

# National Institute for Animal Agriculture – Poultry Committee

## Antibiotics in Poultry



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# Recent Developments

- Roxarsone voluntarily withdrawn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



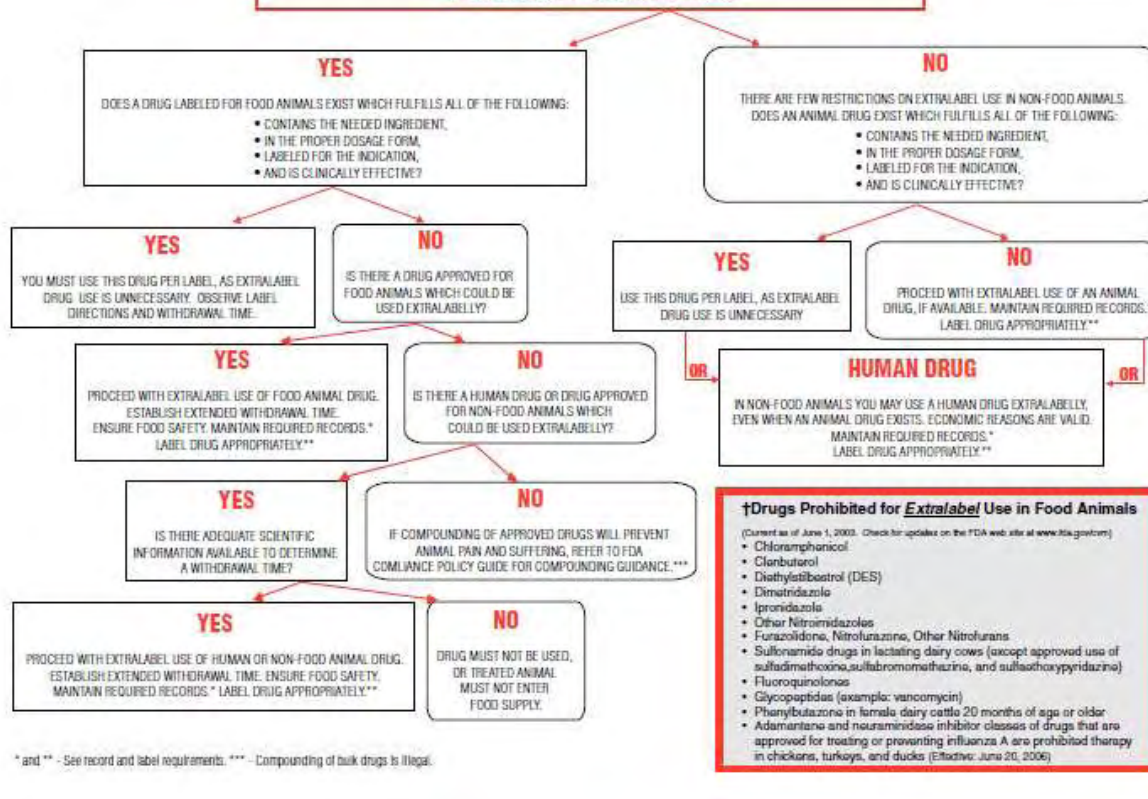
## 3- Nitro<sup>®</sup> (Roxarsone)

- <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm258313.htm> - *Does NOT Pose A Health Risk !!*
- Arsenical with 5 day withdrawal time
- Coccidiostat; also approved for weight gain, feed efficiency and improved pigmentation
- In the study, low levels (ppb) inorganic arsenic was found in chicken livers (not muscle tissue)

# Extra label Drug Use

## EXTRALABEL DRUG USE ALGORITHM

YOU MADE A CAREFUL DIAGNOSIS IN THE PRESENCE OF A VALID VETERINARIAN/CLIENT/PATIENT RELATIONSHIP. YOU ARE CONTEMPLATING EXTRALABEL DRUG USE. YOU MUST ASK YOURSELF \_\_\_\_  
ARE THE ANIMALS TO BE TREATED AS FOOD ANIMALS?



\* and \*\* - See record and label requirements. \*\*\* - Compounding of bulk drugs is illegal.

**†Drugs Prohibited for *Extralabel* Use in Food Animals**  
(Current as of June 1, 2009. Check for updates on the FDA web site at www.fda.gov/cvm)  
• Chloramphenicol  
• Clonbuterol  
• Diethylstilbestrol (DES)  
• Dimetridazole  
• Iprnidazole  
• Other Nitroimidazoles  
• Furazolidone, Nitrofurazone, Other Nitrofurans  
• Sulfonamide drugs in lactating dairy cows (except approved use of sulfadimethoxone, sulfabromothiazine, and sulfathioxypridazine)  
• Fluoroquinolones  
• Glycopeptides (example: vancomycin)  
• Phenylbutazone in lactating dairy cattle 20 months of age or older  
• Adamantane and neuraminidase inhibitor classes of drugs that are approved for treating or preventing influenza A are prohibited therapy in chickens, turkeys, and ducks. (Effective June 20, 2006)



# Cephalosporin Prohibition

## Prohibited Uses:

- dose levels, frequencies, durations, or routes of administration (specifically in ovo was named) NOT on the label
- Using cephalosporins 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](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.keepourfoodsafety.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 separate.



# 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 world. A better world where chickens can cross the road without having their motives questioned.



# DREAMS

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

# AVMA

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