

# Current Veterinary Approaches to Judicious Antimicrobial Use



**A. David Scarfe PhD, DVM, MRSSAF**  
AVMA, Schaumburg, IL USA

Intern'l Symposium on Aquatic Animal Health – Tampa, FL USA  
September 5-9, 2010

## To Cover

- What are the Issues?
- AVMA's Approach – Judicious Use of Antimicrobials
- Policy & Guidance Information
- Key Resources
- Refining regulatory approaches (VFD process & FDA Guide 208)
- Additional Resources



# © Why the Concerns?

- Increasing evidence for antimicrobial (primarily antibiotic - ABX) resistance of veterinary & human products
- Remedial solutions being sought at National & International levels – WHO, FAO, Codex Alimentarius, OIE
- Emerging Legislation e.g. “Preservation of Antibiotics for Medical Treatment Act” (USA)
- Focus in animal products esp.:
  - Sub-therapeutic & non-therapeutic uses (growth promotants)
  - Use in livestock
  - “Under the counter” products

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## Issues

Issues > Antimicrobial Use and Antimicrobial Resistance

### Antimicrobial Use and Antimicrobial Resistance

Posted July 19, 2010

Healthy animals make healthy food, and veterinarians are on the frontlines when it comes to keeping our nation's food supply safe. Antimicrobial use and antimicrobial resistance are hot issues in the news right now, and there's a lot of confusion and misinformation in the media and on the Internet. Advances in animal health care and management have greatly improved food safety over the years and have reduced the need for antimicrobials in food production systems. Nevertheless, antimicrobials are an important part of the veterinarian's toolkit, and veterinarians agree that they should be used judiciously and in the best interest of animal health and public health.



### Resources about antimicrobial use and antimicrobial resistance

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## AVMA Judicious Use Guidelines

- Developed 1995-98
- Primary objectives
  - Optimize therapeutic efficacy & minimize resistance to protect public and animal health
  - Science-based
  - Support educational efforts
  - Preserve efficacy for future use
- 13 Principles – applied to ABX in all species;
- Primarily as guidance for veterinarians, but applies to any use

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## Judicious Use Principles

- Emphasize disease **prevention strategies** – husbandry, hygiene, health monitoring & immunization
- Consider **other therapeutic options** first
- When necessary, **require VCPR** (veterinarian-client-patient relationship) – esp. Rx, VFD & extralabel use
- Extralabel use must **adhere to AMDUCA regulations**
- Veterinarians should **work with users** to ensure judicious use – regardless of the distribution system

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## © Author/ISAAH Judicious Use Principles

- ABX regimens should use **current pharmacological information & principles**
- Carefully review & **justify ABX use when infections are refractory** to human or veterinary ABX
- Use **narrow spectrum ABX** when possible
- Use **culture & sensitivity** tests and clinical relevance in selecting ABX

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## © Author/ISAAH Judicious Use Principles

- Use **ABX for bacterial infections** and not for uncomplicated viral infections
- Optimize length of treatment to **desired clinical response**
- **Limit TX use** to ill, at risk animals & fewest animals possible
- **Minimize environmental contamination** whenever possible
- **Use TX records** to evaluate therapeutic regimens

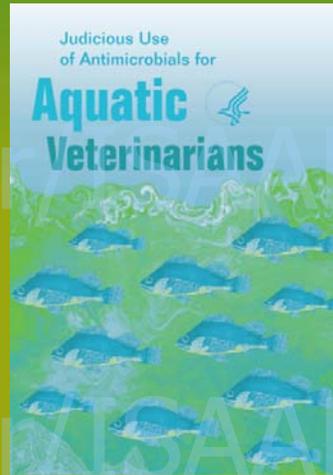
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# Educational Materials using these Principles

- Companion animals
- Equine
- Food animals
  - Beef & Dairy Cattle
  - Poultry
  - Swine & Pork
- Aquaculture
- In livestock feeds



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## Online Resources

[www.avma.org/issues](http://www.avma.org/issues)

- Antimicrobials, Guidelines for Judicious Therapeutic Use of**
- General Guidelines and Resources**
- [Antimicrobial Use and Antimicrobial Resistance](#)
  - [Antimicrobials, Judicious Therapeutic Use of](#)
  - [Antimicrobial Use and Antimicrobial Resistance, Frequently Asked Questions about](#)
- Aquatic**
- [Antimicrobials for Aquatic Veterinarians, Judicious Use of \(PDF\)](#)
  - [Antimicrobials for Treatment of Aquatic Animals by Veterinarians, Judicious Use of](#)
- Companion animals**
- [Antimicrobials, AAEP/AAHA Basic Guidelines for Judicious Therapeutic Use of](#)
- Equine**
- [AAEP Prudent Drug Usage Guidelines](#)
- Food animals**
- [Antimicrobials for Cattle, AABP Prudent Drug Usage Guidelines for](#)
  - [Antimicrobials for Beef Cattle Veterinarians, Judicious Use of](#)
  - [Antimicrobials for Dairy Cattle Veterinarians, Judicious Use of](#)
  - [Antimicrobials for Use in Food Producing Animals, Approval and Availability of](#)
  - [Antimicrobials in Livestock Feeds, Position on](#)
  - [Antimicrobials in Poultry, AAAP Guidelines for Judicious Therapeutic Use of](#)
  - [Antimicrobials for Poultry Veterinarians, Judicious Use of](#)
  - [Antimicrobials in Pork Production, AASV Basic Guidelines of Judicious Therapeutic Use of](#)
  - [Antimicrobials for Swine Veterinarians, Judicious Use of](#)

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# Extralabel Drug Use

## Issues

Issues > ELDU and AMDUCA FAQ

### Frequently Asked Questions about Extralabel Drug Use and AMDUCA

[Printer-friendly version](#) (PDF)

**Q:** What is extra-label drug use (ELDU)?

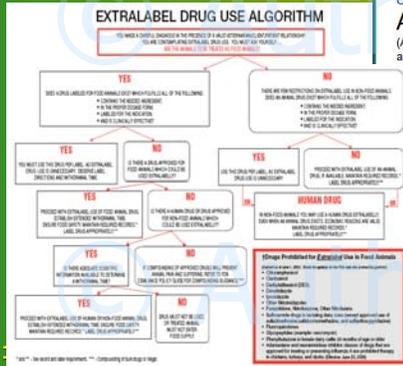
**A:** ELDU describes the use of an approved drug in a manner that is not in accordance with the approved labeling, yet meets the conditions set forth by the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) and U.S. Food and Drug Administration (FDA) regulations. Deviations from FDA-approved labeling include use in another species, use for a different indication, use at a different dose or frequency, and use via a different route of administration.



**Q:** What is the purpose of the Animal Medicinal Drug Use Clarification Act (AMDUCA)?

**A:** The Animal Medicinal Drug Use Clarification Act of 1994

(AMDUCA) allows veterinarians to use approved drugs in a manner not specifically approved by the manufacturer.



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?**

<b>YES</b>	<b>NO</b>
<p>Does a drug labeled for food animals exist which fulfills all of the following?</p> <ul style="list-style-type: none"> <li>Contains the needed ingredient,</li> <li>In the proper dosage form,</li> <li>Labeled for the indication,</li> <li>And is clinically effective?</li> </ul>	<p>There are few restrictions on extralabel use in non-food animals. Does an animal drug exist which fulfills all of the following?</p> <ul style="list-style-type: none"> <li>Contains the needed ingredient,</li> <li>In the proper dosage form,</li> <li>Labeled for the indication,</li> <li>And is clinically effective?</li> </ul>
Yes No	Yes No

# Other Resources

Be part of the **SOLUTION** NOT THE PROBLEM

Each year, pharmaceutical drugs are disposed of improperly and contaminate our environment, especially the water.

### Best Management Practices for Pharmaceutical Disposal

- Incorporate Best For Disposing Of Unused Pharmaceuticals.
- Landfill Unused Pharmaceuticals When Incineration is Not Feasible.
- Never Flush Pharmaceuticals Down The Toilet Or Drain.
- Maintain Close Inventory Control.
- Always Follow Federal And State Guidelines.
- Educate Your Clients On Proper Disposal.



## © Veterinary Feed Directive



- March 29, 2010 – Advance Notice of Proposed Rulemaking & soliciting comments on:
- Potential changes to current regulation related to veterinary feed directive (VFD) drugs
- Particularly suggestions related to **improving efficiency**
- For use in medicated feeds administered under a veterinarian's order and supervision
- Some consider VFD process as being overly burdensome
- Problematic for future increases of approved VFD drugs

Approved VFDs – ; **Florfenicol**

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## © AVMA Suggestions

- Similar paperwork as Rx drugs, including retention, & refill requirements
- e-VFDs
- Flexible Dosing – applicable VFD drug dosage for prevention, treatment, and control of disease
- Patient Specification – multiple barns / geographic locations
- Extralabel for minor species
- “Tiers” or “Batch” VFD Orders:
  - Tier 1 (low human health concern); Tier 2 (greater human health concern)
  - Batches – similar groups of animals for set time period

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## Guide #209

➤ Current thinking on strategies for Judicious Use of **Medically Important Antimicrobial Drugs in Food-Producing Animals**

- **Principle:** *Use should be limited to those uses that are considered necessary for assuring animal health.*
- **Principle:** *Use should be limited to those uses that include veterinary oversight or consultation.*



## AVMA Comments

Generally supportive & reflected in existing Judicious Principles & policy, e.g.:

- veterinarians should be involved in the decision-making process for the use of antimicrobials in animals regardless of the distribution channels through which the antimicrobials were obtained



# The future for antimicrobial use?

TBD

Thank you for your  
attention

