

Complying with California Senate Bill 27 Livestock: Use of Antimicrobial Drugs



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FDA GFI 213

New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209

- ▶ Specific recommendations on how to voluntarily modify the use conditions of their medically important antimicrobial drug products → Then becomes mandatory (Jan 2017)
- ▶ Feed → OTC to VFD
- ▶ Water → OTC to Rx
- ▶ No production use
- ▶ Reasoning: Judicious use involves accurately identifying bacterial disease that is present or likely to be present and selecting the suitable antimicrobial drug

Veterinary Feed Directive Rule

- ▶ Final Rule published June 3, 2015 - Into effect October 1, 2015
- ▶ Rule changes were needed before OTC → VFD (FDA GFI 213)
 - ❖ Under GFI 213 feed OTCs would have automatically become Category II if the rule had not been modified.
- ▶ Cannot use VFD off-label (if OTC, can not write a VFD and visa versa)
- ▶ “Medically Important” reflects likelihood of resistance developing that will effect human health
- ▶ Category I and II reflects risk of residue/withdrawal
- ▶ Type A, B, C reflects concentration
- ▶ Key: only FDA licensed mills can handle Category II, type A ~~and VFD~~

→ eliminates potential licensing bottleneck

Veterinary Feed Directive Rule

- ▶ Record keeping
 - ❖ No oral VFDs but electronic ok
 - ❖ Must include *production* class as well as species and description, but no individual IDs listed
- ▶ Increased flexibility for the producer
 - ❖ Specified duration and approximate number of animals over the duration instead of specific volume of feed

(Addresses concerns with over/under feeding)

Veterinary Feed Directive Rule

Eliminates federal definition of veterinarian-client-patient relationship & defers to state (still must be a licensed veterinarian)

California v-c-p meets the federal standard:

California 16 CCR § 2032.1

(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.*

SB 27 Livestock: Use of Antimicrobial Drugs

- I. Limits Use (January 1, 2018)
- II. Stewardship Guidelines
- III. Monitoring/Surveillance

Limits Use

- Effective January 1, 2018
- Applies to use in livestock, but not species usually kept as pets (what does that mean?)
- Specific to medically important antimicrobials as defined by FDA GFI 152 Appendix A, including updates
- Can only be administered if ordered by a veterinarian via prescription or veterinary feed directive, under a valid veterinarian-client-patient relationship

Limits Use

- Can only be used when in the judgement of a licensed veterinarian is necessary to treat, control and in some cases, prevent disease or infection
- Prevention / Prophylaxis
 - ❖ If related to surgery or medical procedure
 - ❖ If “in the professional judgement of a licensed veterinarian, it is needed for prophylaxis to address an elevated risk of contraction of a particular disease or infection”
 - ❖ If used to prevent disease beyond when related to surgery or medical procedure, *can not be used in a “regular pattern”*
- Can never use solely for weight gain or feed efficiency

Limits Use

- Medically important antibiotics labeled by FDA for over the counter (OTC) sales can still be obtained from retailers *with prescription or VFD*
 - ❖ Veterinary Food Animal Drug Retailer (B&P)
 - ❖ Retail License for Restricted Drugs (FAC)
 - ❖ May need regulations to add clarity
- Violations
 - ❖ Licensed veterinarian: Practice Act disciplinary sanctions
 - ❖ Others: Up to \$250/day; second violation up to \$500/day

Stewardship

- ▶ No delay in implementation
- ▶ Requires that CDFA work with others to develop “antimicrobial stewardship guidelines and best management practices for veterinarians and livestock owners and employees”
- ▶ Must include scientifically validated best practices such as vaccination, sanitation and other management practices that may limit the need for antibiotics

Stewardship

- ▶ Must include guidance on selection of most appropriate antimicrobial drug, dose, duration and route of administration
- ▶ Must include guidance on limiting the number of animals treated and minimizing the duration of treatment

Monitoring

- ▶ No delay in implementation
- ▶ Leveraging federal efforts, gather information that may lead to a better understanding of the links between use patterns and resistance
- ▶ Gather antimicrobial sales and use data, conduct surveillance for resistance, and gather management practice data (including health outcomes)
 - ❖ California's major livestock segments
 - ❖ Regions with significant livestock production
 - ❖ Representative segments of the food production chain

Monitoring

- ▶ Willing participants and respecting veterinary-client-patient confidentiality
- ▶ Authority to request and receive copies of VFD's
- ▶ Information must be held confidential unless aggregated
 - ❖ Can be shared with VMB for enforcement of Practice Act or Federal entities if confidentiality will also be protected under federal law
- ▶ Report to the legislature January 1, 2019

What now?

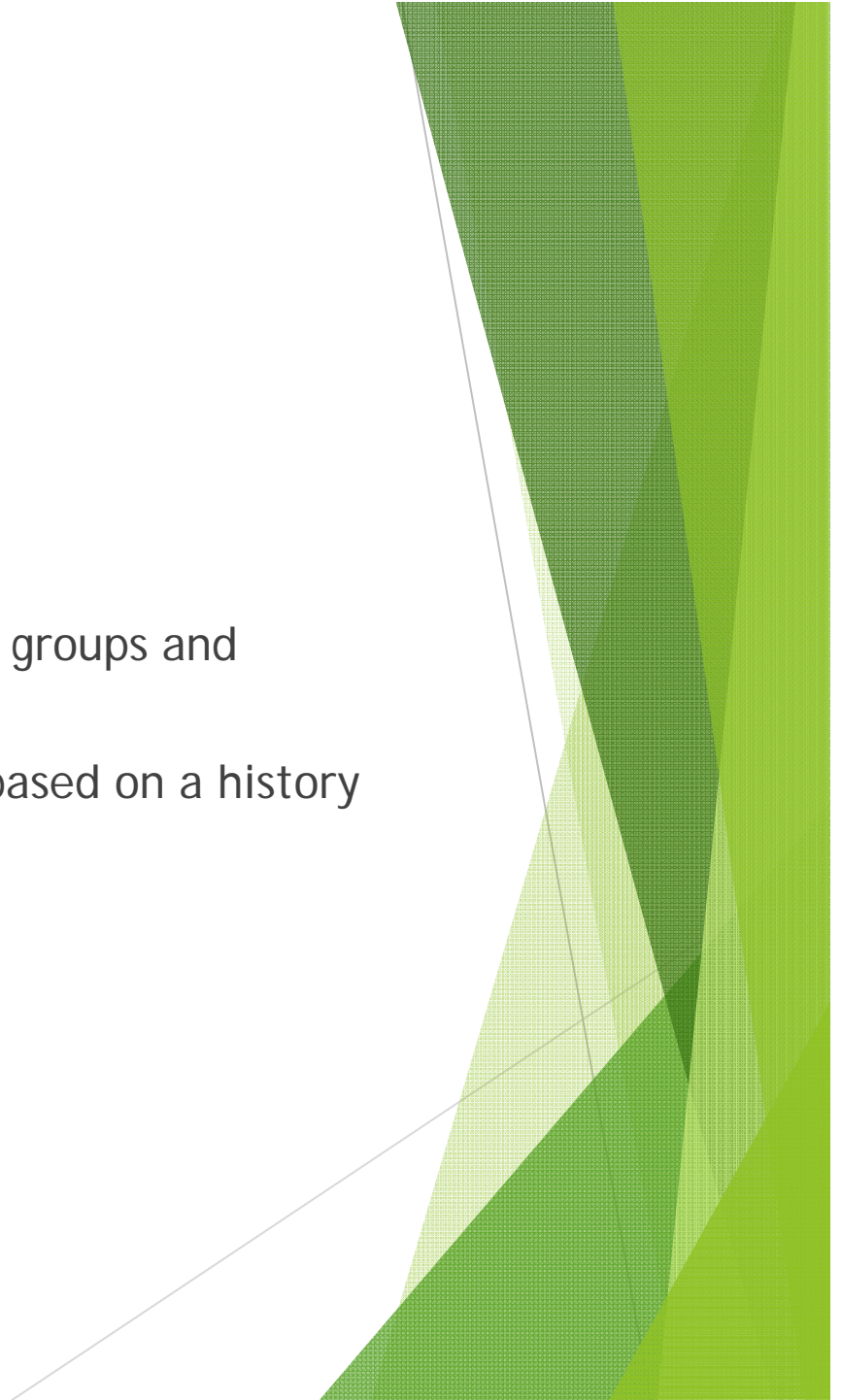
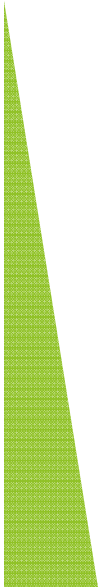
- ▶ Extensive use of ad hoc advisory committees comprised of stakeholders as well as technical specialists and scientific advisors for specific topics
- ▶ Stakeholders include:
 - ✓ Department of Public Health
 - ✓ Board of Pharmacy
 - ✓ Veterinary Medical Board
 - ✓ Producers and producer organizations
 - ✓ Feed mills and feed industry organizations
 - ✓ Retail stores distributing or potentially distributing antibiotics
 - ✓ Pharmaceutical companies and business organizations
 - ✓ Veterinarians and veterinarian professional organizations
 - ✓ Schools of Veterinary Medicine
 - ✓ Consumer advocates
 - ✓ CA Animal Health and Food Safety Laboratory
 - ✓ United States Department of Agriculture (USDA)
 - ✓ Food and Drug Administration
 - ✓ Others TBD

Phase I Funding

- ▶ 8 Positions and \$1.393 million General Fund
 - ▶ Program Administration
 - ▶ 1 position in AHFSS for overall SB 27 implementation management, including efforts to attract supplemental funds (federal grants, etc.)
 - ▶ 1.5 positions in Inspection Services for regulation development and supervision
 - ▶ Regulated Use (2018):
 - ▶ 1 position in Inspection Services for outreach (SSI I)
 - ▶ Monitoring (2016)
 - ▶ 1.5 positions in AHFSS for coordination with national efforts & development and initial implementation of the CA monitoring strategy
 - ▶ 1 position in Inspection Services to gather and analyze appropriate VFD and Registered Retailer sales data
 - ▶ \$50,000 to initiate strategy and capability for pathogen resistance monitoring at CAHFS Laboratory System
 - ▶ Stewardship (2016)
 - ▶ 2 positions to develop strategy and initiate development
 - ▶ \$50,000 in contract funding for species or production type specific expertise

Lessons

- ▶ Engage
- ▶ Drive the dialogue
- ▶ Veterinarian and physician professional groups and academia important for credibility
- ▶ Communicate with commodity groups based on a history of trust



Producers

trust

Consumer
Advocates

Veterinarians



Thanks!

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