Center for Veterinary Medicine: Overview

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Office of New Animal Drug Evaluation
Center for Veterinary Medicine
Food and Drug Administration

USP Veterinary Stakeholder Forum, 11-09-2012
What we regulate:
- Animal drugs
- Animal feeds
- Veterinary devices

What we do **not** regulate:
- The practice of veterinary medicine
- Vaccines for animals (USDA)
Core CVM Mission

- Protecting human and animal health

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**Pet Species in US (in millions)**
- Cats: 88 (32%)
- Dogs: 75 (28%)
- Fish: 75 (28%)
- Rodents/rabbits: 6%
- Reptiles: 5 (2%
- Ferrets: 1 (0%
- Birds: 4% (11 million)

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**Lifestock Species in US (in millions)**
- Chicken: 9,000 (95%)
- Cattle: 97 (1%)
- Turkeys: 262 (3%)
- Pigs: 62 (1%)
- Sheep: 6.2 (0.1%)
- Other: 427.2 (5%)

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Core CVM Mission – Companion Animals

- Increase the level of high quality medical care
- Increase quality of life through medical interventions
- Ensure the availability of animal drugs that prevent the spread of zoonotic diseases
  - 58 – 62% of households own a pet
  - 44% of dogs sleep in the owners bed
Core CVM Mission – Food Producing Animals

- Improve animal welfare and health
- Improve animal production

Increase the availability of food supply to meet the needs of a growing human population
FDA CVM: Major Responsibilities

- Evaluation of data on proposed new veterinary products prior to approval
- Monitoring for violative marketed products through surveillance programs
- Ensuring animal feed safety
- Initiating legal action, if necessary, to bring violators into compliance with the law
- Conducting research to support Center activities
- Educating consumers and regulated industry
Laws Enforced by CVM

- Federal Food, Drug and Cosmetics (FFD&C) Act (1938)
  - Animal Drug Amendments of 1968

- Specific Animal Drug Acts:
  - Animal Drug Availability Act of 1996
  - Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA)
  - Generic Animal Drug and Patent Term Restoration Act (GADPTRA)
  - Minor Use/Minor Species Act of 2004 (MUMS)
  - Animal Drug User Fee Act of 2008 (ADUFA)
  - Animal Generic Drug User Fee Act of 2008 (AGDUFA)

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FFD&C Act Chapter II, Sec. 321(g)(1)

The term "drug" means:

(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them;

(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals;

(D) articles intended for use as a component of any article specified in clause (A), (B), or (C)
Sec. 501 “A drug…shall be deemed to be **adulterated** – if it purports to be or is represented as a drug the name of which is recognized in an official compendium (*USP-NF*), and its strength differs from, or its quality or purity falls below, the standards set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium”

Sec. 502 “A drug…shall be deemed to be **misbranded** - if it purports to be a drug the name of which is recognized in an official compendium,” (*USP-NF*) unless it is packaged and labeled as prescribed therein…
FDA - Approval and Regulations of Animal Drugs

- Similar in theory and practice to the approval of human drugs
- Multiple species considerations
  - Approval only for specific uses/species with adequate safety and effectiveness data
    - Companion-animal drugs - more similar to human approval process
    - Food-animal drugs - human food safety requirements:
      - Toxicology (Delaney clause FD&C amendment of 1938)
      - Limits for drug residues set
The codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government

Divided into 50 titles that represent broad areas subject to Federal regulation:

- CFR Title 21 - Food and Drugs: Parts 1 to 1499
Human vs. Animal Drugs: Comparison of CFR* – What’s the same?

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<tr>
<th>CDER</th>
<th>Title</th>
<th>CVM</th>
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</tr>
</thead>
<tbody>
<tr>
<td>300</td>
<td>General</td>
<td>500</td>
<td>Animal Drugs, Feeds, Related Products</td>
</tr>
<tr>
<td>310</td>
<td>New Drugs</td>
<td>510</td>
<td>New Animal Drugs</td>
</tr>
<tr>
<td>312</td>
<td>Investigational New Drug Application</td>
<td>511</td>
<td>New Animal Drugs for Investigational Use</td>
</tr>
<tr>
<td>314</td>
<td>Applications for FDA Approval</td>
<td>514</td>
<td>New Animal Drug Applications</td>
</tr>
<tr>
<td>316</td>
<td>Orphan Drugs</td>
<td>516</td>
<td>New Animal Drugs for MUMS</td>
</tr>
</tbody>
</table>

Tables modified from Dr. Michael Murphy’s presentation at the AAVPT Veterinary Drug Regulatory Life-Cycle Course (February 2011)
Human vs. Animal Food: Comparison of CFR – What’s similar?

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<thead>
<tr>
<th>CFSAN</th>
<th>Title</th>
<th>CVM</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>101</td>
<td>Food Labeling</td>
<td>501</td>
<td>Animal Food Labeling</td>
</tr>
<tr>
<td>102</td>
<td>Common or Usual Name ...</td>
<td>502</td>
<td>Common or Usual Name for Nonstandardized animal foods</td>
</tr>
<tr>
<td>109</td>
<td>Unavoidable contaminants in food ...</td>
<td>509</td>
<td>Unavoidable contaminants in animal food ...</td>
</tr>
<tr>
<td>170</td>
<td>Food additives</td>
<td>570</td>
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</tr>
<tr>
<td>171</td>
<td>Food additive petitions</td>
<td>571</td>
<td>Food Additive Petitions</td>
</tr>
</tbody>
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## CFR – What’s Unique for Vet. Drugs

<table>
<thead>
<tr>
<th>CVM</th>
<th>Title</th>
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<tbody>
<tr>
<td>515</td>
<td>Medicated feed mill license</td>
</tr>
<tr>
<td>520</td>
<td>Oral dosage form new animal drugs</td>
</tr>
<tr>
<td>522</td>
<td>Implantation or injectable dosage form new animal drugs</td>
</tr>
<tr>
<td>524</td>
<td>Ophthalmic and topical dosage form new animal drugs</td>
</tr>
<tr>
<td>526</td>
<td>Intramammary dosage form</td>
</tr>
<tr>
<td>528</td>
<td>New animal drugs in genetically engineered animals</td>
</tr>
<tr>
<td>529</td>
<td>Certain other dosage form new animal drugs</td>
</tr>
<tr>
<td>530</td>
<td>Extralabel drug use in animals</td>
</tr>
<tr>
<td>556</td>
<td>Tolerances for residues of new animal drugs in food</td>
</tr>
<tr>
<td>558</td>
<td>New animal drugs for use in animal feeds</td>
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Part 510 – New Animal Drugs:

“The term **new animal drug** means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed.
Critical Standards for Evaluation of New Animal Drugs

- Safety
  - Human Food
  - Target Animal
  - Environmental
  - User Safety

- Effectiveness - Substantial Evidence

- Quality Manufactured Product

- Properly Labeled Product
FDA and USP

**FDA**
- Protects public and animal health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products, medical devices, food, cosmetics, dietary supplements.

**USP**
- Sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements.
- No enforcement role; enforcement through FDA.

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FDA (CVM) and USP

CVM responsibilities:
- Review of bi-monthly U.S. Pharmacopeial Forum (USP-PF) issuances and frequent U.S. Pharmacopeia-National Formulary (USP-NF) revision proposals
- Input from pertinent office(s)/division(s)
- Collaboration with CDER (Compendial Operations)
- Feedback to USP on materials posted in PF or in the USP-NF as they relate to veterinary drugs
CVM and USP Collaborations

Expert Committees:

- General Chapters – Dosage Forms: Modric
- General Chapters—Chemical Analysis: Wheless
- Nomenclature, Safety and Labeling: Modric
- Monographs – Small molecules 3: Modric
- Compounding: Bray
CVM and USP Collaborations

Expert Panels:

- Metal Impurities: Guo and Wheless
- Veterinary Drugs Solubility Criteria: Martinez and Modric
Thank you!

http://www.fda.gov/AnimalVeterinary/default.htm

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American Academy of Veterinary Pharmacology and Therapeutics

- **Constituents:**
  - Academia
  - Industry
  - Regulatory Agencies

- **Purpose:**
  - Promotion of the science of veterinary pharmacology and therapeutics
AAVPT Objectives

- To support and promote education and research in comparative pharmacology, clinical veterinary pharmacology and other aspects of pharmacology of interest to the veterinary profession
- To sponsor and conduct workshops, symposia or other scientific and educational meetings in veterinary pharmacology and therapeutics
- To enhance the exchange of educational materials and ideas among veterinary pharmacologists
- To organize committees of experts to research and make recommendations to the profession on current problems in veterinary therapeutics
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