Efforts by the US Food and Drug Administration's Center for Veterinary Medicine to Address Antimicrobial Resistance

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Who is CVM?

- Part of the United States of America's Food and Drug Administration
- Our mission: Protecting Human and Animal Health
- Our direction comes from laws
  - Federal, Food, Drug and Cosmetic Act and its amendments
  - Bills considered by Congress could become our mandate
- We approve drugs for animals
  - Companies develop new animal drugs and seek our approval
  - We do some applied research on drugs

What does CVM think about antimicrobial resistance?

- Antimicrobial resistance is a growing public health concern.
- Developing strategies for reducing antimicrobial resistance is critically important for protecting both public and animal health.
- CVM is committed to working with animal drug sponsors, the veterinary and public health communities, the animal agriculture industry, researchers, and the public, together with U.S. government agencies and the international community to develop practical strategies to address antimicrobial resistance concerns.

What are we doing about it?

- Policy
- Research
- Outreach

Microbial Food Safety

- Part of the evaluation for approval (the Human Food Safety technical section) of a drug for a food-producing species
- Guidance for Industry 152:
  Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern
- Guidance for Industry 159 (VICH GL-36):
  Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI

Veterinary Feed Directive (VFD) Drugs

- Existing framework for veterinary oversight of feed use drugs is the VFD
  - Animal Drug Availability Act of 1996
- Currently there are 2 drugs (antimicrobials) approved as VFDs
- Advance Notice of Proposed Rulemaking to solicit comments on the VFD regulations to improve the efficiency of the VFD process

Extra-label Use

- FDA approves drugs labeled for a specific
  - Dosage
  - Route of administration
  - Species to be treated
  - Purpose for use
- Extra-label use is using a drug in a manner that is not in accordance with the approved labeling.

Extra-label Use

- Animal Medicinal Drug Use Clarification Act
- Regulations: 21 CFR 530

Allows use of:

- An FDA approved animal or human drug,
- By or on the order of a licensed veterinarian within the context of a valid veterinary-client-patient relationship,
- For a therapeutic use (not for production purposes)

Extra-label Use Prohibitions

- FDA may prohibit extra-label use of an approved drug in a food-producing animal if it presents a risk to the public health (21 CFR 530.21)
  - may be a general ban on the extra-label 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.

Prohibitions on Extra-Label Use in Food Animals (21 CFR 530.21)

- Chloramphenicol
- Clenbuterol
- Diethylstilbestrol (DES)
- Dimetridazole
- Ipronidazole
- Other nitroimidazoles
- Furazolidone, nitrofurazone, and other nitrofurans
- Fluoroquinolones
- Glycopeptides
- Sulfonamides in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxypyridazine)
- Phenylbutazone in female dairy cattle ≥ 20 months old
- Adamantane and neuraminidase inhibitor classes of drugs approved for treating or preventing influenza A- in chickens, turkeys, ducks

Draft Guidance 209 "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals"

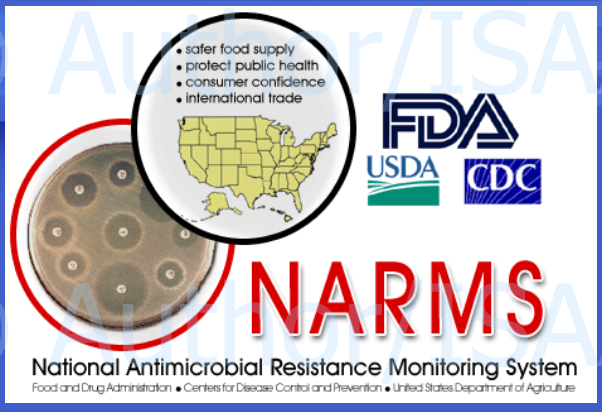
FDA recommends that the use of medically important antimicrobial drugs in food-producing animals be limited to situations where:

1. The use is necessary for assuring animal health (e.g., not for the purpose of increasing growth or feed efficiency), and
2. There is veterinary oversight or consultation

Surveillance and Applied Research

Required Reporting of Quantities of Antimicrobials Sold/ Distributed

- Section 105 of the Animal Drug User Fee Amendments of 2008, effective 2010
- Drug sponsors must submit annual reports on the amount of antimicrobial active ingredient sold or distributed for use in food-producing animals (domestic and exports)
- Summaries will be publicly available



- National Antimicrobial Resistance Monitoring System- Enteric Bacteria
- Monitors trends in antimicrobial susceptibility/resistance among enteric bacteria from humans, food animals, and retail meats
- Non-Typhi *Salmonella*, *Campylobacter*, *Escherichia coli,* and *Enterococcus*
- Also *S. Typhi, Shigella, Listeria,* and *Vibrio* in human samples
- Seafood to be added
- Harmonization with WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR)

Additional Research Efforts

- Development and validation of analytical methods for detection of drugs and other compounds in fish (and other animal) tissue and feed
- Clinical and Laboratory Standards Institute (CLSI) Subcommittee on Veterinary Antimicrobial Susceptibility Testing-Aquaculture Working Group (VAST-AWG)
  - Charlie Gieseker will present on current research
- Phish-Pharm: a searchable online database of drug residue data and PK parameters in fish reported in literature

Judicious Use of Antimicrobials for Aquatic Veterinarians

- Educational booklet published in cooperation with the American Veterinary Medical Association
- Emphasizes the importance of:
  - Preventative management strategies such as optimal husbandry, use of vaccines
  - Veterinary involvement
  - Careful selection of the antimicrobial

International Dialogue

- Codex Alimentarius Task Force on Antimicrobial Resistance (TFAMR)
  - *Scope:* to assess the risks to human health associated with the presence in food and feed including aquaculture and the transmission through feed and food of antimicrobial resistant microbes and resistance genes and to develop appropriate risk management strategies
  - *Goal:* to develop a Codex antimicrobial resistance risk analysis approach that allows countries or regions to implement actions based upon identified and prioritized needs and resources
  - Four meetings in Korea (2007-2009), group preparing "Proposed draft guidelines for risk analysis of food-borne antimicrobial resistance" (includes chapters on risk profiling, risk assessment, risk management)
- FAO Expert Workshop on Improving Biosecurity through Prudent and Responsible Use of Veterinary Medicine (Antimicrobials) in Aquatic Food Production
- OIE

Conclusion

- Developing strategies for reducing antimicrobial resistance is critically important for protecting both public and animal health.
- We are committed to working with collaboratively with others to address this issue.
- CVM promotes principles of judicious use.
- Continued surveillance and applied research to inform clinicians and policy makers is important.