producers shall gather information on medically important antimicrobial sales and usage as well as antimicrobial-resistant bacteria and livestock management practice data. Monitoring efforts shall not be duplicative of the National Animal Health Monitoring System or the National Antimicrobial Resistance Monitoring System, and, to the extent feasible, will coordinate with the United States Department of Agriculture, the Centers for Disease Control and Prevention, and the United States Food and Drug Administration in the development of these efforts.

(b) In coordinating with the National Animal Health Monitoring System and the National Antimicrobial Resistance Monitoring System, the department of health, the state board of veterinary medicine and the department of agriculture and markets shall gather representative samples of biological isolates from all of the following:

(i) New York state's major livestock segments;

(ii) regions with considerable livestock production; and

(iii) representative segments of the food production chain.

(c) The department of health, the state board of veterinary medicine and the department of agriculture and markets shall report to the legislature by January first, two thousand twenty-one, the results of their outreach activities and monitoring efforts.

§ 6727. Authority to receive Veterinary Feed Directives. The department of agriculture and markets has the authority to request and receive copies of all Veterinary Feed Directives issued in the state from veterinarians, livestock owners, feed mills, or distributors to fully implement the provisions of this article.

§ 6728. Violations. 1. A person or entity who violates this article shall be liable for a civil penalty of not more than two hundred and fifty dollars per farm operation for each day a violation occurs.

2. (a) For a second or subsequent violation, a person or entity who violates this article shall be punishable by an administrative fine in the amount of five hundred dollars per farm operation for each day a violation occurs.

(b) In addition to the administrative fine, the violator shall attend an educational program to be jointly developed by the department of health and the state board of veterinary medicine on the judicious use of medically important antimicrobials. The violator shall successfully complete the program and provide proof to the board within ninety days from the occurrence of the violation.

3. Subdivisions one and two of this section shall not apply to licensed veterinarians. A veterinarian who violates this section is subject to discipline as defined in subarticle three of article one hundred thirty of title eight of this chapter.

4. The moneys collected pursuant to this article shall be deposited into the antibiotics education fund established pursuant to section ninety-seven-j of the state finance law and be available for expenditure upon appropriation by the legislature.

§ 3. The state finance law is amended by adding a new section 97-j to read as follows:

§ 97-j. Antibiotics education fund. 1. There is hereby established in the custody of the state comptroller a special fund to be known as the "antibiotics education fund".

2. Such fund shall consist of all monies recovered from the assessment of any penalty authorized by article one hundred thirty-five-A of the education law.

3. Moneys of the fund shall be deposited to the credit of the fund and shall, in addition to any other moneys made available for such purpose, be available to the department for the purpose of antibiotics educational programs. All payments from the antibiotics education fund shall be made on the audit and warrant of the state comptroller on vouchers certified and submitted by the commissioner.

§ 4. This act shall take effect January 1, 2020.

Guidelines for Veterinarians: Judicious Use of Antimicrobials

July 17, 2019

Annette Jones, DVM

Rosie Busch, DVM

California Department of Food and Agriculture

Overview

- California's "Livestock: Use of Antimicrobial Drugs" law: How it Applies to Veterinarians
- Review of Revised Judicious Use Guidelines (Veterinarian)
- Questions and Comments

“Livestock: Use of Antimicrobial Drugs” law

Additions to the Food and Agricultural Code:
Division 7, Chapter 4.5, Sections 14400-14408

Featured Sections

- **14401: VCPR Requirement**
- **14402: Limitations of Use**
- **14404: Guideline Development Mandate**

At the same time:

Federal restrictions on feed and water MIADs (took affect 2017)

Veterinarian CE requirement: SB 361 (2015)

Food and Agricultural Code

Division 7, Chapter 4.5

Section 14401. 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.

Food and Agricultural Code

Division 7, Chapter 4.5

Section 14402.

(a) Beginning January 1, 2018, a medically important antimicrobial drug may be used when, in the professional judgment of a licensed veterinarian, the medically important antimicrobial drug is any of the following:

(1) Necessary to treat a disease or infection.

(2) Necessary to control the spread of a disease or infection.

(3) Necessary in relation to surgery or a medical procedure.

(b) A medically important antimicrobial drug may also be used when, in the professional judgment of a licensed veterinarian, it is needed for prophylaxis to address an elevated risk of contraction of a particular disease or infection.

(c) A person shall not administer a medically important antimicrobial drug to livestock solely for purposes of promoting weight gain or improving feed efficiency.

(d) Unless the administration is consistent with subdivision (a), a person shall not administer a medically important antimicrobial drug in a regular pattern.

Food and Agricultural Code

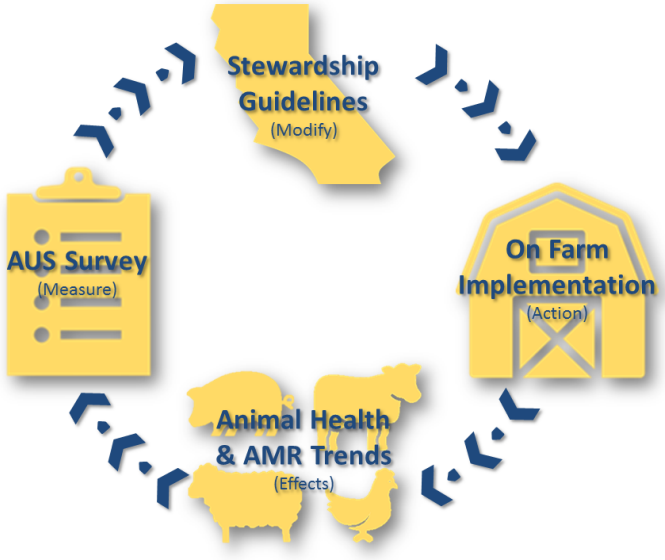
Division 7, Chapter 4.5

Section 14404.

- (a) The department, in consultation with the Veterinary Medical Board, the State Department of Public Health, universities, and cooperative extensions, shall develop antimicrobial stewardship guidelines and best management practices for veterinarians, as well as livestock owners and their employees who are involved with administering medically important antimicrobial drugs, on the proper use of medically important antimicrobial drugs for disease treatment, control, and prevention. The guidelines shall include scientifically validated practical alternatives to the use of medically important antimicrobial drugs, including, but not limited to, the introduction of effective vaccines and good hygiene and management practices.
- (b) The department shall consult with livestock producers, licensed veterinarians, and any other relevant stakeholders on ensuring livestock timely access to treatment for producers in rural areas with limited access to veterinary care.
- (c) For purposes of this section, “antimicrobial stewardship” is a commitment to do all of the following:
- (1) To use medically important antimicrobial drugs only when necessary to treat, control, and, in some cases, prevent, disease.
- (2) To select the appropriate medically important antimicrobial drug and the appropriate dose, duration, and route of administration.
- (3) To use medically important antimicrobial drugs for the shortest duration necessary and to administer them to the fewest animals necessary.

Other Requirements

- Voluntary data gathering from producers
- CDFA to promulgate regulations of sales of MIADs
- Timely access to veterinary treatment
  - Identify ‘rural’ areas with limited access to veterinary care
  - Consult with producers and licensed veterinarians
- CDFA to develop stewardship guidelines



Why Antimicrobial Stewardship?

- Reduce the need for antimicrobial drugs with infectious disease prevention
- Use antimicrobials appropriately to optimize livestock health and minimize selection for antimicrobial resistance

How Guidelines Will Be Used

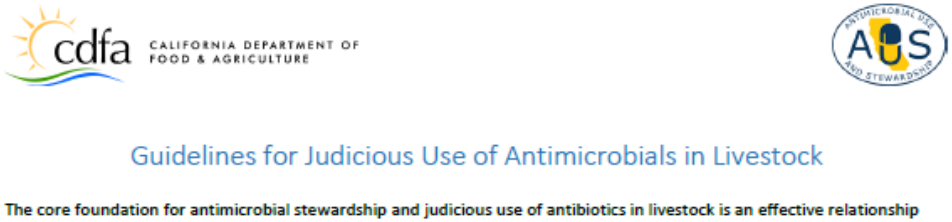
To be used by veterinarians to implement good antimicrobial stewardship

Almost 2 year process of drafting and review, with animal science and veterinary experts, as well as legal authority contributing

Goal: science based policy and direction

Outline of Judicious Use Guidelines

1. Guideline Text *(3 pages)*
2. Appendix A: Title 16, California Code of Regulations, Section 2032.1 – Veterinarian-Client-Patient Relationship *(1 page)*
3. Appendix B: Title 21, Code of Federal Regulations, Part 530 – Extralabel Drug Use in Animals *(7 pages)*
4. Compliance Policy Guide 615.115 – Extralabel Use of Medicated Feeds for Minor Species *(1 page)*
5. Appendix C: Definitions of Antimicrobial Use for Treatment, Control and Prevention *(1 page)*
6. Appendix D: Division 7, Food and Agriculture Code, Chapter 4.5 – Livestock: Use of Antimicrobial Drugs §14402 *(1 page)*
7. References *(1 page)*



cdfa CALIFORNIA DEPARTMENT OF FOOD & AGRICULTURE

Guidelines for Judicious Use of Antimicrobials in Livestock

The core foundation for antimicrobial stewardship and judicious use of antibiotics in livestock is an effective relationship between a veterinarian and livestock owners. Biosecurity and herd health plans developed and revised under the guidance of a veterinarian are vital to maintain productivity, animal health and welfare, as well as a safe and secure food supply. Livestock owners, and their employees responsible for animal care, play a critical role in the success of a herd health plan. Recognizing early signs of illness in animals, such as slight changes in behavior, requires skill and experience, and it demonstrates a dedication to animal care and stockmanship. Various tools and/or scoring systems (e.g., monitoring feed and water consumption, calf health scores, the California Mastitis Test, and automated animal health trackers) may assist with the training and day-to-day activities of those responsible for animal care.

In California, the potential use of medically important antimicrobial drugs (hereafter referred to as antibiotics) in livestock must be deemed necessary under the professional judgment of a California licensed veterinarian, within the context of a valid veterinarian-client-patient relationship (VCPR) and in accordance with current veterinary medical practice and legal parameters.[a] To use antibiotics effectively and responsibly, a veterinarian must first develop a preliminary or general diagnosis, or have an indication of elevated risk of disease or infection.[b,c] The diagnostic process includes consideration of the history, clinical judgement, and epidemiological knowledge of the veterinarian.

Once the need for antibiotic therapy has been established, the following are essential to practice the judicious use of antibiotics:

These guidelines are intended to aid livestock owners and their employees responsible for animal care in responsible antibiotic use under the guidance of a veterinarian in compliance with state and federal laws.

1) The decision to use antibiotics for sick or at-risk animals should be made promptly and, when appropriate, antibiotic therapy should be initiated in a timely manner to minimize the infectious burden, improve therapeutic outcomes, and reduce the development of antibiotic resistance.

2) In deciding to implement the use of an antibiotic, a veterinarian may consider the expected benefit from therapy.
   a) Antibiotic therapy may be indicated for treatment in animals with an infectious disease or evidence of an infectious disease before a final diagnosis can be made. The veterinarian may assess the likelihood the illness is a result of a bacterial infection, the expected outcome of starting antibiotic therapy, and potential adverse effects of antibiotic therapy.
   b) Antibiotic therapy may be required for control to decrease the severity of disease, reduce shedding of infectious bacteria, and minimize chances for spreading the disease to additional animals.
   c) Antibiotic therapy may be necessary for prevention to address an elevated risk of contracting a particular disease or infection when the ability to predict outcomes to infectious exposure is not possible, but infection is anticipated based on the veterinarian's professional judgment regarding animal-specific risk factors.
   d) Medically important antibiotics shall not be administered to livestock solely for purposes of promoting weight gain or improving feed efficiency.
   e) Keeping accurate treatment and production records that include health outcomes of treated animals may aid the veterinarian in monitoring the effectiveness of animal health and disease prevention plans, reviewing treatment

[a] Medically important antimicrobial drugs and are defined as those listed in Appendix A of the U.S. Food and Drug Administration's Guidance for Industry #152.
[b] Defined in the Veterinary Medicine Practice Act, Title 16 of the California Code of Regulations, Section 2032.1.
[c] Allowable and prohibited uses of medically important antimicrobial drugs in livestock are described in 4.5 FAC § 14402. Attached in Appendix D.

Guideline Text Review

- Covering veterinary guidance only
- Producer guidance mirrors veterinary

Outline of Guideline Text

Introduction: Antimicrobials must be used with valid VCPR.

1. Antibiotics should be used for sick or at-risk animals.
2. Veterinarians consider many factors when prescribing MIADs.
3. Supportive Care and Alternatives can be used when scientifically supported and no negative animal welfare effects.
4. Selection of appropriate antibiotics and legal restrictions.
5. Dispensing and storing medication considerations for MIADs.

Next Steps for CDFA

Final Reviews of Judicious Use Guidelines

(and align Producer guidelines with any changes)

Formally Finalized with Support from CDFA Executive Office

Published on Website for public use

Veterinary Education and Promotion

Questions or Comments?

Thank You

Additional Information