FDA Center for Veterinary Medicine Updates

Comments by Bettye K. Walters, DVM

For the 2012 JIFSAN Advisory Council Meeting

Greenbelt Marriott Hotel

December 4, 2012
Vision and Mission

Vision

“Excellence, Innovation, Leadership”

Mission

“Protecting Human and Animal Health”
Regulation of Animal Health Across Government

Animal Drugs and Feeds:
Antimicrobials, Antiparasiticides, Production Drugs, Medicated Feeds

Veterinary Biologics:
Vaccines, Bacterins, Antisera, Diagnostic Kits, Other products of biological origin, Animal products (meat, milk, liquid/dried/frozen eggs)

Pesticides:
Insecticides, Fungicides, Rodenticides
The Center for Veterinary Medicine: Mission
Protecting Human and Animal Health

• Assures that animal drugs and medicated feeds are safe and effective and that foods from treated animals are safe for humans to consume
• Federal Food, Drug, and Cosmetic Act
The Center for Veterinary Medicine: Mission
Protecting Human and Animal Health

Companion Animals, Minor Species, and Food-producing Animals

• ~70 million pet dogs and ~74 million pet cats
• ~7 million horses
• Minor species include all animals other than the following 7 major species: cattle, swine, chickens, turkeys, horses, dogs and cats
The Center for Veterinary Medicine: Mission
Protecting Human and Animal Health

Animal Health and Animal Food Safety

From:
- Animal Drug Manufacturers (~300)
- Feed Manufacturers (~6,600)

Given to or used on:
- ~9.2 billion chickens & turkeys
- ~159 million cattle & pigs
- ~8.7 million sheep & goats

Consumed by:
- ~310 million humans in the U.S.
The Center for Veterinary Medicine

• Approximately 525 employees
  • Headquarters – Rockville, Maryland
  • Research Campus – Laurel, Maryland
Scientific and Technical Disciplines at CVM

- **Veterinary Medical Officers**: 107
- **Consumer Safety Officers**: 58
- **Chemists**: 51
- **Biologists**: 48
- **Microbiologists**: 49
- **Other Scientific Disciplines**: 49
- **Mathematical Statisticians**: 16
- **Regulatory Counsel**: 11

Full-Time Equivalent Positions
## FY 2012 Appropriation

<table>
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CVM’s **High Priority** Public Health Issues

- Implementing the Food Safety Modernization Act of 2010 (FSMA)
- Animal Biotechnology (genetic engineering and cloning)
- Unapproved Animal Drugs
- Animal Drug User Fee Act (ADUFA)
- Animal Generic Drug User Fee Act (AGDUFA)
- Approving Drugs for Minor Use/Minor Species (MUMS)
- Illegal Drug Residues in Animal Derived Foods
- Antimicrobial Resistance (includes the National Antimicrobial Resistance Monitoring System [NARMS])
- International Activities
- Animal Health Literacy – Outreach to Consumers and Stakeholders
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Current Priorities

Implementation of the Food Safety Modernization Act (FSMA)

- Preventive controls
- Inspection and Compliance
- Response
- Imported food safety
- Enhanced Partnerships
Animal Biotechnology – Genetic Engineering

• ‘Revolutionary crossroads in American agriculture’
• Final Guidance for Industry: “Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constraints.”
• No new rules or laws required; Reviewed under the new Animal Drug Provisions of the FFDCA.
  • Definition of a drug: “article intended to affect the structure or function of the body.”
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Current Priorities

Potential for Genetically Engineered Animals

- Biopharm
- Research
- Xenotransplant, scarce cells, tissues, organs
- Disease resistance
- Animal derived food products
Unapproved Animal Drugs

Bring marketed unapproved animal drugs into compliance with FDA laws and regulations.

• Many unapproved drug products
• May have a long history of use
• CVM is examining unapproved products within the framework of the Federal Food, Drug and Cosmetic Act
• Compliance and Enforcement are important tools to help the Center address this issue
Animal Drug User Fee Act (ADUFA)

Timely review of applications so more animal drugs are readily available to the public

• Reauthorization of ADUFA II signed into law on August 14, 2008
• ADUFA II sunsets on October 1, 2013
• Kicked off renegotiation process for ADUFA III with a public meeting on November 7, 2011
• Final package of recommendations for ADUFA III is due to Congress January 2013
• The minutes of meetings between FDA and the regulated industry are posted on the FDA Internet: http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucmo42891.htm
Animal Generic Drug User Fee Act (AGDUFA)

Improve review time of generic applications in order to increase the number and sources of new animal drugs available for use

- Authorization of the Animal Generic Drug User Fee Act (AGDUFA) of 2008 signed into law on August 14, 2008
- AGDUFA sunsets on October 1, 2013
- Kicked off renegotiation process for AGDUFA II with a public meeting on November 7, 2011
- Final package of recommendations for AGDUFA II is due to Congress January 2013
- Minutes of meetings between FDA and the regulated industry are posted on the FDA Internet: [http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm270232.htm](http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm270232.htm)
Approving Drugs for Minor Use Minor Species (MUMS)

Expand availability of drugs to treat minor animal species and uncommon diseases in the major animal species

- Minor Use/Minor Species Animal Health Act of 2004
- MUMS Regulations:
  - Designation – sponsor granted seven years of exclusive marketing rights (similar to Orphan Drug Act); 106 designations granted
  - Indexing - for non-food minor species - sponsors allowed to legally market unapproved new animal drugs added to an index list based mainly on evaluation of an expert
  - Conditional Approval - sponsor can market drug for up to 5 years while collecting effectiveness data
- MUMS Grant Program initiated in FY 2009
  - $750,000 to award
Illegal Drug Residues in Animal Derived Foods

Ensure meat, poultry, seafood and milk are safe from harmful veterinary drug residues

• Investigating violative residues is a high priority for CVM
The Center for Veterinary Medicine

Current Priorities

Antimicrobial Resistance (includes NARMS)

• Increasing resistance to antibiotic treatment in bacteria that infect humans raises concerns about drug use in food-producing animals

• Finalized guidance: “The Judicious Use of Medically Important Antimicrobial Drugs in Food Producing Animals” (April 2012)

• Monitoring resistance among enteric pathogens in both animals and humans through National Antimicrobial Resistance Monitoring System (NARMS)
  • Collaborative agreement with USDA, CDC, and FDA
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**Current Priorities**

### International Activities

- Strengthen animal drug regulatory infrastructures in other countries
- World Organization for Animal Health (OIE)
- Administered animal drug workshops
  - Mexico, China, Chile, Costa Rica, Paraguay, Canada, European Union and South Africa

### Codex Alimentarius Activities

- Chair of Codex Committee on Residues of Veterinary Drugs in Foods
- Participation on Codex Task Force on Antimicrobial Resistance
- Participation in Codex Electronic Working Group on Animal Feeding
Animal Health Literacy
Outreach to Consumers and Stakeholders

- Timely information for the benefit of all animals and their humans
Keep Up To Date
www.fda.gov/AnimalVeterinary

Reference the CVM Website for the most current information
Thank you!!!

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