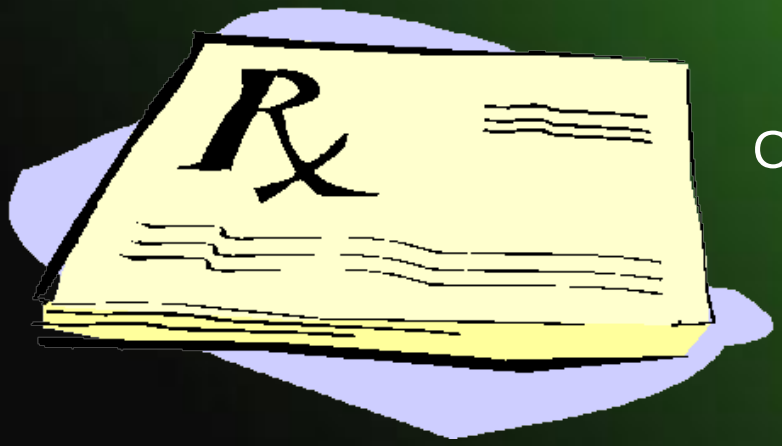
National Institute for Animal Agriculture – Antibiotics Council

Veterinary Oversight of Antimicrobials



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AVMA
Scientific Activities Division
March 27, 2012

National Institute for Animal Agriculture – Poultry Committee

Antibiotics in Poultry

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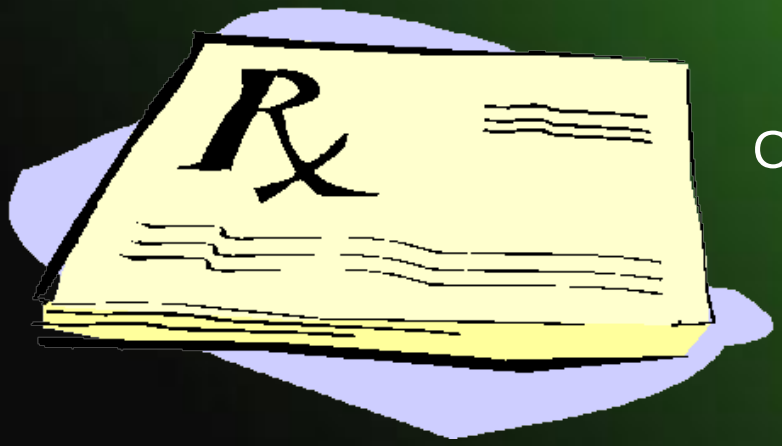
National Institute for Animal Agriculture – Antibiotics Council

Veterinary Oversight of Antimicrobials



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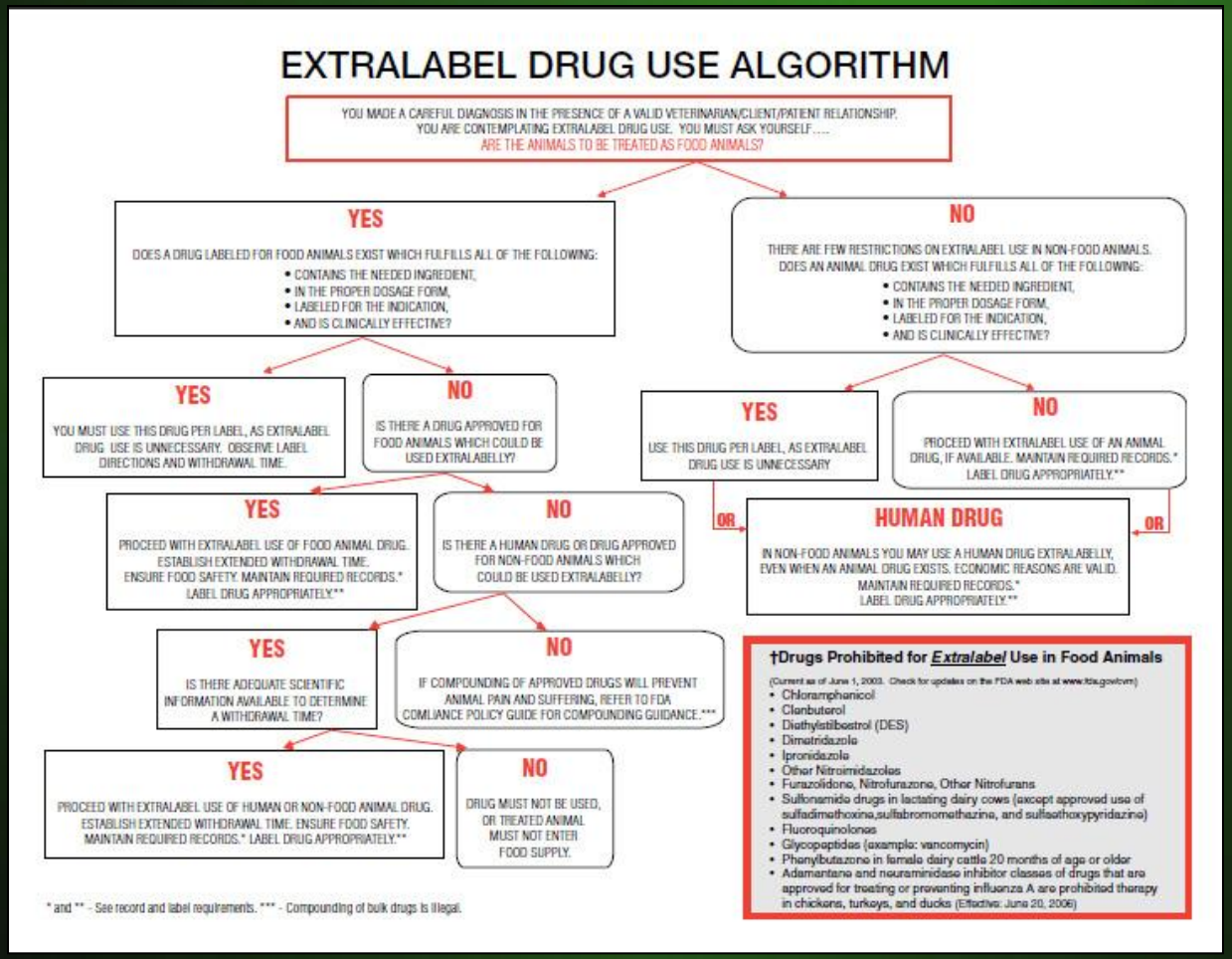
Recent Developments

- ELDU Prohibition on cephalosporins
- VFDs and the VCPR
- Court ruling on penicillin and tetracyclines

Extra label Drug Use



www.avma.org/reference/amduca/extralabel_brochure.pdf

Cephalosporin Prohibition

Prohibited Uses:

- dose levels, frequencies, durations, or routes of administration NOT on the label
- Using cepahlosporins that are not approved for use in that species (e.g., cephalosporin drugs approved for use in humans or companion animals)
- Using cephalosporins for prevention

Cephalosporin Prohibition

Allowed Extralabel Uses:

- Cephapirin (only approved for intramammary)
- Veterinarians will still be able to use or prescribe cephalosporins for a different disease indication in cattle, swine, chickens or turkeys as long as they follow the dose, frequency, duration, and route of administration that is on the label.
- Minor food producing species are exempted

Cephalosporin Prohibition

AVMA's response:
http://www.avma.org/advocacy/federal/regulatory/practice_issues/drugs/FDA-ELDU-Order-of-Prohibition.asp

AVMA@work blog:
http://atwork.avma.org/2012/01/04/fda-issues-more-targeted-eldu-prohibition-on-cephalosporins/

Podcast:
http://www.keepourfoodsafe.org/2012/02/new-podcast-sheds-light-on-antibiotics-fda-ban/

Veterinary Feed Directive (VFDs)

- Vehicle for greater veterinary oversight of antimicrobials
- Draft Guidance For Industry #209 indicated a need for greater veterinary oversight
- Guidance For Industry #213 (yet to be released) will outline how pharmaceutical companies are to seek approvals for therapeutic claims

Veterinary Feed Directive (VFDs)

- AVMA has a Steering Committee to work with the FDA specifically on this issue
- Draft codified language is expected to be released for public comment
- AVMA has requested that this be prioritized by HHS Secretary Sebelius and Commissioner Hamburg

VFDs and the VCPR!?!

Mass confusion!

- Current VFD language requires a VCPR that is defined in AMDUCA 21 CFR Part 530.3 http://www.gpo.gov/fdsys/pkg/CFR-2001-title21-vol6/pdf/CFR-2001-title21-vol6-part530.pdf
- The requirement of concern–

"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."

The "other" VCPRs

- AVMA's Model Veterinary Practice Act
- AVMA's Principle of Veterinary Medical Ethics
- State requirements in the individual state veterinary practice acts; **Some states do not require a VCPR to dispense prescription products and this is state regulated with the exception of VFDs (which are federally regulated)**

AVMA's Model Practice Act VCPR

- New draft language to be considered:

"This means that the veterinarian is personally acquainted with the keeping and care of the patient by virtue of:

- *a timely examination of the patient by the veterinarian, or*
- *medically appropriate and timely visits by the veterinarian to the operation where the patient is managed."*

What on Earth does this mean!?!

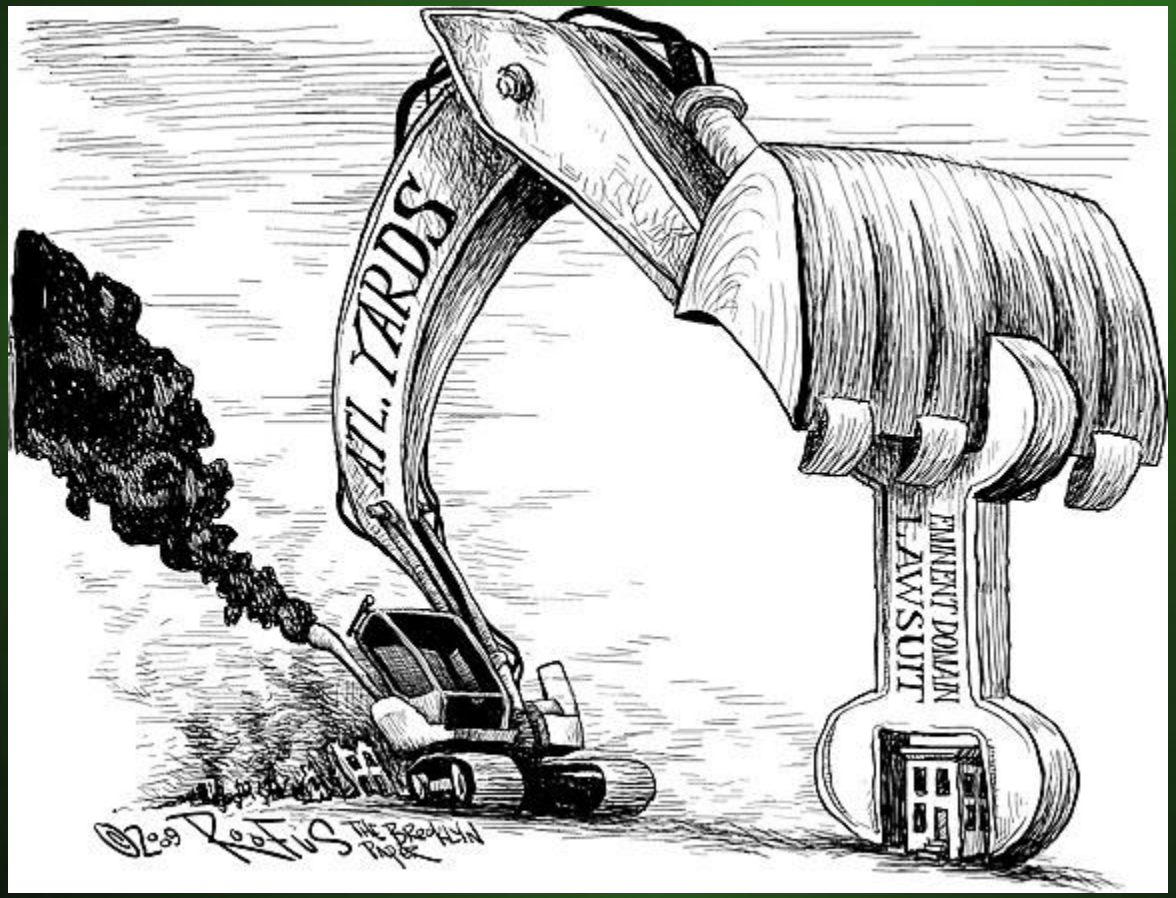
- Multiple VCPRs?
  - Yes, but there are already multiple VCPRs in different states.
- If approved, there will be no changes to the AMDUCA VCPR and individual states will choose whether or not to accept AVMA's model veterinary practice act with the VCPR.
- The VCPR with the Principles of Veterinary Medical Ethics will be considered separately.

VFDs

- What do we want for VFDs?
  - Again, the current requirement is the VCPR that is in AMDUCA for ELDU
  - What is expected in draft codified language is more prescription-like such as “Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.”

YAY or NAY?

Penicillins and Tetracyclines



Federal Court Ruling

"*The Commissioner of the FDA or the Director of the CVM must re-issue a notice of the proposed withdrawals… and provide an opportunity for a hearing to the relevant drug sponsors; if drug sponsors timely request hearings and raise a genuine and substantial issue of fact, the FDA must hold a public evidentiary hearing. If, at the hearing, the drug sponsors fail to show that the use of the drugs is safe, the Commissioner must issue a withdrawal order.*"

DREAMS

I dream of a normal place without stupids and idiots. Is it difficult?

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AMERICAN VETERINARY MEDICAL ASSOCIATION