U.S. Food and Drug Administration

Department of Health and Human Services

CENTER FOR VETERINARY MEDICINE

Center for Veterinary Medicine: Overview

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Office of New Animal Drug Evaluation

Center for Veterinary Medicine

Food and Drug Administration

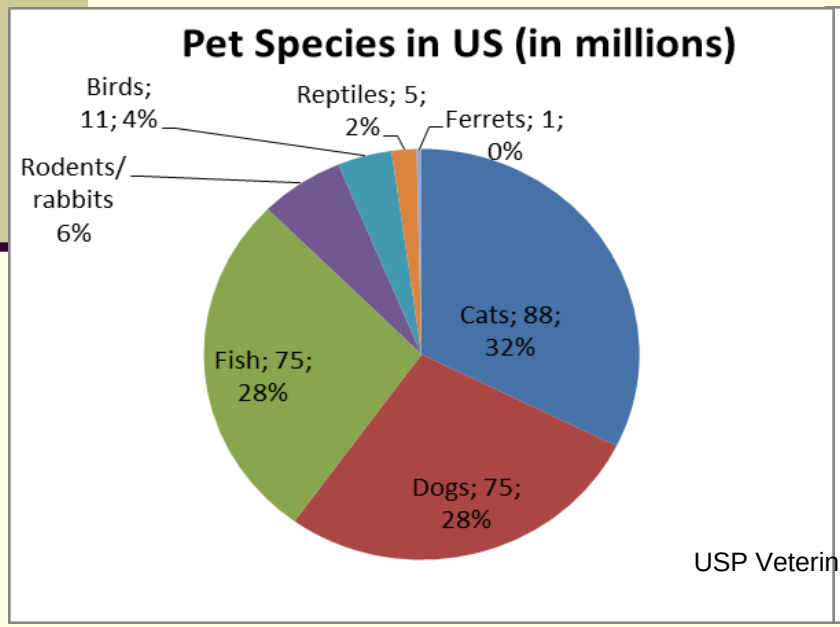
FDA Center for Veterinary Medicine

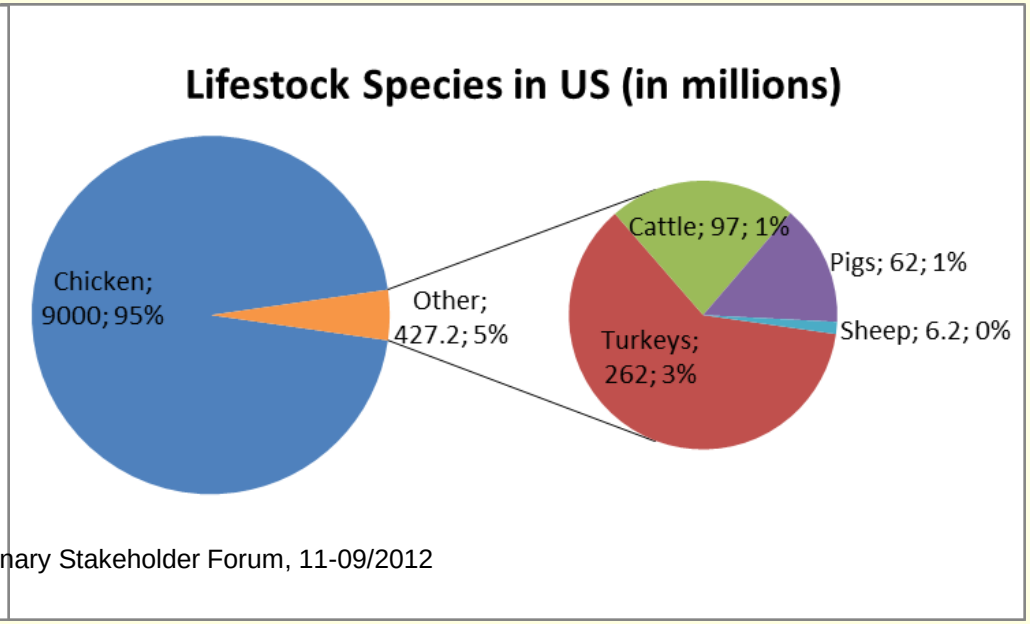
- **What we regulate**:
  - Animal drugs
  - Animal feeds
  - Veterinary devices

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

Core CVM Mission

- **Protecting human and animal heath**





Core CVM Mission – Companion Animals

- 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)

Federal Food, Drug, and Cosmetic Act (1938) – Chapter II

- 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)

Federal Food, Drug, and Cosmetic Act (1938) – Chapter V

- 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

Code of Federal Regulations (CFR)

- 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?

CDER	Title	CVM	Title
300	General	500	Animal Drugs, Feeds, Related Products
310	New Drugs	510	New Animal Drugs
312	Investigational New Drug Application	511	New Animal Drugs for Investigational Use
314	Applications for FDA Approval	514	New Animal Drug Applications
316	Orphan Drugs	516	New Animal Drugs for MUMS

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?

CFSAN	Title	CVM	Title
101	Food Labeling	501	Animal Food Labeling
102	Common or Usual Name …	502	Common or Usual Name for Nonstandardized animal foods
109	Unavoidable contaminants in food …	509	Unavoidable contaminants in animal food …
170	Food additives	570	Food Additives
171	Food additive petitions	571	Food Additive Petitions

CFR – What's **Unique** for Vet. Drugs

CVM	**Title**
515	Medicated feed mill license
520	Oral dosage form new animal drugs
522	Implantation or injectable dosage form new animal drugs
524	Ophthalmic and topical dosage form new animal drugs
526	Intramammary dosage form
528	New animal drugs in genetically engineered animals
529	Certain other dosage form new animal drugs
530	Extralabel drug use in animals
556	Tolerances for residues of new animal drugs in food
558	New animal drugs for use in animal feeds

New Animal Drugs

Code of Federal Regulation Title 21 – Food and Drugs

Chapter I – Food and Drug Administration

Subchapter E- Animal Drugs, Feeds, and Related Products

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 biologial 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

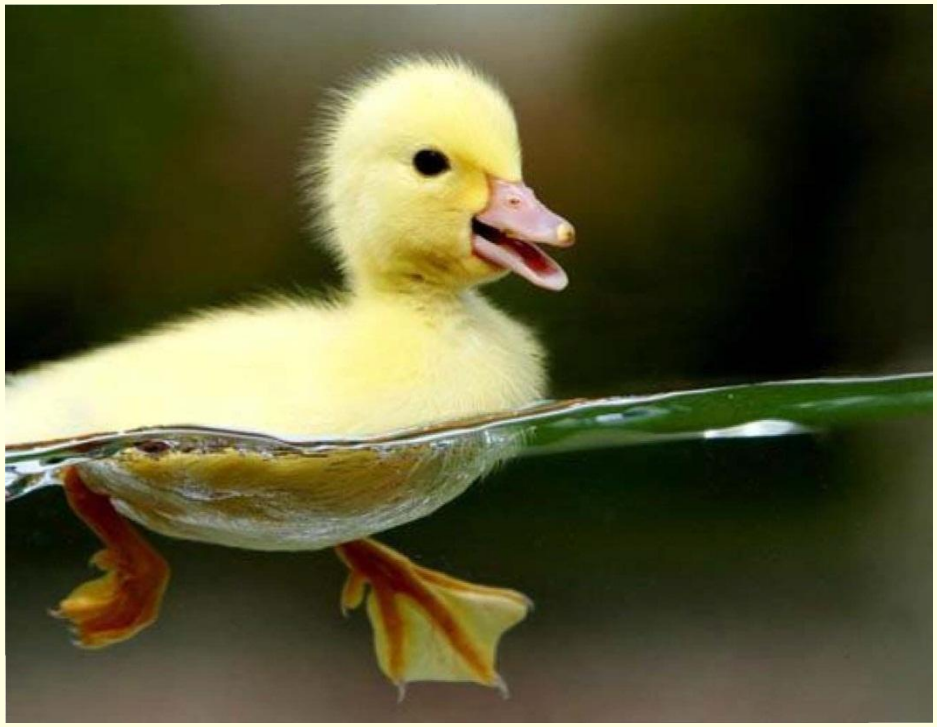
Expert Committees:

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

CVM and USP Collaborations

- **Expert Panels:**
  - Metal Impurities: Guo
  - Veterinary Drugs Solubility Criteria: Martinez and Modric

Thank you!



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