

Center for Veterinary Medicine (CVM)

**May 4, 2017
FDLI Annual Conference**

CVM Organizational Chart

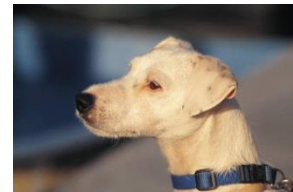


CVM's Vision and Mission



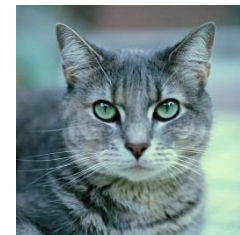
Vision

Excellence, Innovation, Leadership



Mission

Protecting Human and Animal Health

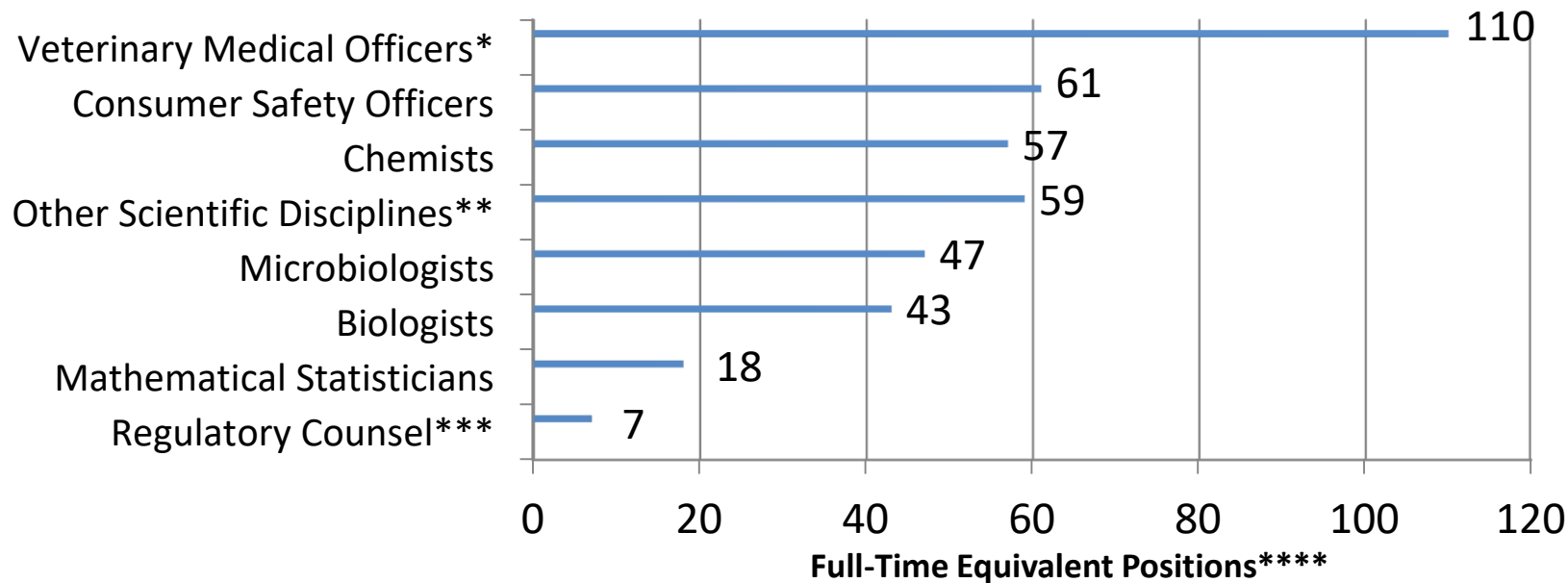


CVM's Budget

	FY 2016 Enacted
CVM Program Level	\$122,508,000
CVM Budget Authority	\$94,005,000
<i>ADUFA*</i>	<i>\$20,125,000</i>
<i>AGDUFA*</i>	<i>\$8,378,000</i>

** Non-add, CVM portion only*

Scientific and Technical Disciplines at CVM



*In addition to the number of employees listed here as Veterinary Medical Officers, CVM employs approximately 20 additional employees with a D.V.M./V.M.D. degree who are in positions with titles other than Veterinary Medical Officer.

**Includes Animal Scientists, Health Scientists, Epidemiologists, Toxicologists, Pharmacologists, Physiologists, Physical Scientists, and Animal Caretakers.

***CVM employs approximately 10 additional employees with a J.D. degree who are in positions with titles other than Regulatory Counsel to include Regulatory Policy Analysts and Government Information Specialists.

****Total CVM FTEs are 582. Data as of September 30, 2016.

Foods and Veterinary Medicine (FVM) Program Strategic Plan



<https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/UCM507379.pdf>

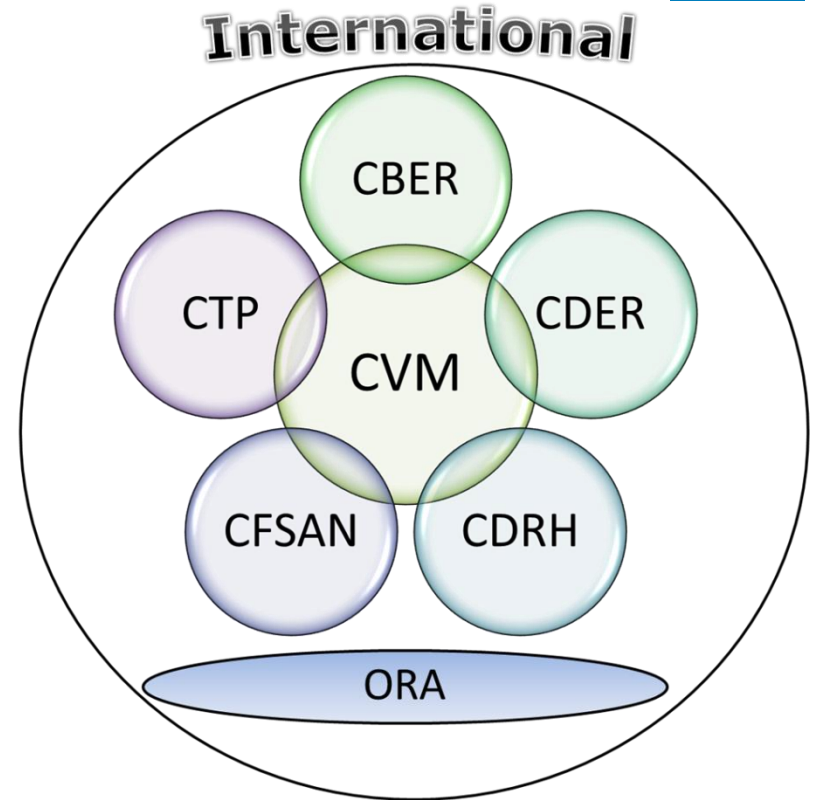
- Identifies the Goals, Objectives, and Strategies necessary to:
 - protect America's consumers and animals from foreseeable hazards
 - foster an environment to promote healthy and safe food choices
 - protect human and animal health by enhancing the safety and effectiveness of animal health products
 - continuously improve the leadership, management, staffing and organizational capacity of the FVM Program to protect public health



Microcosm of FDA



- *Center for Biologics Evaluation and Research (CBER):* Biologics produced by genetically engineered animals
- *Center for Drug Evaluation and Research (CDER):* Animal Drugs
- *Center for Devices and Radiological Health (CDRH):* Animal Devices (post-market only)
- *Center for Food Safety and Applied Nutrition (CFSAN):* Food Safety, Feed Additive Petitions and GRAS
- *Center for Tobacco Products (CTP):* Information on health effects of second hand smoke and pet health
- *Office of Regulatory Affairs (ORA):* Partner in Regulatory Oversight
- *International Activities:* Strengthen animal drug and feed regulatory infrastructures and harmonize product standards.



Companion Animal and Minor Species Medicine



CVM is responsible for regulating drugs, devices and food additives used in companion animals (dogs, cats and horses) and minor animal species



- Increase the availability and diversity of safe and effective products that relieve animal pain and suffering, sustain their health, and do not compromise human health.
- Minor Species include all animals other than the 7 Major Species: cattle, pigs, chickens, turkeys, horses, dogs and cats.



Animal Health and Animal Food Product Safety: Farm to Table



CVM is also responsible for regulating animal drugs, devices and food additives
used in food producing animals



- ~2.1 billion chickens & turkeys
- ~162 million cattle & pigs
- ~7.9 million sheep & goats



- Animal Drug Manufacturers
- Domestic and Foreign Animal and Human Feed Manufacturers
- Livestock and Poultry Producers
- Specialized Industry/Firms



- Million of humans in the U.S. and other countries

CVM's Key Initiatives



Animal Drug Review

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

Food Safety Modernization Act (FSMA) Implementation

Antimicrobial Resistance Strategy

- National Antimicrobial Resistance Monitoring System (NARMS)

Emerging Technologies and Innovation

- Genome Editing and Genetic Engineering
- Whole-Genome-Sequencing and Stem Cell Research

Unapproved Animal Drugs Strategy (including compounding)

Post-Market Safety and Quality

- Adverse Drug Experiences (ADEs)
- Veterinary Laboratory Investigation and Response Network (Vet-LIRN)

Outreach to Consumers and Stakeholders

Animal Drug Review

- CVM evaluates new animal drug applications for pioneer and generic drugs intended for animals that produce food, for companion animals, and for minor species.
- When the drug is for use in food-producing animals, not only must the safety to the animal be demonstrated, but also the safety of the food products derived from the treated animals that are intended for human consumption.
- CVM reviews safe, effective, quality manufactured, and properly labeled new animal drug products through a science-based approach in a regulatory environment.



Animal Drug Review: Animal Drug User Fee Act (ADUFA)

ADUFA provides CVM with resources to enhance the timeliness and predictability of new animal drug applications for pioneer drug products

- ADUFA is currently in the third authorization, which sunsets at the end of FY 2018
 - ADUFA I (FY2004-FY2008), ADUFA II (FY2009-FY2013), ADUFA III (FY2014-FY2018)
- ADUFA III includes a target revenue of \$114 million over the 5 years
- ADUFA significantly reduced review times for a single cycle, from 500+ days prior to the authorization of ADUFA I to 180 days
- CVM has met and exceeded all performance goals since the start of the program in FY 2004
- CVM is currently negotiating the reauthorization with the Animal Health Institute
 - Negotiations are set to finish in 2017, will move through clearance with FDA, HHS, and OMB, and must be submitted to Congress by January 15, 2018



Animal Drug Review: Animal Generic Drug User Fee Act (AGDUFA)

AGDUFA provides CVM with resources to enhance the timeliness and predictability of generic new animal drug applications

- AGDUFA is currently in the second authorization, which sunsets at the end of FY 2018
 - AGDUFA I (FY2009-FY2013), AGDUFA II (FY2014-FY2018)
- AGDUFA II includes a target revenue of \$38 million over the 5 years
- AGDUFA significantly reduced review times for a single cycle, from 700+ days prior to the authorization of AGDUFA I to 270 days
- CVM has met and exceeded all performance goals since the start of the program in FY 2009
- CVM is currently negotiating the reauthorization of AGDUFA with the Generic Animal Drug Alliance
 - Negotiations are set to finish in 2017, will move through clearance with FDA, HHS, and OMB, and must be submitted to Congress by January 15, 2018



Animal Drug Review:

Minor Use and Minor Species (MUMS)

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

- MUMS Programs from the Minor Use/Minor Species Animal Health Act of 2004:
 - Designation – sponsor granted 7 years of exclusive marketing rights (similar to Orphan Drug Act) – 137 designations to date. Eligibility to apply for MUMS grants (initiated in FY 2009).
 - Indexing (for non-food minor species) – sponsors allowed to legally market unapproved new animal drugs added to the index based partly on evaluation of an outside expert panel – 13 index listed products to date.
 - Conditional Approval – after completing all safety sections of a new animal drug application, a sponsor can market drug up to 5 years while collecting effectiveness data.
- Liaison to USDA's NRSP-7 program – research to support approval of new animal drugs for minor species of agricultural importance.

Food Safety Modernization Act (FSMA)

Implementation



Protecting public health by preventing food safety problems

FSMA directs FDA to build a food and feed safety system based on the public health principles of comprehensive prevention, enhanced focus on risk-based resource allocation, and partnerships across the public and private sectors to minimize hazards from farm to table.

Enhanced Partnerships	Prevention	Inspection, Compliance and Response	Imports
<ul style="list-style-type: none">- State/local and international capacity building- National agriculture and food defense strategy	<ul style="list-style-type: none">- Mandatory preventive controls for facilities- Intentional contamination	<ul style="list-style-type: none">- Administrative detention- Recalls (upon enactment)- Suspension of registration	<ul style="list-style-type: none">- Foreign supplier verification program- Accredited third-party certification program- Voluntary Qualified Importer Program

Antimicrobial Resistance

The National Strategy outlines 5 goals and Objectives:

1. Slow the emergence of resistant bacteria and prevent the spread of resistant infections.
2. Strengthen National One-Health surveillance efforts to combat resistance.
3. Advance development and use of rapid diagnostic tests for identification and characterization of resistant bacteria.
4. Accelerate basic and applied research and development for new antibiotic, other therapeutics and vaccines.
5. Improve international collaboration and capacities for antibiotic resistance prevention, surveillance, control, and antibiotic research and development.

Antimicrobial Resistance Strategy

Provide safe use of antimicrobials in food animals while ensuring that significant human antimicrobial therapies are not compromised or lost

- Guidance for Industry #209 describes the overall policy direction regarding the judicious use of antimicrobial drugs.
 - Key principles are limiting use of medically important antimicrobial drugs in food-producing animals to those uses:
 - considered necessary for ensuring animal health (therapeutic uses)
 - that include veterinary oversight or consultation
- Limit the use of antimicrobial drugs in food-producing animals (eliminate growth promotion and feed efficiency claims on medically important antibiotics)
- Enhance the quality and accuracy of data on antimicrobial drug sales and distribution

Antimicrobial Resistance Strategy



- Guidance for Industry #213 provides more detail on implementing the judicious use principles outlined in Guidance #209:
 - Defines “medically important” (i.e., define what products are affected)
 - Establishes a 3-year implementation timeline to voluntarily remove claims relating to production uses, and bring remaining therapeutic uses under veterinary oversight by changing marketing status from over-the-counter (OTC) to veterinary feed directive (VFD) or prescription (Rx)
- As of January 3, 2017, all affected drug applications have either aligned with judicious use principles outlined , or their approvals have been voluntarily withdrawn.
- Of the 292 approved drug applications identified as being affected by Guidance for Industry #213 including pioneer, generic, and combination approvals:
 - 84 drug applications were withdrawn
 - 93 applications for oral dosage form products intended for use in water were converted from OTC to RX
 - 115 applications for products intended for use in feed were converted from OTC to VFD
- Production (e.g. growth promotion) indications were withdrawn from all affected applications

Antimicrobial Resistance Strategy

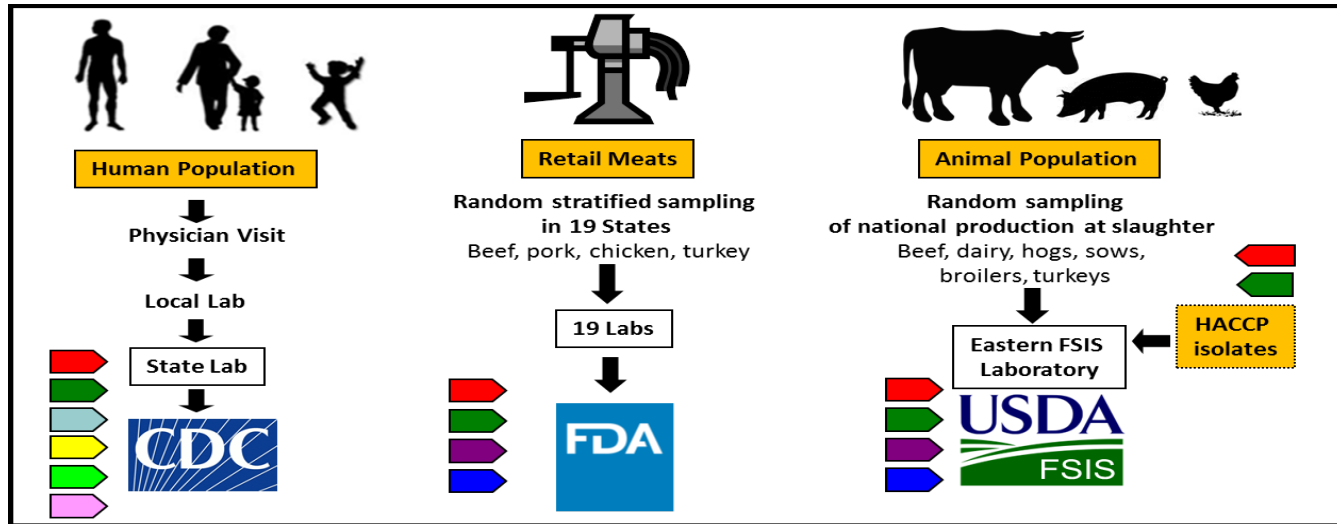
National Antimicrobial Resistance Monitoring System (NARMS)

NARMS Mission

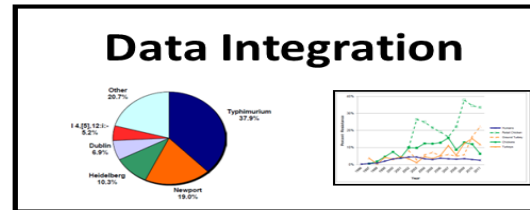
- Monitor trends in antimicrobial resistance among foodborne bacteria from humans, retail meats, and animals
- Disseminate timely information on antimicrobial resistance to promote interventions that reduce resistance among foodborne bacteria
- Conduct research to better understand the emergence, persistence, and spread of antimicrobial resistance
- Assist the FDA in making decisions related to the approval of safe and effective antimicrobial drugs for animals

Antimicrobial Resistance Strategy

NARMS



- Campylobacter*
- Non-typhoidal *Salmonella*
- Enterococcus*
- Generic *E. coli*
- Typhoidal *Salmonella**
- E. coli* O157*
- Non-cholera *Vibrio**
- Shigella**



*not included in the NARMS Integrated Report

NARMS Integrated Report: 2014

The National Antimicrobial Resistance Monitoring System: Enteric Bacteria

Emerging Technologies and Innovation



Genome Editing and Genetic Engineering

Revolutionary Crossroads in American Agriculture

- Genome Editing is the term used to describe a relatively new set of technologies that enable one to make *precise* changes in the DNA of a plant, animal or other living organism.
- Genetic Engineering is the process in which recombinant DNA (rDNA) technology is used to introduce desirable traits into organisms.
 - Current Guidance for Industry #187 *Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs*, published January 2009; revised draft GFI #187, *Regulation of intentionally Altered Genomic DNA in Animals*, issued January 19, 2017. Comment period closes June 19, 2017.
 - First food animal approval: Aqua Advantage Salmon
 - “Bio-pharm” animals are used to make human biologics or other therapeutics (e.g. ATryn – human anticoagulant – a therapeutic protein produced in milk of GE goats approved in February 2009).

Emerging Technologies and Innovation

Whole-Genome-Sequencing and Stem Cell Research



Whole-Genome-Sequencing (WGS)

- WGS reveals the complete DNA make-up of an organism, enabling FDA to better understand variations both within and between species.
- This technology is being used to perform basic foodborne pathogen identification, which has the potential to help reduce foodborne illnesses and deaths over the long term.

Mesenchymal stem cell (MSC)

- Expected to be the most common cell type for stem cell products.
- Dog and horse products are being developed.
- Draft Guidance for Industry #218 *Cell Based Products for Animal Use* published July 2014.
- Stem cell markers in canine MSC derived from various tissue sources have been identified
- Addresses data gap in cell identification.
- Assists with bioequivalence and safety requirements.



Unapproved Animal Drugs Strategy

(including compounding)

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

- These drugs are considered adulterated under the FD&C Act, and have the potential to compromise food safety, place animals or humans at undue risk from unsafe or ineffective treatment, and undermine the incentives to develop and submit new animal drug applications to FDA.
- Although Congress passed ***The Drug Quality & Security Act*** (11-2013) applicable to the compounding of human drugs, this legislation does not apply to the compounding of drugs intended for use in animals.
- CVM is developing enforcement strategies for unapproved drugs to further support the approval process and to protect human and animal health.
- CVM published draft Guidance for Industry #230, Compounding Animal Drugs from Bulk Drug Substances, in May 2015. We are currently considering the numerous comments we received on the draft.

Post-Market Safety and Quality



Oversight and surveillance of post-market product use assures
the safety of FDA-regulated products

Initial product safety and effectiveness data comes from small clinical trials, however once a product is approved and on the market for broader use we have to rely on post-market monitoring and surveillance to assure its safety and take action early on if needed.

Adverse Drug Experiences

Monitors adverse events for approved animal drugs, unapproved animal drugs, and veterinary devices to identify safety signals and effectiveness issues of concern

- For approved drug products, CVM scientists use the adverse drug event database to assist with decisions about product safety which may include changes to the label or other regulatory action.
 - It is the largest animal drug adverse event regulatory agency database in the world, containing over 719,000 cases as of April 2017.
- CVM participates in outreach programs to encourage veterinarian participation in the pharmacovigilance program.
 - In FY 2016, approximately 99,000 Adverse Drug Experience (ADE) reports were received.

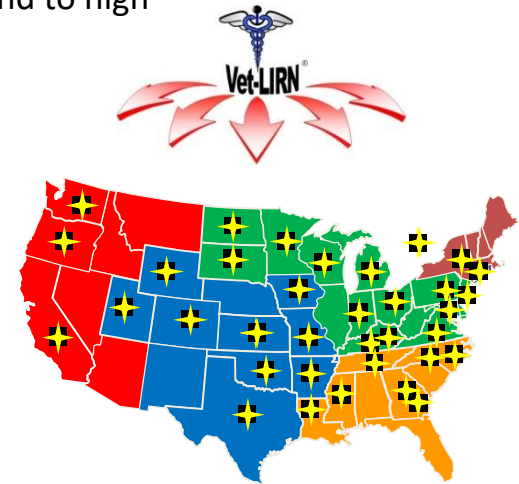
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)



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

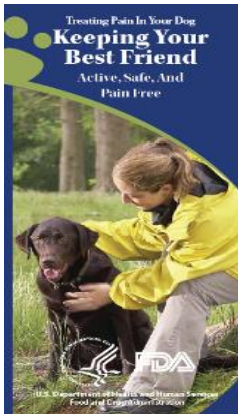
This program coordinates facilities, equipment, and professional expertise of government and veterinary diagnostic laboratories across the country and Canada to respond to high priority chemical and microbial feed/drug contamination events.

- Network includes 38 Laboratories
- Develop 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 including jerky pet treats cases



Outreach to Consumers and Stakeholders

Timely information for the benefit of all animals and humans

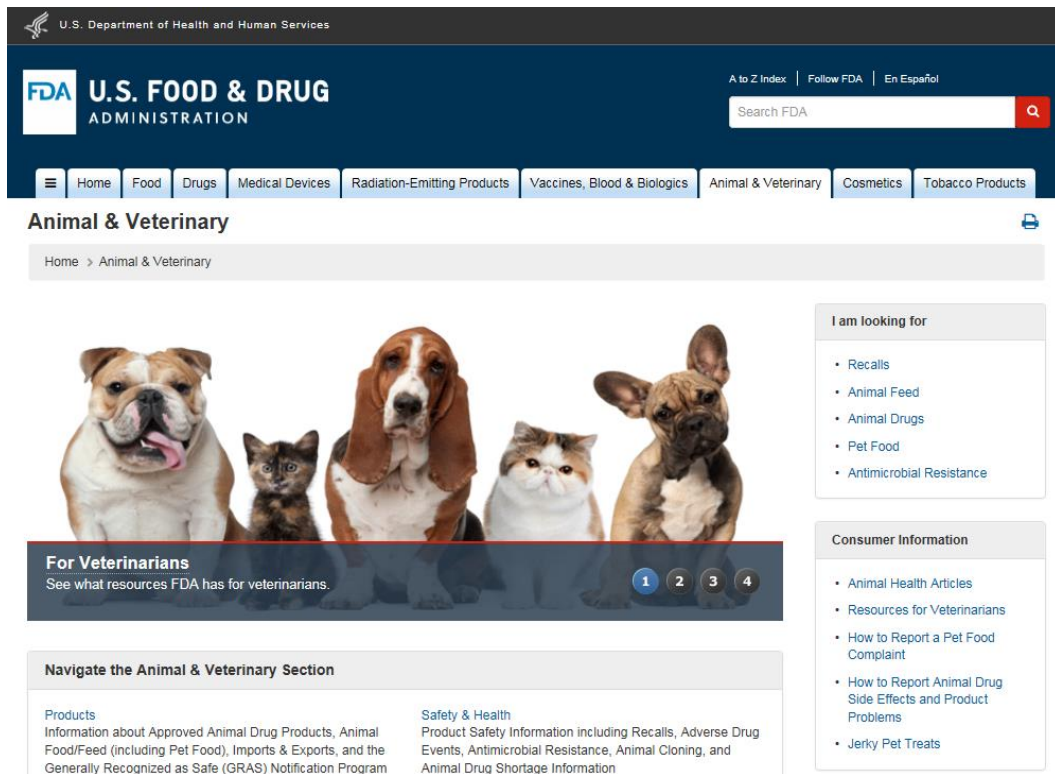


- With continuous communication and outreach, CVM strives to enhance public trust, promote safe and effective use of the animal health products we regulate, and share our scientific endeavors
- CVM provides reliable, science-based information to promote animal and human health
- Timely information provided to consumers, industry, trade, and government organizations via social media, consumer updates, email subscriptions, etc.

Keep Up To Date

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

Reference the CVM Website for the most current information



The screenshot shows the FDA's Animal & Veterinary website. At the top is the U.S. Department of Health and Human Services header. Below it is the FDA U.S. Food & Drug Administration logo and navigation links (A to Z Index, Follow FDA, En Español). A search bar is also present. The main navigation menu includes Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The 'Animal & Veterinary' section is highlighted, showing a breadcrumb trail: Home > Animal & Veterinary. Below this is a large image of five animals: a bulldog, a kitten, a beagle, a cat, and a French bulldog. To the right of the image is a sidebar with 'I am looking for' and 'Consumer Information' sections. The 'I am looking for' section lists: Recalls, Animal Feed, Animal Drugs, Pet Food, and Antimicrobial Resistance. The 'Consumer Information' section lists: Animal Health Articles, Resources for Veterinarians, How to Report a Pet Food Complaint, How to Report Animal Drug Side Effects and Product Problems, and Jerky Pet Treats. Below the animal image is a 'For Veterinarians' section with the text 'See what resources FDA has for veterinarians.' and a numbered list (1, 2, 3, 4). At the bottom is a 'Navigate the Animal & Veterinary Section' section with two columns: 'Products' (Information about Approved Animal Drug Products, Animal Food/Feed (including Pet Food), Imports & Exports, and the Generally Recognized as Safe (GRAS) Notification Program) and 'Safety & Health' (Product Safety Information including Recalls, Adverse Drug Events, Antimicrobial Resistance, Animal Cloning, and Animal Drug Shortage Information).

U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

A to Z Index | Follow FDA | En Español

Search FDA

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.

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

**Center for Veterinary Medicine
Protecting Human and Animal Health**



Thank you!



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

2017 FDLI Annual Conference

Center for Veterinary Medicine Breakout

Pet Food

Rosemary Extract



DEPARTMENT OF HEALTH & HUMAN SERVICES

March 2, 2006

Food and Drug Administration
Rockville MD 20857

Ms. Nancy K. Cook
Vice President, Technical and Regulatory Affairs
Pet Food Institute
2025 M Street, Northwest
Suite 800
Washington, District of Columbia 20036

Dear Ms. Cook:

The Center for Veterinary Medicine (CVM) is concerned that several feed ingredient suppliers and feed manufacturers are marketing and using rosemary extracts as a "natural preservative" for the purpose of preventing oxidative degradation of animal feeds. Rosemary and rosemary extracts are generally recognized as safe (GRAS) in animal feeds, including pet foods, for the intended use as a spice or flavoring agent, as provided in 21 CFR 582.10 and 21 CFR 582.20. As a spice or flavor, rosemary and rosemary extracts typically do not exceed 50 ppm in the finished product. To be effective as a preservative, rosemary and rosemary extract must be used at significantly higher levels than necessary for GRAS uses. At these higher levels, rosemary and rosemary extract may present safety concerns to animals. There are alternative substances that are approved or affirmed for use as chemical preservatives in animal feed.

If you would like to discuss the safety or suitability of using rosemary or rosemary extracts as a preservative in feed, please contact Dr. Karen Ekelman in CVM's Division of Animal Feeds. Dr. Ekelman can be reached at (240) 453-6851, or karen.ekelman@fda.hhs.gov.

Sincerely,

A handwritten signature in cursive script that reads "Sharon A. Benz".

Sharon A. Benz, Ph.D.
Director
Division of Animal Feeds
Center for Veterinary Medicine

Rosemary and rosemary extracts are generally recognized as safe (GRAS) in animal feeds, including pet foods, for the intended use as a spice or flavoring agent, as provided in 21 CFR 582.10 and 21 CFR 582.20. As a spice or flavor, rosemary and rosemary extracts typically do not exceed 50 ppm in the finished product. To be effective as a preservative, rosemary and rosemary extract must be used at significantly higher levels than necessary for GRAS uses. At these higher levels, rosemary and rosemary extract may present safety concerns to animals. There are alternative substances that are approved or affirmed for use as chemical preservatives in animal feed.

Peruvian balsam	Myroxylon pereirae Klotzsch.
Petitgrain	Citrus aurantium L.
Petitgrain lemon	Citrus limon (L.) Burm. f.
Petitgrain mandarin or tangerine	Citrus reticulata Blanco.
Pimenta	Pimenta officinalis Lindl.
Pimenta leaf	Pimenta officinalis Lindl.
Pipsissewa leaves	Chimaphila umbellata Nutt.
Pomegranate	Punica granatum L.
Prickly ash bark	Xanthoxylum (or Zanthoxylum) Americanum Mill. or Xanthoxylum clava-herculis L.
Rose absolute	Rosa alba L., Rosa centifolia L., Rosa damascena Mill., Rosa gallica L., and vars. of these spp.
Rose (otto of roses, attar of roses)	Do.
Rose buds	Do.
Rose flowers	Do.
Rose fruit (hips)	Do.
Rose geranium	Pelargonium graveolens L'Her.
Rose leaves	Rosa spp.
Rosemary	Rosmarinus officinalis L.
Rue	Ruta graveolens L.
Saffron	Crocus sativus L.
Sage	Salvia officinalis L.
Sage, Greek	Salvia triloba L.
Sage, Spanish	Salvia lavandulaefolia Vahl.
St. John's bread	Ceratonia siliqua L.
Savory, summer	Satureia hortensis L.
Savory, winter	Satureia montana L.
Schinus molle	Schinus molle L.
Sloe berries (blackthorn)	

“Natural”

Food

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Labeling & Nutrition

[Changes to the Nutrition Facts Label](#)

[Food Labeling Guide](#)

[Topic-Specific Labeling Information](#)

[Menu and Vending Machines Labeling Requirements](#)

[Small Business Nutrition Labeling Exemption](#)

"Natural" on Food Labeling

[f SHARE](#) [t TWEET](#) [in LINKEDIN](#) [p PIN IT](#) [e EMAIL](#) [p PRINT](#)

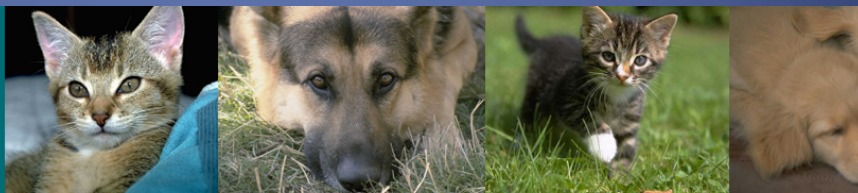
The FDA Requests Comments on Use of the Term "Natural" on Food Labeling

Because of the changing landscape of food ingredients and production, and in direct response to consumers who have requested that the FDA explore the use of the term "natural," the agency asked the public to provide information and comments on the use of this term in the labeling of human food products.

The FDA is taking this action in part because it received three Citizen Petitions asking that the agency define the term "natural" for use in food labeling and one Citizen Petition asking that the agency prohibit the term "natural" on food labels. We also note that some Federal courts, as a result of litigation between private parties, have requested administrative determinations from the FDA regarding whether food products containing ingredients produced using genetic engineering or foods containing high fructose corn syrup may be labeled as "natural."

Although the FDA has not engaged in rulemaking to establish a formal definition for the term "natural," we do have a longstanding policy concerning the use of "natural" in human food labeling. The FDA has considered the term "natural" to mean that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in that food. However,

Natural



- » Home
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- » Selecting the Right Pet Food
- » Who's Responsible?
- » The Role of AAFCO in Pet Food
- » Regulators' Role
- » How to File a Complaint About a Pet Food
- » Reading Labels
- » Safe Pet Food
- » What's in the Ingredients List?
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- » Byproducts
- » Organic
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- » "Human-Grade"
- » Calories
- » Treats and Chews

You are here: [Natural](#)

Natural

"Natural" is a descriptive term that sounds positive, even though misperceptions about the word abound in regards to pet food labeling and claims. In the past, the term was undefined in both state and federal feed control jurisdictions and was not seen in the marketplace. But in an effort to appeal to customers, marketers have increasingly used the term on pet food product labeling.

Presently, AAFCO's definition of natural is:

a feed or feed ingredient derived solely from plant, animal or mined sources, either in its unprocessed state or having been subject to physical processing, heat processing, rendering, purification, extraction, hydrolysis, enzymolysis or fermentation, but not having been produced by or subject to a chemically synthetic process and not containing any additives or processing aids that are chemically synthetic except in amounts as might occur in good manufacturing practices.

In the majority of states, which have adopted the AAFCO Model Bill and Model Regulations, pet food labelers/guarantors must comply with this definition to display the term.

The U.S. Food and Drug Administration (FDA) has not yet defined natural in relation to pet food labeling. Instead, it

Rachael Ray's Dog Food Slammed For False 'Natural' Labels

Share us on: By [Suevon Lee](#)

Law360, Los Angeles (March 1, 2017, 4:57 PM EST) -- The company that sells celebrity chef Rachael Ray's dog food brand was slapped with a putative class action in California federal court Tuesday for false advertising over the "natural" labeling on Nutrish lines of dog food products when the items allegedly contain chemicals. Ainsworth Pet Nutrition Holdings LLC and several related businesses are accused of marketing the Rachael Ray Nutrish lines of dry and wet dog food products as "natural" and containing "no artificial preservatives" when in fact they include harmful additives and synthetic ingredients, according to the complaint. "By deceptively marketing the products as 'natural' and having 'no artificial preservatives,' defendants wrongfully capitalized on, and reaped enormous profits from, consumers' strong preference for natural food products made free of artificial preservatives," alleged Christina Grimm, a California resident seeking to represent a class of other Golden State residents who purchased the dog food from February 2010 to the present.

4. Defendants engaged in deceptive labeling practices by expressly representing on the Products' labels and website that the Products are "natural" and have "no artificial preservatives" despite the presence of L-Ascorbyl-2-Polyphosphate, Menadione Sodium Bisulfite Complex, Thiamine Mononitrate, "natural flavors," and a variety of caramel color.

Substantiation

Claim Substantiation

Advertisers must have a “reasonable basis” for an advertising claim *before* the claim is disseminated.

- **FTC Policy Statement Regarding Advertising Substantiation:**

- “First, we reaffirm our commitment to the underlying legal requirement of advertising substantiation-that advertisers and ad agencies have a reasonable basis for advertising claims before they are disseminated.”



FTC v. MARS PETCARE

The image displays two side-by-side black and white advertisements for Eukanuba dog food. Both ads feature a vertical banner on the left with the Eukanuba logo and a circular seal stating 'Eukanuba is DEDICATED TO HEALTHIER LONGER LIVES'. The top half of each ad contains text about a dog's age and lifespan, followed by a photograph of the dog and a small image of an Eukanuba product bag at the bottom.

Utah at age 17.
Living 30% longer
than his typical lifespan.

He's enjoying an exceptionally long life, with many more adventures ahead.

Eukanuba

Eukanuba Dedicated to Healthier, Longer Lives
Learn about the long life study at Eukanuba.com

Iowa at age 17.
Living 30% longer
than her typical lifespan.

She's enjoying an exceptionally long life, with plenty of chase left to give.

Eukanuba

Eukanuba Dedicated to Healthier, Longer Lives
Learn about the long life study at Eukanuba.com

FTC v. MARS PETCARE

Count I

False or Unsubstantiated Efficacy Claims

7. In connection with the advertising, promotion, offering for sale or sale of Eukanuba brand dog food, Respondent has represented, directly or indirectly, expressly or by implication, that

- A. With Eukanuba, dogs live 30 percent or more longer than their typical lifespan;
and
- B. Eukanuba brand dog foods enable dogs to live exceptionally long lives.

8. The representations set forth in Paragraph 7 were, and are, false or misleading or were not substantiated at the time the representations were made.

FTC v. MARS PETCARE

Count II False Establishment Claims

9. In connection with the advertising, promotion, offering for sale or sale of Eukanuba brand dog food, Respondent has represented, directly or indirectly, expressly or by implication, that

- A. Scientific tests prove that, with Eukanuba, dogs live 30 percent or more longer than their typical lifespan; and
- B. Scientific tests prove that Eukanuba brand dog foods enable dogs to live exceptionally long lives.

10. In fact,

- A. Scientific tests do not prove that, with Eukanuba, dogs live 30 percent longer than their typical lifespan; and
- B. Scientific tests do not prove that Eukanuba brand dog foods enable dogs to live exceptionally long lives.

Among other things, the evidence relied on by Respondent for its representations concerning the Eukanuba brand dog food consisted primarily of results from a single study, the results of which showed no significant difference in the median age at death of the dogs in the study relative to the typical age at death of dogs of the same breed. Therefore, the representations set forth in Paragraph 8 were, and are, false or misleading.

Violations of Sections 5 and 12

11. The acts and practices of Respondent as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce

AAFCO on Substantiation

- No general substantiation requirements
- Minimum testing methods for Substantiation of nutritional adequacy claims and calorie content claims