



# Center for Veterinary Medicine (CVM)

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*Moderated by* **Sean Lee**, Of Counsel, Shook, Hardy & Bacon LLP



# Center for Veterinary Medicine (CVM)

**FDLI Annual Conference  
May 2, 2019**

**Steven M. Solomon, D.V.M., M.P.H.  
Director, CVM**

# Guiding Principles

- Protecting public health
- Regulating based on the best evidence and science
- Leveraging and collaborating with domestic and international health and regulatory partners
- Operating transparently
- Encouraging continuous quality improvement
- Engaging stakeholders



# CVM Vision and Mission



## Vision

*“Excellence, Innovation, Leadership”*

## Mission

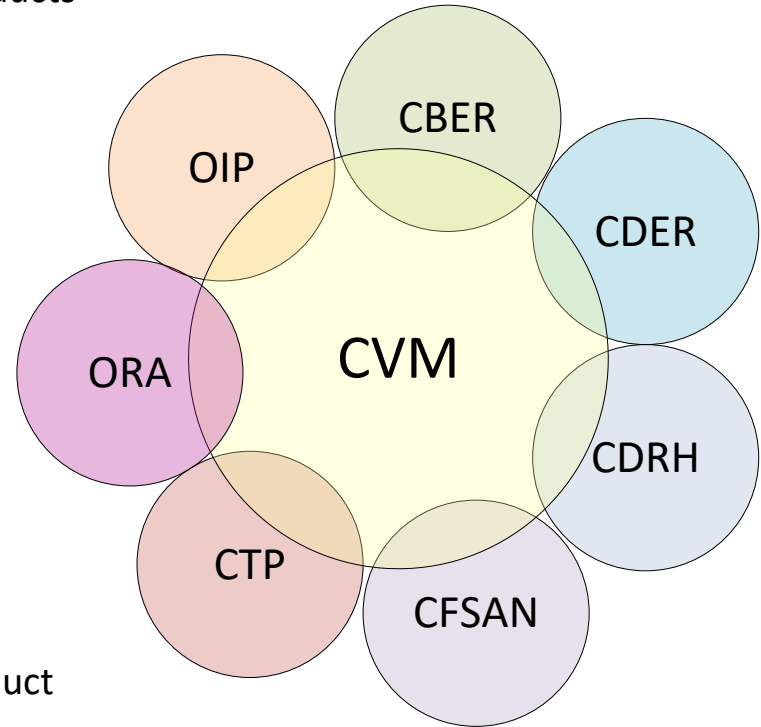
*“Protecting Human and Animal Health”*



# CVM as a Microcosm of FDA



- ***Center for Biologics Evaluation and Research***  
CVM: Genetically Altered Animals and Cell-based Products
- ***Center for Drug Evaluation and Research***  
CVM: Animal Drugs
- ***Center for Devices and Radiological Health***  
CVM: Animal Devices (post-market only)
- ***Center for Food Safety and Applied Nutrition***  
CVM: Food Safety and Food Additive
- ***Center for Tobacco Products***  
CVM: Second-hand Smoke and Pet Health
- ***Office of Regulatory Affairs***  
CVM: Partner in Regulatory Oversight
- ***International Activities***  
CVM: Strengthen animal drug and food regulatory infrastructures in other countries and harmonize product standards



# CVM Organizational Chart

## Office of the Center Director

### *Director*

Steven M. Solomon, DVM, MPH

### *Deputy Director*

Tracey Forfa, JD

### *Deputy Director, Science Policy*

William Flynn, DVM, MS

## Office of Management

### *Director*

Roxanne Schweitzer

### *Deputy Director*

Lynnette Riggio

## Office of New Animal Drug Evaluation

### *Director*

Matthew Lucia, DVM

### *Deputy Director*

Elizabeth A. Luddy, DVM

## Office of Surveillance and Compliance

### *Director*

Timothy Schell, PhD

### *Deputy Director*

Martine Hartogensis, DVM

## Office of Research

### *Director*

**Vacant**

### *Acting Director*

CAPT Brianna L. Skinner,  
DVM, MPH

### *Deputy Director*

Mary Allen, PhD

## Office of Minor Use Minor Species Animal Drug Development

### *Director*

Margaret Oeller, DVM

# CVM's Core Values

## We Serve

We are a mission-driven, public health, regulatory Center. Safeguarding human and animal health is what we do. We serve our stakeholders and hold their trust in the highest regard. Collaboration and communication, across all disciplines, are the tools we use to provide the greatest level of service.

## We Lead

Everyone makes a difference. Each of us contributes our ideas and skills to influence CVM's direction regardless of their title or position. New leaders emerge every day.

## We Learn

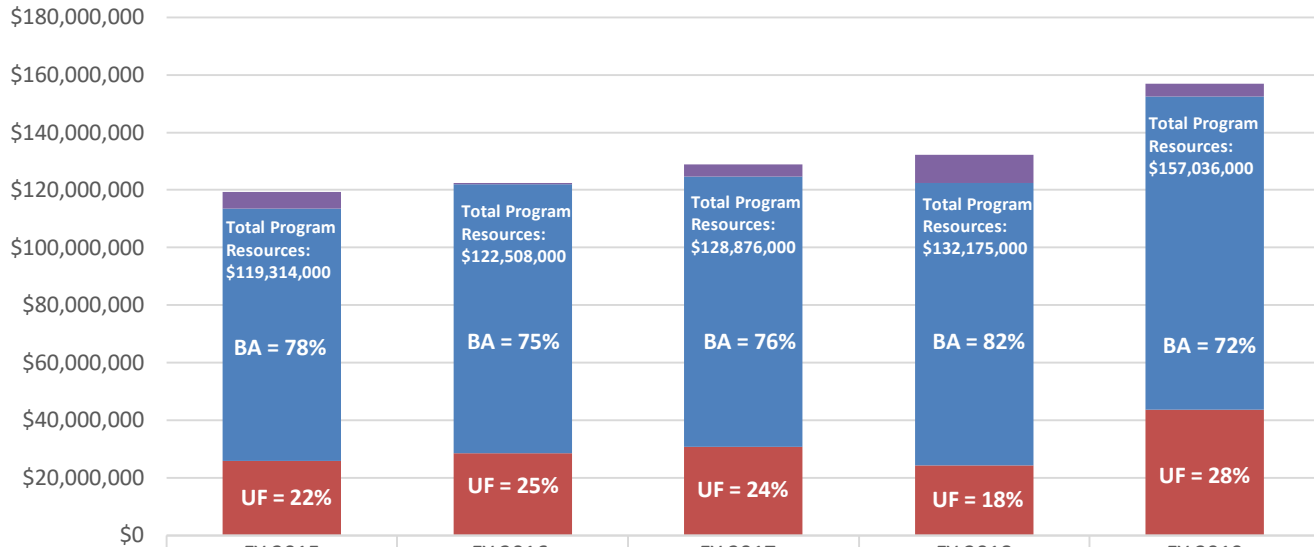
We continuously learn, stretch, and grow. We provide opportunities for people to develop their skills and cultivate diverse talents. Our individual expertise is the expertise of the organization.

## We Honor

CVM appreciates the exceptional people who work here. We encourage and support everyone to dream, inspire each other, and live our best lives, personally and professionally. We celebrate all life experiences, cultures, and backgrounds for the wealth of perspectives they bring to CVM.

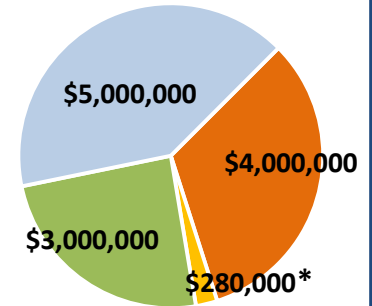


# CVM Budget, FY 2015 – FY 2020



	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
BA Increase	\$5,659,000	\$500,000	\$4,200,000	\$9,700,000	\$4,500,000
Budget Authority	\$87,846,000	\$93,505,000	\$94,005,000	\$98,205,000	\$108,919,000
User Fees	\$25,809,000	\$28,503,000	\$30,671,000	\$24,270,000	\$43,617,000

## FY 2020 Budget Authority Increase Request \$12,280,000



- New Medical Data Enterprise
- Advancing FSMA
- Outbreak Response
- Innovation & Emerging Tech

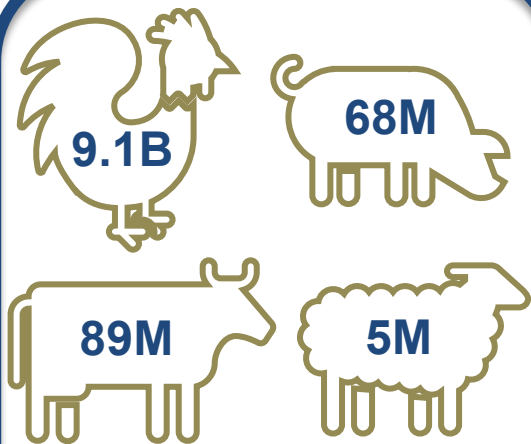
\* Companion to \$5,600,000 ORA request



# FDA's Animal Health "Hoof" Print



CVM protects and promotes the health of humans and animals by ensuring the safety of the American food supply, the safety of animal food and devices, and the safety and effectiveness of animal drugs.

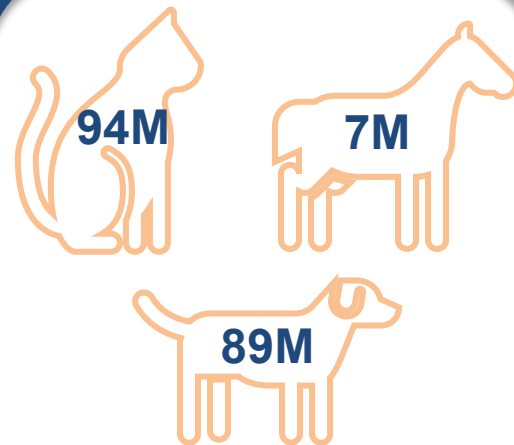
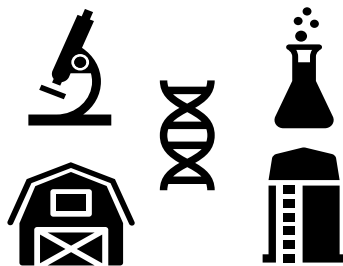


## Food-producing Animals

- ~ 9.1 billion chickens
- ~ 68 million pigs
- ~ 89 million cows
- ~ 5 million sheep

## U.S. Animal Health & Related Industries

- ~ **\$11.4B** in animal health products
- ~ **\$560B** total economic impact: food production, animal production, veterinary services, pet care, and animal health
- ~ **1.4M** jobs in animal health and related industries



## Companion Animals (Pets)

- ~ 94 million cats
- ~ 89 million dogs
- ~ 7 million horses

# Agenda

- **Modernizing Human and Animal Food Safety**
- **Recall and Response Activities**
- **Veterinary Laboratory Investigation and Response Network (Vet-LIRN)**
- **Antimicrobial Resistance**
- **Pre-market Animal Drug Review**
- **Emerging Technologies and Innovation**
- **Innovation and Flexibility**
- **Regulatory Reform**
- **Unapproved Animal Drugs Compounded from Bulk Drug Substances**
- **Post-market Drug Safety, Effectiveness, and Quality**
- **Lifecycle Approach**
- **International Activities**
- **Outreach to Consumers and Stakeholders**

# Modernizing Human and Animal Food Safety



- **FSMA: Training, education, and outreach**
- **Modernized inspections for**
  - **Current good manufacturing practices (CGMPs)**
  - **Preventive controls for animal food**
- **Human food by-products**
- **New Era of Smarter Food Safety**

# Recall and Response Activities

- Pet food safety
- Recalls and outbreak response activities
- Natural disaster response activities

**Toxic Amounts of Vitamin D Spur Dog Food Recall**  
December  
WebMD

**Feed Mills Mixing Errors Cause Monensin Toxicity in Horses**  
October 25, 2018  
the Fence Post

**Salmonella outbreak hitting pet food brands**  
FEBRUARY 19, 2019  
CBS NEWS

**Dog food brands recalled over euthanasia drug**  
February 18, 2018  
CNN

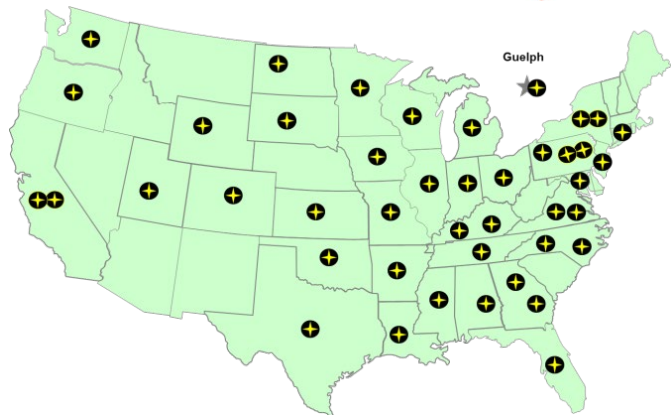


Hurricanes Harvey, Irma, Maria, Florence, Michael;  
California wildfires; Midwest flooding

# Veterinary Laboratory Investigation and Response Network (Vet-LIRN)



To promote human and animal health by collaborating with veterinary diagnostic laboratories to provide scientific information, build lab capacity, and investigate issues with CVM-regulated products



- Network includes 43 laboratories
- Develops mechanisms for conducting investigations
  - Confidentiality agreements
  - Grants/contracts
  - Collaborate with other networks
- Activities
  - Proficiency and product testing
  - Fanconi testing
  - Necropsy examinations
  - Emergency response exercises
  - Investigate consumer complaint cases



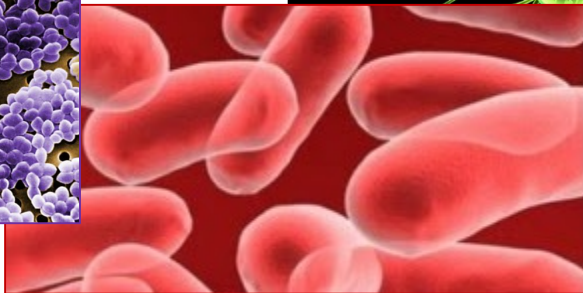
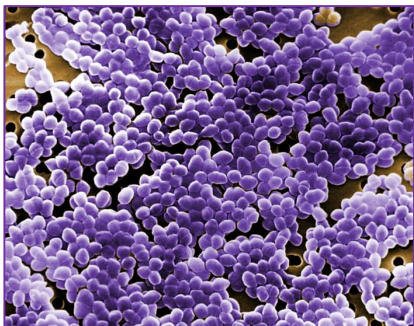
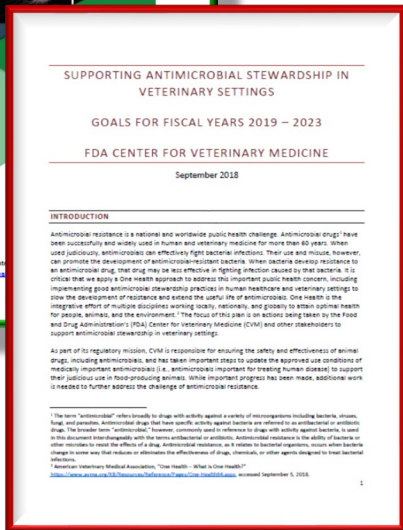
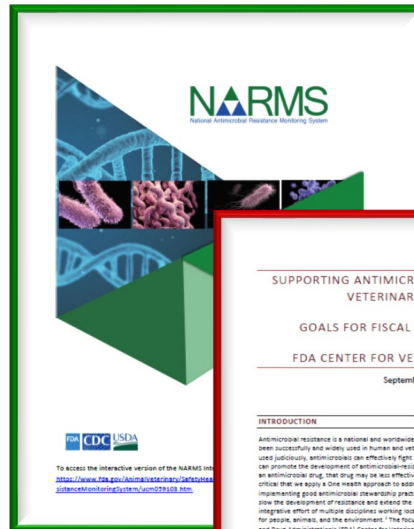
# Antimicrobial Resistance

- **Supporting Antimicrobial Stewardship in Veterinary Settings (5-Year Plan)**

[www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/UCM620420.pdf](http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/UCM620420.pdf)

- **National Antimicrobial Resistance Monitoring System (NARMS)**

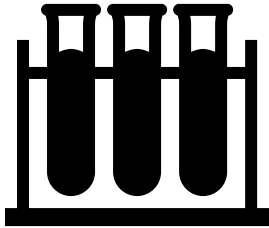
[www.fda.gov/animalveterinary/safetyhealth/antimicrobialresistance/nationalantimicrobialResistanceMonitoringSystem/default.htm](http://www.fda.gov/animalveterinary/safetyhealth/antimicrobialresistance/nationalantimicrobialResistanceMonitoringSystem/default.htm)



# Pre-market Animal Drug Review



- **Animal Drug User Fee Act (ADUFA)**
- **Animal Generic Drug User Fee Act (AGDUFA)**
- **Minor Use/Minor Species (MUMS)**

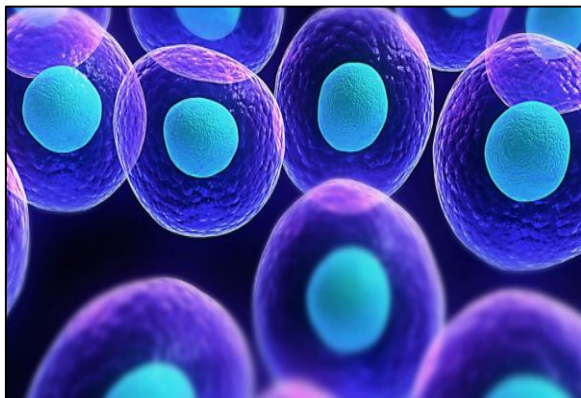


# Emerging Technologies & Innovation



## Animal Biotechnology

- Intentional Genomic Alteration (IGA) technology continues to advance (e.g., CRISPR, CAS9, TALENs)
- Stem cells and cell-based therapeutics



[www.fda.gov](http://www.fda.gov)

<https://www.fda.gov/Safety/Biotechnology/ucm624416.htm>



## Plant and Animal Biotechnology Innovation Action Plan

- Flexible regulatory approach based on risk
- Ensure safety, quality, and consumer confidence
- Includes Veterinary Innovation Program (VIP)

## Pre-Market Animal Food

- Food additives
- GRAS (generally recognized as safe)
- New animal food ingredients
- “GE” or “BE” plants





# Innovation and Flexibility

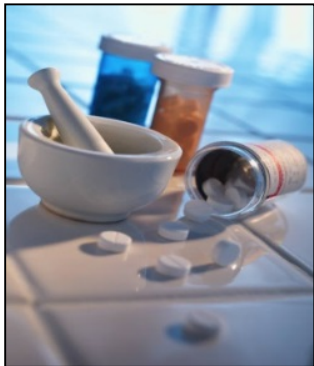
- **Public webinar about genome editing in animals**
- **Public meeting on alternative approaches in clinical investigations**
- **Research programs to address certain challenges of drug development**
- **Initiatives to develop predictable pathways for novel products**

# Regulatory Reform



- We heard you
- We're considering opportunities for animal drug development and public health
- We're developing appropriate responses

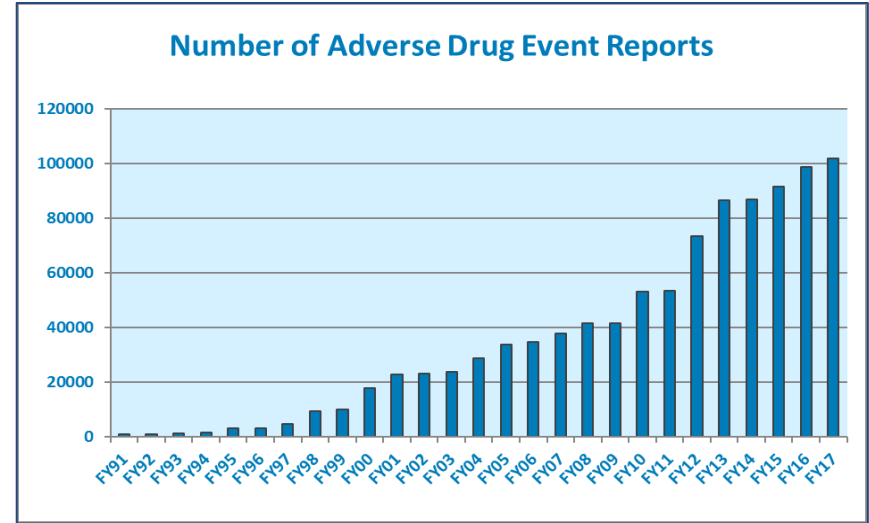
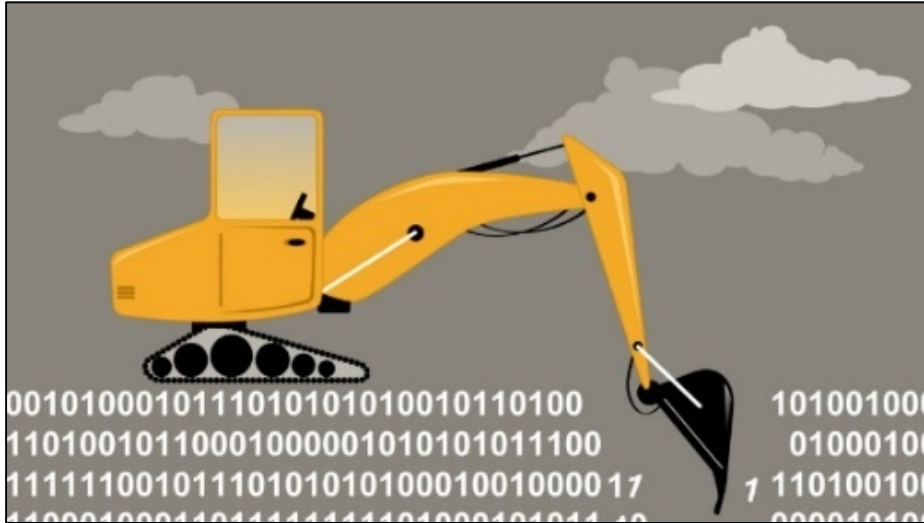
# Unapproved Animal Drugs Compounded from Bulk Drug Substances



- CVM is concerned about the number of animal drug products being sold to animal owners and veterinarians that are compounded from bulk drug substances
- Compounded copies of approved animal drugs have not demonstrated safety or efficacy
- Compounded copies undermine the legal drug approval process



# Post-market Drug Safety, Effectiveness, and Quality



# Lifecycle Approach

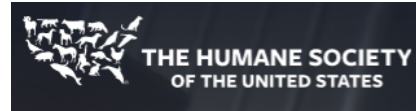
- Looking more holistically at pre- and post-market drug review
- Similar to the approach taken by FDA's other medical product centers
- Allows CVM to leverage great expertise and anticipate and address post-market concerns for **target animal safety** and **human user safety**

# International Activities

- **VICH** (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products) – Trilateral (EU-Japan-USA)
- **CODEX Alimentarius** (UN Food and Agriculture Organization / World Health Organization)
  - Codex Committee on Residues of Veterinary Drugs in Foods
  - Task Force on Antimicrobial Resistance
- **US-EU MRA** (Mutual Recognition Agreement) – Veterinary Drugs (EU)
- **ICCF** (International Cooperation for the Convergence of Technical Requirements for the Assessment of Feed Ingredients) – Trilateral (EU-Canada-USA + industry)
- **OIE** (World Organisation for Animal Health)
- **VDD** (Veterinary Drugs Directorate – Canada)
- **EMA** (European Medicines Agency)
- **Systems Recognition**



# Outreach to Consumers & Stakeholders



- Proactively engaging with diverse and disparate stakeholders on a wide variety of public health priorities



American Veterinary Medical Association



NATIONAL RENDERERS ASSOCIATION



National Grain and Feed Association



# Keep Up To Date



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[go.usa.gov/xP7W6](http://go.usa.gov/xP7W6)

[www.fda.gov](http://www.fda.gov)

<http://www.fda.gov/AnimalVeterinary>

Reference the CVM Website  
for the most current information

U.S. Department of Health and Human Services

**FDA U.S. FOOD & DRUG ADMINISTRATION**

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Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | **Animal & Veterinary** | Cosmetics | Tobacco Products

### Animal & Veterinary

Home > Animal & Veterinary

**For Veterinarians**  
See what resources FDA has for veterinarians. 1 2 3 4

**Navigate the Animal & Veterinary Section**

**Products**  
Information about Approved Animal Drug Products, Animal Food/Feed (including Pet Food), Imports & Exports, and the Generally Recognized as Safe (GRAS) Notification Program

**Safety & Health**  
Product Safety Information including Recalls, Adverse Drug Events, Antimicrobial Resistance, Animal Cloning, and Animal Drug Shortage Information

**I am looking for**

- Recalls
- Animal Feed
- Animal Drugs
- Pet Food
- Antimicrobial Resistance

**Consumer Information**

- Animal Health Articles
- Resources for Veterinarians
- How to Report a Pet Food Complaint
- How to Report Animal Drug Side Effects and Product Problems
- Jerky Pet Treats



# FDA – Center for Veterinary Medicine

## Protecting both Human and Animal Health

### Thank you!





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