ANIMAL DRUGS AND FEED

(Dollars in Thousands)	FY 2015 Final	FY 2015 Actuals	FY 2016 Enacted	FY 2017 President's Budget	FY 2017 +/- FY 2016
Animal Drugs and Feed	**174,783**	**175,024**	**188,632**	**196,736**	**8,104**
Budget Authority	***147,577***	***147,564***	***158,652***	***161,852***	***3,200***
User Fees	***27,206***	***27,460***	***29,980***	***34,884***	***4,904***
Center	119,314	120,925	122,508	129,533	7,025
Budget Authority	93,505	93,496	94,005	97,205	3,200
User Fees	25,809	27,429	28,503	32,328	3,825
Animal Drug (ADUFA)	*19,814*	*19,357*	*20,125*	*20,265*	140
Animal Generic Drug (AGDUFA)	*5,995*	*8,072*	*8,378*	*8,949*	571
Food and Feed Recall	---	---	---	---	---
Food Facility Registration and Inspection	---	---	---	*1,586*	1,586
Food Import	---	---	---	*1,528*	1,528
Field	55,469	54,099	66,124	67,203	1,079
Budget Authority	54,072	54,068	64,647	64,647	---
User Fees	1,397	31	1,477	2,556	1,079
Animal Drug (ADUFA)	*404*	*31*	*411*	*414*	3
Animal Generic Drug (AGDUFA)	*186*	---	*259*	*277*	18
Food and Feed Recall	---	---	---	---	---
Food Reinspection	*807*	---	*807*	*807*	---
Food Facility Registration and Inspection	---	---	---	*1,058*	1,058
FTE	**851**	**880**	**910**	**933**	**23**

Authorizing Legislation: Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-399); Public Health Service Act (42 U.S.C. 201, *et seq.*); Animal Drug Amendments (1968) (21 U.S.C. 360b); Generic Animal Drug and Patent Term Restoration Act (1988); Animal Medicinal Drug Use Clarification Act of 1994; Animal Drug Availability Act of 1996; FDA Export Reform and Enhancement Act of 1996; Food and Drug Administration Modernization Act of 1997; Antimicrobial Regulation Technical Corrections Act of 1998; Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Animal Drug User Fee Act of 2003 (21 U.S.C. 379j-11 - 379j-12); Minor Use and Minor Species Animal Health Act of 2004; Sanitary Food Transportation Act of 2005; Food and Drug Administration Amendment Act of 2007; Animal Drug User Fee Amendments of 2008 (P.L. 110-316); Animal Generic Drug User Fee Act of 2008 (P.L. 110-316); Patient Protection and Affordable Care Act; FDA Food Safety Modernization Act (P.L. 111-353); FDA Safety and Innovation Act (P.L. 112-144); Animal Drug User Fee Reauthorization Act of 2013 (P.L. 113-14); Animal Generic Drug User Fee Reauthorization Act of 2013 (P.L. 113-14); Drug Quality and Security Act (2013)

Allocation Methods: Competitive grant; Contract; Direct Federal/intramural

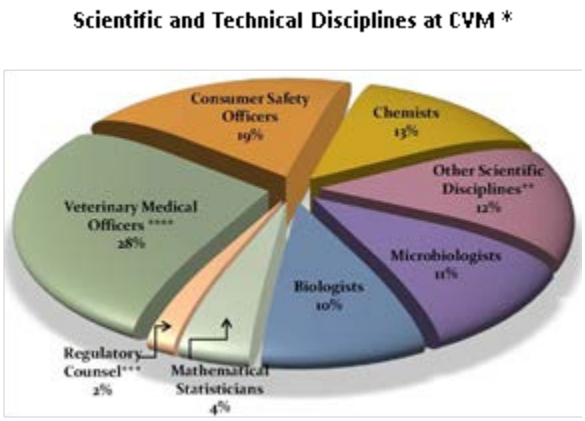
PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

The Animal Drugs and Feeds Program began in 1968 with the amendment of the Federal Food, Drug, and Cosmetic (FD&C) Act to include new authorities for regulating animal drugs, devices, and feed. The Animal Drugs and Feeds Program is a component of the FDA Foods and Veterinary Medicine (FVM) Program. The purpose of the FVM Program is to protect and promote the health of humans and animals by ensuring the safety of the American food supply, as well as the safety of animal feed and devices and the safety and effectiveness of animal drugs.

The FVM Program comprises the Animal Drugs and Feeds and the Foods Programs, including field activities in the Office of Regulatory Affairs (ORA). The operations of the Animal Drugs and Feeds and the Foods Programs are administered by the Center for Veterinary Medicine (CVM) and the Center for Food Safety and Applied Nutrition (CFSAN) respectively, both in

collaboration with ORA. The Office of Foods and Veterinary Medicine provides leadership and strategic direction to the FVM Program.

The Animal Drugs and Feeds Program supports FDA's mission by approving safe and effective products for animals and by enforcing applicable provisions of the FD&C Act and other authorities. Safe and effective animal drugs and feeds play an important role in protecting animal health and the safety of America's food supply.



Congress recognized the unique challenges FDA faces in the area of food safety in the 21st Century and gave FDA a modern legislative mandate to meet these challenges by enacting the FDA Food Safety Modernization Act (FSMA). FSMA directs FDA to build a food and feed safety system based on the public health principle of comprehensive prevention, an enhanced focus on risk-based resource allocation, and partnerships across the public and private sectors to minimize hazards from farm to table.

The FDA FVM Program Strategic Plan[37] provides a framework for the implementation of FSMA and places a high priority on the prevention of foodborne illness of both unknown origins and illness that can be specifically attributed to known sources. FVM also regulates the safety and effectiveness of animal drugs. In support of this endeavor, the Animal Drugs and Feeds Program is aligned with the FVM Strategic Plan goals of standards setting, compliance, risk assessment and regulatory science, nutrition and food labeling, response, and animal drug safety.

To achieve the goals of the FVM Strategic Plan, the Animal Drugs and Feeds Program focuses on:

- timely premarket review of new animal drugs
- appropriate use of approved animal drugs
- scientific research solutions for the safety of animal-derived food and health products
- minimizing the illegal sale of compounded and unapproved drugs
- prevention of marketing of unsafe products.

The Animal Drugs and Feeds Program also ensures that animal drugs and feeds used in the care of food-producing animals do not result in unsafe residues in food products, such as milk, that are harvested or produced from these animals. Further, the program protects the health of companion animals and addresses zoonotic diseases – animal diseases that can be transmitted to humans. It also ensures a food supply that is safe for both humans and animals, and protects

[37] The strategic plan can be found at: http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/UCM273732.pdf.
*Total CVM FTEs are 564. Data as of FY15.
**Includes Animal Scientists, Health Scientists, Toxicologists, Pharmacologists, Pharmacists, Physiologists, Physical Scientists, and Animal Caretakers.
***CVM employs approximately 7 additional employees with a J.D. degree who are in positions with titles other than Regulatory Counsel to include Regulatory Policy Analysts and Regulatory Information Specialists.
****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.

billions of poultry, cattle, swine, horses and minor animal species, as well as millions of companion animals in the United States.

A combination of appropriations and user fee programs funds the regulatory process to assure product safety and effectiveness. User fees are authorized under the Animal Drug User Fee Act (ADUFA), the Animal Generic Drug User Fee Act (AGDUFA), and the FDA Export Reform and Enhancement Act (Export Certificate program).

The ADUFA and AGDUFA user fee programs supplement the appropriated portion of the new animal drug review program to continue improving the quality and timeliness of the pioneer animal drug and generic new animal drug review processes. The Export Certificate program promotes the export of products made in the U.S., facilitates international trade, and provides assurance the products exported can be marketed in the U.S. or meet specific U.S. regulations.

Recent major accomplishments include critical work on combating antimicrobial resistance, which has included the publication of Guidance for Industry #213 to support the judicious use of antimicrobials. FDA published the final Veterinary Feed Directive in FY 2015 to bring the use of all medically important antibacterial drugs in animal feed under the oversight of licensed veterinarians.

Other major accomplishments are the extensive work on the "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals" final FSMA rule and the use of grant funds to bolster efforts to validate testing methods as part of the Veterinary Laboratory Investigation and Response Network (Vet-LIRN).

The following selected accomplishments demonstrate the Animal Drugs and Feeds Program's delivery of its regulatory and public health responsibilities within the context of current priorities.[38]

Improve and Safeguard Access

The Animal Drugs and Feeds Program is responsible for regulating animal drugs and feeds. Premarket responsibilities include ensuring the product review process is as effective and efficient as possible, and working collaboratively with partners in the private sector, public sector, and academia to facilitate product development. Within this goal area, the Program addresses the following FDA Strategic Priorities:

- Safety and Quality,
- Regulatory Science, and
- Globalization.

Animal Drug Review

The Animal Drugs and Feeds Program increases the availability and diversity of safe and effective products that relieve animal pain and suffering, sustain their health, and do not compromise human health. The animal drug user fee acts require that FDA meet specified timeframes for review and action on 90 percent of new animal drug applications received during a fiscal year.

[38] Please visit www.fda.gov for additional program information and detailed news items.

FDA exceeded all performance goals and completed the review and action on 98.3 percent of original New Animal Drug Applications (NADAs) and other ADUFA sentinel submissions within timeframes specified by ADUFA for applications received and reviewed in FY 2014. FDA also exceeded the performance goals and completed the review and action on 100 percent of original Abbreviated New Animal Drugs Applications (ANADAs) and Reactivations and other AGDUFA sentinel submissions as required and within the timeframes for applications received and reviewed in FY 2014.

Selected Product Approvals

Below are the most recent Animal Drugs and Feeds Program significant product approvals that occurred during calendar year 2015. This list does not represent any degree of importance or priority ranking of products.[39]

Date	Product Name	Purpose or Benefit
Sep 2015	CLARO (Florfenicol, terbinafine, mometasone furoate)	For the treatment of inflammation of the outer ear and ear canal in dogs associated with susceptible strains of yeast and bacteria
Aug 2015	ONSIOR (robenacoxib)	For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy and castration in cats over 4 months of age
Aug 2015	LUTALYSE HighCon Injection (dinoprost tromethamine)	For estrus synchronization and treatment of chronic endometritis in cattle. Use with FACTREL to synchronize estrous cycles to allow fixed-time artificial insemination in lactating cows
Jun 2015	CORAXIS (moxidectin)	For the prevention of heartworm disease and treatment of hookworm in dogs that are at least 7 weeks old and weigh at least 3 pounds
May 2015	KAVAULT (avilamycin) Type A Medicated Article	For the reduction in incidence and overall severity of diarrhea in the presence of pathogenic *Escherichia coli* in groups of weaned pigs.

The term “Significant Approvals” means the approval of an original or supplemental NADA or ANADA that required CVM’s review of safety or effectiveness data. This type of approval applies to new animal drug products, new chemical entities, or changes such as:

- additions to the indication section of the label of a new target species
- a new significant class of target animals
- a new disease indication
- a new route of administration
- a new tolerance or withdrawal period.

In FY 2015, FDA approved three generic copies of RIMADYL (carprofen), one an injectable solution and two oral tablets, providing veterinarians and dog owners with greater access to drugs for the relief of pain and inflammation associated with osteoarthritis and for the control of post-operative pain associated with soft tissue and orthopedic surgery.

[39] For more information on product approvals and designations visit http://www.fda.gov/NewsEvents/ProductsApprovals/.

In November 2015, FDA approved an application related to AquAdvantage Salmon, an Atlantic salmon that is genetically engineered (GE) to reach a growth point important to the aquaculture industry faster than its non-GE counterpart. FDA regulates GE animals under the new animal drug provisions of the Federal Food, Drug, and Cosmetic Act because the recombinant DNA (rDNA) construct introduced into the animal meets the definition of a drug. In this case, the rDNA construct introduces a trait that makes the AquAdvantage Salmon reach a key growth point faster. FDA found that AquAdvantage Salmon is safe for consumption, the rDNA construct is safe for the fish itself, and the salmon meets the sponsor's claim about faster growth. FDA also found that there are no material differences between this GE salmon and its non-GE counterpart that would require additional labeling.

Additionally, in December 2015, FDA approved Kanuma (sebelipase alfa) as the first treatment for humans with a rare disease known as lysosomal acid lipase (LAL) deficiency. Patients with LAL deficiency have no or little LAL enzyme activity resulting in a build-up of fats within the cells of various tissues that can lead to liver and cardiovascular disease and other complications. The approval was a collaboration between the Center for Veterinary Medicine (CVM) and the Center for Drug Evaluation and Research (CDER). CVM approved an application for a recombinant DNA (rDNA) construct in chickens that are genetically engineered (GE) to produce a recombinant form of human lysosomal acid lipase (rhLAL) protein in their egg whites. CDER approved the human therapeutic biologic (Kanuma), which is purified from those egg whites, based on its safety and efficacy in humans with LAL deficiency. FDA has worked closely with the sponsors to assure that these GE chickens, and their eggs, do not enter the food chain.

Selected Guidances Issued 2015

Below are guidances issued by the Animal Drugs and Feeds Program in 2015. These guidances help address various issues and can be further described in the attached links and narratives in this section.[40]

Date Issued	#	Title	Description
Oct 2015	FDA-2015-D-0235	Evaluating the Effectiveness of New Animal Drugs for the Reduction of Pathogenic Shiga Toxin-Producing *E. coli* in Cattle	Final - Recommendations on study design and criteria to evaluate effectiveness of new animal drugs to reduce pathogenic Shiga toxin producing Escherichia coli in cattle
Sep 2015	FDA-2014-D-1177	Electronic Exchange of Documents: File Format Recommendations	Final - Recommendations on global harmonization of the specifications for the electronic file format of documents between industry and regulatory authorities.

[40] For more information on guidance please visit http://www.fda.gov/RegulatoryInformation/Guidances/.

Date Issued	#	Title	Description
Jun 2015	FDA-2014-D-0634	Cell-based Products for Animal Use	Final - To clarify FDA's jurisdiction over cell-based products meeting the definition of a new animal drug and how existing regulations apply to cell-based products
Mar 2015	FDA-2015-D-0839	Target Animal Safety Data Presentation and Statistical Analysis	Recommendations on presentation and statistical analyses of target animal safety data submitted as part of a study report supporting a new animal drug approval

In October 2015, FDA issued final Guidance for Industry #229 "Evaluating the Effectiveness of New Animal Drugs for the Reduction of Pathogenic Shiga Toxin-Producing *E. coli* in Cattle" providing recommendations to industry relating to study design and describes criteria that CVM has determined are the most appropriate for evaluating the effectiveness of new animal drugs intended to reduce pathogenic Shiga toxin-producing *E. coli* (STEC) in cattle.

CVM will evaluate study designs to support indications for the reduction in the prevalence or quantity of pathogenic STEC in live animal feces, taken several times during the animals' lives throughout the study, which contaminate beef carcasses primarily during the removal of an animal's hide.

On June 11, 2015, FDA issued final Guidance for Industry #218 "Cell-Based Products for Animal Use" describing FDA's current thinking on cell-based products for animal use that meet the definition of a new animal drug. The guidance is directed at facilities and individuals manufacturing and marketing such products for animal use.

A cell-based product – including an animal stem cell-based product – that is intended to diagnose, cure, mitigate, treat, or prevent disease in animals or is intended to affect the structure or function of the animal generally meets the definition of a new animal drug. Cell-based products that meet the definition of a new animal drug are subject to the same statutory and regulatory requirements as other new animal drugs and require an approved or conditionally approved NADA or index listing to be legally marketed.

Animal Drug Inspections

FDA's field force conducts preapproval inspections to support the review of premarket applications for pioneer and generic animal drugs. In addition to aiding the preapproval process, bioresearch monitoring (BIMO) inspections of study facilities, clinical investigators, or sponsors, or contract research organizations are conducted to help assure the integrity of scientific testing and the reliability of test data submitted to FDA.

Once animal drug products are available on the market, the field continues oversight by inspecting manufacturing establishments to determine their ability to manufacture the product to the specifications stated in their application and to ensure manufactured products are free from contaminants.

Also, FDA performs inspections of non-clinical laboratories engaged in the collection of data to determine whether Good Laboratory Practices have been followed. Accurate data is essential to

the review and approval of new animal drugs and helps to ensure that the rights and welfare of animals are protected.

Minor Use Minor Species

FDA reviews conditional drug approvals, designation requests, and index requests to increase the number of safe and effective new animal drug products available for minor animal species and uncommon diseases in major animal species. Conditional approval allows animal drugs for minor use or minor species for infrequent conditions or in a limited population. The drug company must only show the drug to have a "reasonable expectation of effectiveness" without proving that it meets the "substantial evidence" standard of effectiveness for full approval.

Sponsors of "designated" new animal drugs are eligible to apply for grants to support safety and effectiveness testing. FDA administers a grant program to support the development of these new drugs. As of December 10, 2015, FDA granted 134 drug designations. In September 2015, FDA added Chlorambucil, an oral drug for the treatment of chronic lymphocytic leukemia in dogs, to the designation list.

In some cases, a minor species drug is intended for use in species that are too rare or too varied to be the subject of adequate and well-controlled studies in support of a drug approval and therefore cannot reasonably go through the standard drug approval process. In such cases, FDA may add the drug to the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (the Index). As of December 10, 2015, FDA has a total of eleven animal drugs on the Index.

International Activities

The Animal Drugs and Feeds Program engages in numerous international partnerships that promote and protect animals, as well as the humans who are exposed to them, and develop harmonized product standards and conformity assessment procedures, which help regulators ensure that health, safety or environmental conditions are met. FDA partners with the European Food Safety Authority (EFSA) on the Animal Feed Cluster, which allows feed safety experts from both FDA and EFSA to discuss issues of joint interest such as reviews of safety assessments of various animal feed ingredients.

FDA is also a major participant in the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). In FY 2015, FDA continued serving on the VICH Steering Committee and chaired a workgroup to finish developing a strategy for international training directed to developing countries.

The Animal Drugs and Feeds Program has a strong partnership with Health Canada through the U.S.- Canada Regulatory Cooperation Council (RCC), a council that works to reduce unnecessary regulatory differences. The Veterinary Drug Initiative (VDI), a part of the RCC that enhances the premarket evaluation of veterinary drugs, encourages the U.S. and Canada to seek greater alignment in regulatory approaches to:

- remove duplicative requirements
- reduce costs
- provide timely access to animal drug products.

The cornerstone of the RCC action plan to advance regulatory cooperation was the inaugural simultaneous review by regulators in FDA and Health Canada's Veterinary Drug Directorate

(VDD) of Elanco's veterinary drug product, Comfortis. Since the approval of Comfortis, continued and steady progress has been achieved by both the U.S. and Canada.

Moreover, with the onset of the FSMA, deliberative efforts were made to expand the class of medicines to include both food and non-food animals. The Animal Drugs and Feeds Program participated in many sponsor meetings with RCC on products under simultaneous review, continuing to promote the concurrent availability of drugs and expanding applications under joint review by 25%.

In October 2015, the RCC conducted a successful stakeholder meeting addressing international stakeholder concerns; completed the Regulatory Partnership Statement[41]; and collaborated with VDD to draft the Joint Forward Plan[42], which was distributed to the public in June 2015.

In FY 2015, import field investigators performed more than 6,353 field and label examinations on entry lines of animal drugs and feeds. These activities were performed to identify violations, such as verifying the product matches the information transmitted electronically and the product labeling meets applicable compliance requirements.

Enhance Oversight

The Animal Drugs and Feeds Program protects human and animal health by ensuring that animal drugs and feeds including medicated feed are safe and effective and that food from treated animals is safe to eat. To accomplish this goal, the Program provides critical oversight of production, manufacturing, and the global supply chain for regulated products. The Program also provides surveillance of postmarket product use and assures the safety of FDA regulated products. Within this goal area, the following FDA Strategic Priorities are addressed:

- Safety
- Quality, and
- Regulatory Science.

In 2015, the FSMA Preventive Control (PC) Training Workgroups began developing current good manufacturing practices and the PC Animal Food Regulator training curriculum, in coordination with the Division of Human Resource Development. These accomplishments represent significant collaborate efforts among experts from CVM, CFSAN, ORA, and state regulatory partners. Courses will begin during FY 2016.

Selected Rules Published 2015

Below are rules published by the Animal Drugs and Feeds Program in 2015. These rules help address various issues and are further described in the attached links and narratives in this section.[43]

[41] The RCC Regulatory Partnership Statement can be found at: http://www.trade.gov/rcc/documents/a-rps-hc-fda-rps.pdf
[42] The RCC Joint Forward Plan can be found at: https://www.whitehouse.gov/sites/default/files/omb/oira/irc/us-canada-rcc-joint-forward-plan.pdf
[43] For more information on FDA rules please visit http://www.fda.gov/RegulatoryInformation/RulesRegulations/default.htm.

Date Issued	#	Title	Purpose or Benefit
Sep 2015	FDA-2011-N-0922	Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (final rule)	Preventive Controls for Animal Food establish current good manufacturing practices for animal food requiring certain facilities establish and implement hazard analysis and risk-based preventive controls
Jun 2015	FDA-2010-N-0155	Veterinary Feed Directive (final rule)	Amending regulations regarding distribution and use of veterinary feed directive (VFD) drugs to improve efficiency of the VFD program while protecting human and animal health
May 2015	FDA-2012-N-0447	Collect Antimicrobial Sales and Distribution Data by Animal Species (proposed rule)	Proposing administrative procedures for animal drug sponsors who report under ADUFA section 105, including an additional requirement to report species-specific estimates of product sales

Preventive Controls for Animal Food

The Animal Drugs and Feeds Program published the FSMA final rule on "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals" in September 2015. Under this rule, facilities that manufacture, process, pack, or hold food for animals, including pet food, would be required to adhere to current good manufacturing practices and implement hazard analysis and risk-based preventive controls.

This rule is one of FDA's foundational rules to implement the modern prevention-focused food safety mandate granted to FDA under FSMA. The final rule is practical, flexible, and effective for industry while still advancing FDA's food safety goals and including requirements from the public input received during the comment period for preventive controls proposals.

Safety Standards

The Animal Drugs and Feeds Program evaluates industry compliance with safety standards throughout the production and handling stages of the global food - including pet food - and feed supply chain. Under FSMA, FDA received the authority to suspend a facility's registration if FDA determines that food and feed manufactured, processed, packed, received, or held by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals.

Before the passage of FSMA, FDA was able to detain a food product only with credible evidence that the product presented a threat of serious adverse health consequences or death to humans or animals. Training grants have been awarded to state and local food safety partners to ensure consistent implementation and application of the national integrated food safety system and FSMA training requirements related to setting standards and administering training and education programs to state, local, territorial, and tribal food safety officials.

For example, a course in animal production from the medicated feed and food safety perspective was created to address proper use of medicated feeds and avoidance of cross contamination in feed mills. Also, several manuals were developed for the training and education programs regarding production animal management and nutrition for beef and dairy cattle and swine.

In March 2015, FDA issued draft Guidance for Industry #203 "Ensuring Safety of Animal Feed Maintained and Fed On-Farm" to help animal producers ensure the safety of animal feed that is used on-farm. The draft guidance outlines steps animal producers can take to identify and

prevent feed contaminants that are sometimes present in the farm production environment and that may jeopardize the health of farm animals and the safety of human food derived from the animals. The draft guidance accepted public comment through June 3, 2015 and FDA is currently reviewing the submissions.

Intentional Adulteration

The Animal Drugs and Feeds Program played a key role in drafting and publishing the proposed FSMA rule "Forced Mitigation Strategies to Protect Food Against Intentional Adulteration." This rule helps address this important issue and protects the public from potentially catastrophic results including illness and death. FDA anticipates publishing the final rule in FY 2016.

Antimicrobial Resistance

As part of its overall responsibility for ensuring the safety of animal drugs, the Animal Drugs and Feeds Program continues to address public health safety concerns associated with antimicrobial drug use in animals and the related development of antimicrobial resistant bacteria. FDA is a major partner in the White House's National Strategy and Action Plan for Combating Antibiotic-Resistant Bacteria (CARB).

FDA released final Guidance for Industry (GFI) #213 on removing production claims for medically important antimicrobials, requesting affected sponsors to notify FDA in writing within three months of their intent to engage with FDA as defined in GFI #213. All 26 affected sponsors, holding 283 affected applications, confirmed in writing their intent to engage with FDA and have given consent to make their names public. While GFI #213 specified a three-year timeframe - until December 2016 - for drug sponsors to complete the recommended changes to their antimicrobial products, some sponsors have already begun to implement them. FDA issued a biannual progress report on judicious use of antimicrobials in food-producing animals in August 2015[44] to update the public on current and planned activities.

FDA's data on antibiotic use in food-producing animals was used at a joint public meeting on September 30, 2015 with U.S. Department of Agriculture (USDA) and the Centers for Disease Control and Prevention (CDC) in order to measure FDA's judicious use strategy as defined in GFI #213. The data collection plan is intended to provide the data needed to assess the rate of adoption of changes defined in GFI #213, help gauge the success of antibiotic stewardship efforts and guide their continued evolution and optimization, and assess associations between antimicrobial use practices and resistance trends over time.

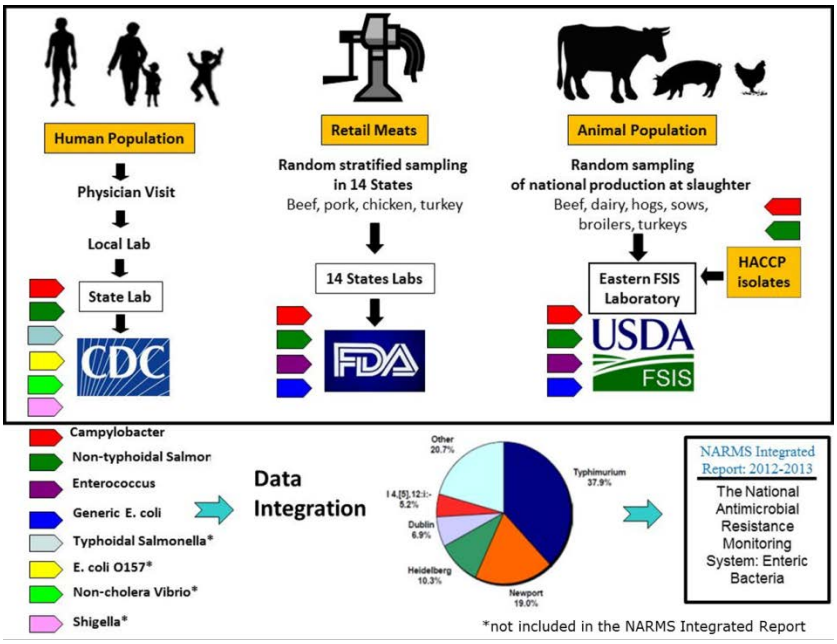
FDA published the Veterinary Feed Directive (VFD) final rule in June 2015,[45] an important piece of the overall strategy to promote the judicious use of antimicrobials in food-producing animals. This strategy will bring the use of these drugs under veterinary supervision so that they are used only when necessary for assuring animal health. The VFD final rule defines the process for authorizing use of VFD drugs - animal drugs intended for use in or on animal feed that require the supervision of a licensed veterinarian - and provides veterinarians in all states with a framework for authorizing the use of medically important antimicrobials in feed when needed for specific animal health purposes.

In September 2015, FDA issued revised Guidance for Industry #120, "Veterinary Feed Directive (VFD) Regulation Questions and Answers", which clarified how a veterinarian can authorize or

[44] The judicious use biannual progress report can be found at: http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm459365.htm
[45] The veterinary feed directive final rule can be found at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm448446.htm

limit the use of a VFD drug when used in combination with over-the-counter drugs and also included a question and answer about VFD authorization for pioneer and generic drugs.

FDA revised the annual summary of the amount of antimicrobials sold or distributed for use in food-producing animals reported under Section 105 of the Animal Drug User Fee Act to include additional data tables. The added data tables provide more detailed information and improve transparency. In December 2015, FDA published its sixth annual report under Section 105 for 2014 data, which also includes sales and distribution data for 2013 through 2014. 46 In May 2015, FDA released a proposed rule to collect antimicrobial sales and distribution information by animal species in order to obtain estimates of sales by major food-producing species (cattle, swine, chickens, and turkeys). The additional data would improve understanding about how antimicrobials are sold or distributed for use in major food-producing species and help FDA further target its efforts to ensure judicious use of medically important antimicrobials.



National Antimicrobial Resistance Monitoring System (NARMS)

The Animal Drugs and Feeds Program monitors antimicrobial resistance among enteric (intestinal) bacteria via NARMS. Because NARMS data has played key roles in various regulatory activities, the Animal Drugs and Feeds Program must continue to re-evaluate its sampling approach to assure that the data being generated can withstand scrutiny from both a scientific and regulatory perspective. NARMS implemented a new sampling design within the collaborative surveillance framework that is more statistically representative, scientifically sound, and better supports FDA regulatory activities.

In April 2015, FDA published the NARMS 2012 Retail Meat Annual Report47 and the 2013 NARMS Retail Meat Interim Report.48 These reports measure antimicrobial resistance in certain bacteria isolated from raw meat and poultry collected through NARMS. In August 2015, FDA published online, for the first time, raw NARMS data collected over the past 18 years,

[46] The 2013 Sales and Distribution Data Report can be found at: http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM440584.pdf
[47] The NARMS 2012 Retail Meat Report can be found at: http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/UCM442212.pdf
[48] The NARMS 2013 Retail Meat Interim Report can be found at: http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/UCM442215.pdf

enabling the scientific community to contribute ideas and expertise about combating antibiotic-resistant bacteria. FDA also published the 2012-2013 NARMS Integrated Annual Report for the first time in August 2015, replacing the NARMS Executive Summary Report and highlighting antimicrobial resistance patterns in bacteria isolated from humans, retail meats, and animals at slaughter. Through an interagency agreement with FDA, the USDA's Food Safety Inspection Service (FSIS) implemented a greatly improved food animal sampling scheme for federally inspected slaughter houses that is designed to generate a more representative data set for the purposes of NARMS. FDA also worked with the USDA's Agriculture Research Service (ARS) to develop a new consortium of ARS research centers and select universities to collect and test on-farm samples for the first time. In addition, the Animal Drugs and Feeds Program is implementing whole genome sequencing technology and supportive bioinformatics to provide definitive information on the nature, origin and spread of resistant bacteria in foods.

Research Studies related to Antibiotic Resistance and Salmonella

FDA provides scientific research solutions that ensure the safety of human and animal health. In FY 2014 and FY 2015, FDA completed several additional research studies to assess the safety of distillers' grains, which are a by-product of ethanol production and are frequently used in animal feed. Methods to measure antibiotic concentrations in distillers grains, along with techniques to assess the effect of these drugs on bacteria, will allow FDA to determine if antibiotic residues remaining from the fermentation process are present at concentrations that can lead to the development of antibiotic resistance.

In addition, the high capacity and low costs of rapid DNA sequencing technology and advances in analysis software have made it affordable and much easier to routinely determine and interpret the complete DNA sequence obtained from microorganisms. Advancements in whole genome sequencing (WGS) represent a revolution in infectious disease diagnosis and surveillance because this technique provides a complete picture of acquired traits that are present in a microorganism, such as known virulence and antibiotic resistance traits.

Further, FDA is using a technique developed at the University of Georgia to switch from traditional, labor intensive, expensive, Salmonella serotyping to rapidly identifying the most commonly occurring 200 serotypes of Salmonella from the WGS data obtained from cultured bacteria. During FY 2014 and the first half of FY 2015, FDA sequenced over 3,000 bacteria species. A subset of Salmonella species isolated in 2011-2012 from retail meats and human patients have been sequenced and the data used to evaluate the correlation between the presence of antimicrobial resistance genes and antimicrobial resistance traits that can be measured using standardized clinical microbiological methods.

Selected Guidances Issued

Below are guidances issued by the Animal Drugs and Feeds Program in 2015. These guidances help address various issues and can be further described in the attached links and narratives in this section.[49]

[49] For more information on guidance please visit http://www.fda.gov/RegulatoryInformation/Guidances/.

Date Issued	#	Title	Description
Sep 2015	FDA-2010-N-0155	Veterinary Feed Directive (VFD) Regulation Questions and Answers	Final - revised the VFD regulations in 21 CFR 558.6 and introduced clarifying changes to the definitions in 21 CFR 558.3
Sep 2015	FDA-2008-D-0165	Blue Bird Medicated Feed Labels	Final - Information about how to label medication that will be diluted with other ingredients before being given to an animal
Jun 2015	FDA-2013-D-0928	Recommendations for Preparation and Submission of Animal Food Additive Petitions	Final - Describes information that FDA recommends for inclusion in food additive petitions (FAPs) for food additives used in animal food

Compounded and Unapproved Animal Drug Products

In addition to focusing on providing timely premarket review of new animal drugs, FDA is leading the effort to aggressively combat the growing problem of compounded and unapproved animal drug products being marketed and sold.

In FY 2015, FDA expanded its Animal and Veterinary compliance and enforcement webpage to include a page dedicated to: Inspections, Recalls, and Other Actions with Respect to Firms that Engage in Animal Drug Compounding.[50] FDA has initiated the regulatory framework that will bring substandard and illegally marketed drugs into the regulatory fold, and significantly reduce the risk of harm to human and animal health.

In May 2015, FDA released a draft Guidance for Industry #230 "Compounding Animal Drugs from Bulk Substances" for public comment. Current law does not permit compounding of animal drugs from bulk drug substances, but FDA recognizes that there are limited circumstances when an animal drug compounded from bulk drug substances may be an appropriate treatment option. FDA's GFI #230 outlines specific conditions under which FDA generally does not intend to take action against state-licensed pharmacies, veterinarians, and facilities registered as outsourcing facilities when drugs are compounded for animals from bulk drug substances. FDA has received comments on the draft guidance and is taking them into consideration during preparation of final guidance.

Milk Residue Survey

In March 2015, FDA released results from its milk sampling survey,[51] involving the testing of nearly 2,000 dairy farms for drug residues in milk. More than 99 percent of the samples were free of drug residues of concern, underscoring the safety of the U. S. milk supply. These findings provide evidence that the nation's milk safety system is effective in helping to prevent

[50] The webpage can be accessed at: http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/UnapprovedAnimalDrugs/ucm417562.htm
[51] The Milk Sampling Survey can be found at: http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/UCM435759.pdf

drug residues of concern in milk, even in those limited instances when medications are needed to maintain the health of dairy cattle.

Adverse Drug Review
The Animal Drugs and Feeds Program receives approximately 91,500 Adverse Drug Experience (ADE) reports annually and is the largest animal drug ADE database in the world, with over 620,000 cases. Over the past few years, the Animal Drugs and Feeds Program eliminated the paper submission backlog and made substantial improvements to the electronic portal, allowing for almost 98 percent of reports to be submitted electronically. This database provides the ability to analyze data for use in both premarket and postmarket animal drug evaluation. The efforts to increase the functionality, utilization, and analysis of this pharmacovigilance database have improved animal drug safety.

In December 2014, FDA issued final guidance #214 "*Pharmacovigilance of Veterinary Medicinal Products Electronic Standards for Transfer of Data*." The guidance provides recommendations to help animal drug manufacturers create a single electronic adverse event message that can be used by multiple regulatory authorities. The need for drug manufacturers and regulatory bodies to exchange and send information on a worldwide scope is essential to monitoring potential health risks and ensuring drug safety. GFI #214 supports the FDA's work with the VICH, an international program aimed at harmonizing technical requirements for veterinary product regulation. The guidance is the FDA's version of VICH Guideline (GL) 35 and provides a standardized format to allow for electronic exchange of information between stakeholders.

PREDICT
Since FDA's completion of the full national rollout of Entry Review and the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) to all 16 import districts, FDA has improved the rules that support a risk-based approach to import screening. PREDICT allows FDA to make efficient and accurate admissibility decisions and allows FDA field office staff to target the examination of higher risk imported products. Thus, PREDICT enhances the prevention for entry of adulterated, misbranded, or otherwise violative goods and expedites the entry of non-violative goods.

Vet-LIRN
The Animal Drugs and Feeds Program offers grant funds to bolster efforts to validate testing methods as part of the Veterinary Laboratory Investigation and Response Network (Vet-LIRN). Vet-LIRN is a network of state and university laboratories that receive funding from FDA to increase testing capabilities and assist FDA with investigations into potential problems with animal feeds, including pet foods, and animal drugs.

FDA has been actively investigating the cause of illnesses reported in pets which may be associated with the consumption of pet jerky treat products In FY 2015, FDA continued to work on pet illnesses related to jerky-type pet treats. Hundreds of samples were collected and analyzed, but no disease-causing contaminants were identified. FDA continues to perform inspections and collect samples both domestically and internationally, conduct tests on pet jerky treat products, and follow up on consumer complaints.

Enforcement Strategies
The Animal Drugs and Feeds Program protects human and animal health by developing and implementing appropriate enforcement strategies, such as inspections, to ensure the compliance

of marketed products. Through the establishment of a High Risk Working Group (HRWG) in FY 2012, FDA identified and addressed policy and process changes required for the implementation of a high risk (HR) inspection program for food and feeds. These HR inspections are targeted on a three year cycle. This information, along with data included in the cycle beginning in FY 2014, assisted with more targeted inspections in FY 2015.

When firms violate the FDA requirements of the FD&C Act, FDA takes regulatory action and assists the firms in reaching full compliance while ensuring that products of concern do not reach U.S. consumers. When firms refuse to comply with FDA regulations, FDA takes further enforcement action to ensure unsafe products do not reach U.S. consumers and requests the firm's potential shut down of operations. FDA issued 118 warning letters in FY 2015 as a result of field recommendations for regulatory action based on violative inspection findings. FDA also monitors recalls of veterinary products and feed and ensures the effectiveness of the firm's recall to remove the defective product from commerce. In FY 2015, FDA classified 9 Class I (most serious), 18 Class II, and 11 Class III recalls of regulated animal products.

Food Additive Petition

FDA reviews and approves food additive petitions, establishes standards for feed contaminants, and directs FDA's medicated feed and pet food programs. FDA monitors the safety and usefulness of food additives to ensure the health and safety of livestock, poultry, fish, and pets. FDA works with stakeholders to promote responsibility through the identification, development, and implementation of new regulations and guidance to further support the production of safe food for animals.

FDA is committed to moving to an all-electronic work environment to support CVM's business processes. CVM is leveraging its pre-market Electronic Document Submission and Review (EDSR) system for pre-market Food Additive Petitions and Investigational Food Additive files.

Nanotechnology

The Animal Drugs and Feeds Program is an integral partner in FDA's regulation of nanotechnology products. Nanotechnology is an emerging technology that allows scientists to create, explore, and manipulate materials on a scale measured in nanometers – billionths of a meter or particles so small that they cannot be seen with a regular microscope. Such materials can have chemical, physical, and biological properties that differ from those of their larger counterparts.

In August 2015, FDA issued final Guidance for Industry #220 "Use of Nanomaterials in Food for Animal" addressing the use of nanotechnology in food for animals. This guidance addresses the legal framework for ingredients in food for animals and includes recommendations for submitting a Food Additive Petition (FAP) for a nanomaterial animal food ingredient.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2013 Actual	$147,774,000	$125,841,000	$21,933,000
FY 2014 Actual	$164,313,000	$141,566,000	$22,747,000
FY 2015 Actual	$175,024,000	$147,564,000	$27,460,000
FY 2016 Enacted	$188,632,000	$158,652,000	$29,980,000
FY 2017 President's Budget	$196,736,000	$161,852,000	$34,884,000

BUDGET REQUEST

The FY 2017 Budget Request is $196,736,000, of which $161,852,000 is budget authority and $34,884,000 is user fees. The budget authority increases by $3,200,000 compared to the FY 2016 Enacted level and user fees increase by $4,904,000. The FY 2017 Budget allows the Animal Drugs and Feed Program to improve and safeguard access and enhance oversight of animal drugs, devices, and feed.

The FY 2017 Budget allows the Animal Drugs and Feeds Program to meet its mission to protect human and animal health by increasing the availability and diversity of safe and effective products that relieve animal pain and suffering, sustain their health, and do not compromise human health. The activities of greatest public health importance are prioritized to maintain support for FDA core mission goals, to enhance oversight of FDA-regulated products and improve access to FDA-regulated products that benefit human and animal health. These activities include:

- monitoring the safety of animal devices and the safety and effectiveness of animal drugs on the market
- approval of marketed animal drug products
- approving feed additives
- ensuring food for animals is safe.

The Animal Drugs and Feeds Program will approve safe and effective products for animals in the pre-approval process, and provide grants to support minor use and minor species (MUMS) drug approval or conditional approval as part of the MUMS Animal Health Act of 2004. The requested increase enables the Animal Drugs and Feeds Program to meet statutory requirements for user fee collections under the Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA). These user fees supplement the appropriated portion of the new animal drug review program while enabling the Animal Drugs and Feeds Program to retain user fee supported staff. With these user fees, the Program will continue to improve the quality and timeliness of the pioneer animal drug and generic new animal drug review processes. FDA will also conduct preapproval inspections in support of the animal drug review process.

In addition, the Animal Drugs and Feeds Program will continue important postmarket efforts to protect human and animal health. These efforts include reviewing Adverse Drug Experience reports which provide the ability to data mine, an important tool to analyze data in real time in large complex databases with the goal of discovering unexpected occurrences of adverse event signals, for use in both pre and postmarket approval animal drug work. The program will

investigate pet illnesses and will enforce compliance actions in support of ensuring safe and effective products. The Animal Drugs and Feeds Program will continue efforts to reduce the availability of illegally marketed unapproved animal drugs, including compounded animal drugs.

The Food Safety Modernization Act (FSMA) will be implemented by creating a modern, prevention-focused, science- and risk-based food and feed safety system. In addition, field inspections, investigations, and enforcement activities will be conducted to ensure the adherence of laws to protect and advance human and animal health.

The Animal Drugs and Feeds Program will continue to address the source and magnitude of antimicrobial resistance with the release of final Guidance for Industry (GFI) #213 on removing production claims for medically important antimicrobials and the final rule revising the Veterinary Feed Directive (VFD), which brings remaining therapeutic claims for these products under veterinary oversight. This work supports the Presidential initiative Combating Antibiotic Resistant Bacteria (CARB) to improve the safety and quality of a significant portion of the medical products available in the U. S. In addition, the National Antimicrobial Resistance Monitoring System (NARMS) will be utilized to monitor antimicrobial resistance among enteric (intestinal) bacteria.

These activities in the FY 2017 Budget Request support mission critical program activities and Presidential, HHS, and FDA human and animal health priorities.

BUDGET AUTHORITY

Medical Product Safety and Availability: $36.5 million (+$3.2 million)

Combating Antibiotic Resistant Bacteria: +$1.0 million
Center: +$1.0 million

Antibiotics are important in combating infectious diseases in humans and animals. Antibiotic resistance, the ability of bacteria to evade or resist antibiotics, is a growing public health threat. *The National Action Plan for Combating Antibiotic-Resistant Bacteria*, issued by the White House in March 2015, is intended to guide the activities of the U.S. Government as well as guide action by public health, healthcare, and veterinary partners in a common effort to address urgent and serious drug-resistant threats. This effort supports the continued work to address public health safety concerns associated with antimicrobial drug use in animals and to better protect antibiotic effectiveness for both human and animal populations.

With increased funding, FDA will work in collaboration with USDA to support efforts to monitor antimicrobial drug use in food-producing animals through the periodic collection of nationally representative on-farm data on antimicrobial-use practices and resistance. FDA will also coordinate with USDA to develop a U.S. Government annual assessment report, including identification of key outcome measures.

Supporting Animal Drug Review: +$2.2 million
Center: +$2.2 million

The Animal Drug Review Program for pioneer animal drugs is an important FDA program, supporting both human and animal health. The program strives to meet performance goals for statutory review timeframes, which has allowed pioneer animal drugs to advance to market faster and ensure the availability of animal drug products that are safe and effective for animals as well as for the public with respect to animals intended for food consumption. The increased funding

requested will enable FDA to continue to meet premarket animal drug review requirements by having the necessary review staff to carry out these activities.

USER FEES

Current Law User Fees: +$0.73 million

Center: +$0.71 million / Field: +$0.02 million

The Animal Drugs and Feeds Program request includes an increase of $0.73 million for current law user fees, which will allow FDA to fulfill its mission of protecting human and animal health and accelerating innovation in the industry.

Proposed User Fees: +$4.2 million

Proposed Food Import Fee: +$1.5 million
Center: +$1.5 million

One of the most transformative aspects of FSMA is the new set of import authorities and mandate to FDA to create a modern, prevention-oriented import oversight system that can meet the challenges of the global food system, with its complex supply chains and increasing volume of imports. FSMA provisions create new obligations for food and feed importers to have a risk-based foreign supplier verification program in place to ensure that their suppliers produce human food and animal food in compliance with processes and procedures that offer the same level of protection as FDA's preventive controls requirements and produce safety standards, and is not otherwise adulterated or misbranded with respect to food allergen labeling.

The Animal Drugs and Feeds Program will conduct the following activities with this user fee:

- Establish new systems to prevent the import of unsafe animal food
- Develop program to support voluntary qualified importer program and third party accreditation rule
- Develop the International Comparability Assessment Tool (ICAT) for animal feed to evaluate the feed safety systems of foreign countries.

Proposed Food Facility Registration and Inspection Fee: +$2.7 million
Center: $1.6 million / Field: +$1.1 million

Revenue from the proposed Food Facility and Registration Fee would enable FDA to fully modernize the FDA inspection program through the further development and implementation of new inspection models and tools. This includes training of FDA inspectors and compliance staff and their state counterparts in the new models and information technology to improve targeting and risk-based efficiency of inspection.

In addition, this user fee will allow FDA to implement preventive controls in animal food processing facilities through the support, implementation, and enforcement of preventive controls in animal food processing facilities. FDA will be able to communicate and share information regarding food facility inventory with our state regulatory partners which is a necessary component to advance FDA's workplanning process with state agencies to ensure FDA meets the FSMA inspection frequency mandate. FDA will be able to advance development of new inspection tools, such as the Observation and Corrective Action Reporting (OCAR) system. FDA will continue to assist the states in the implementation of the Animal Feed

Regulatory Program Standards (AFRPS) and in their development and implementation of operational plans for animal food preventive controls.

PERFORMANCE

The Animal Drugs and Feeds Program's performance measures focus on premarket animal drug application review, high risk inspections including BSE, warning letter review, and lab coordination for detection and response, as detailed in the following table.

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2016 Target	FY 2017 Target	FY 2017 +/- FY 2016
243201: Complete review and action on original New Animal Drug Applications (NADAs) and reactivations of such applications received during the fiscal year. *(Output)*	FY 2014: 98.3% w/in 180 days Target: 90% w/in 180 days (Target Exceeded)	90% w/in 180 days	90% w/in 180 days	maintain
243202: Complete review and action on Non-administrative original Abbreviated New Animal Drug Applications (ANADAs) and reactivations of such applications received during the fiscal year. *(Output)*	FY 2014: 100% w/in 270 days Target: 90% w/in 270 days (Target Exceeded)	90% w/in 270 days	90% w/in 270 days	maintain
244202: Number of domestic and foreign high-risk animal drug and feed inspections. *(Output)*	FY 2015: 303 Target: 250 (Target Exceeded)	250	250	maintain
244203: Cover 100% of targeted prohibited material BSE actual inventory. *(Output)*	FY 2015: 100% Target: 100% (Target Met)	100%	100%	maintain
244204: Complete review and action on warning letters received within 15 working days to better safeguard our food supply by alerting firms to identified deviations in order to become compliant. *(Output)*	FY 2015: 71% w/in 15 working days Target: 60% w/in 15 working days (Target Exceeded)	50% w/in 15 working days	50% w/in 15 working days	maintain

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2016 Target	FY 2017 Target	FY 2017 +/- FY 2016
244301: Total number of collaborating laboratories that will provide coordinated response to high priority chemical and microbial animal feed including pet food contamination events. *(Outcome)*	FY 2015: 36 Target: 26 (Target Exceeded)	36	36	maintain

The following selected items highlight notable results and trends detailed in the performance table.

New Animal Drug Application Review
CVM exceeded ADUFA performance goals, except for one submission, in ten out of eleven years. Additionally, CVM exceeded AGDUFA performance goals, except for one submission, in five out of six years. CVM completed review and action on 98.3 percent of original NADAs as well as other ADUFA sentinel submissions within the timeframes specified during FY 2014. CVM also completed review and action on 100 percent of original ANADAs as well as other AGDUFA sentinel submissions within the time frames specified in FY 2014.

Warning Letters
FDA monitors marketed animal drugs, food additives, and veterinary devices to assure their safety and effectiveness. Warning Letters are issued when medicated feed manufacturers are found to be in violation of acceptable manufacturing processes. Violators are encouraged to take prompt action to correct violations; otherwise FDA may take additional regulatory action without further notice, including seizure of products and/or injunction. The resources required to review each warning letter may vary greatly, depending on the subject matter and evidence, and some warning letters require additional input and clearance and time to process. Nevertheless, CVM reviewed and acted on 7% more warning letters within 15 days than the previous fiscal year and exceeded the target by 11%. The FY 2016 and FY 2017 targets will decrease to 50% due to the additional effort needed to implement important provisions of the Food Safety Modernization Act (FSMA) and the newly rewritten Veterinary Feed Directive (VFD).

Conduct Highest Risk BSE Inspections
Since establishing this performance goal, the aim has been to inspect 100% of the licensed and unlicensed feed mills, renderers and protein blenders that make or use prohibited materials in their feed manufacturing operation. However, the total inventory of these firms has been dropping for several years as firms are either combined through mergers or just stop using prohibited materials. ORA will continue to cover 100% of the targeted prohibited BSE inventory, even though we estimate a reduction of 35% of the BSE inventory over the next few years.

PROGRAM ACTIVITY DATA

Animal Drugs & Feeds Program Activity Data (PAD)

CVM Workload and Outputs	FY 2015 Actual	FY 2016 Estimate	FY 2017 Estimate
New Animal Drug Applications (NADAs) [1]			
Received	12	18	20
Completed	10	16	18
Approved	8	13	16
Pending [2]	3	5	7
New Animal Drug Application Supplements [1, 3]			
Received	514	1,000	1,000
Completed	516	500	500
Approved	407	400	400
Pending [2]	116	616	1,116
Abbreviated New Animal Drug Applications (ANADAs) [1]			
Received	25	70	70
Completed	32	32	32
Approved	20	20	20
Pending [2]	10	48	86
Abbreviated New Animal Drug Application Supplements [1, 3]			
Received	227	500	500
Completed	225	225	225
Approved	166	160	160
Pending [2]	116	391	666
Investigational New Animal Drug (INAD) Files [4]			
Received	3,734	4,000	4,000
Completed	3,805	3,800	3,800
Pending [2]	335	535	735
Generic Investigational New Animal Drug (JINAD) Files [4]			
Received	354	750	750
Completed	358	450	450
Pending [2]	78	378	678
Food (Animal) Additive Petitions Completed	81	80	80
Investigational Food Additive Petitions Completed	120	130	130
Adverse Drug Event (ADE) [5]			
ADE Reports Received	91,592	90,000	90,000
Post-Approval ADE Data Reviews	135	100	100

[1]Includes originals applications and reactivations. If the application is not approvable, the sponsor may submit additional information until FDA is able to approve the application.

[2]Reflects submissions received during the fiscal year that still require review.

[3]A supplemental application is a sponsor request to change the conditions of the existing approval. Supplemental applications can be significant (such as a new species or indication), or routine (such as product manufacturing changes). The estimates do not include invited labeling change supplement applications because it is not possible to accurately project sponsor or CVM requests for this type of application.

[4]An INAD or JINAD file is established at the request of the sponsor to archive all sponsor submissions for a phased drug review including requests for interstate shipment of an unapproved drug for study, protocls, technical sections, data sets, meeting requests, memos of conference, and other information.

[5] This measure tracks the number of "Post-approval ADE data reviews" completed each fiscal year. A Post-approval ADE Data Review is a comprehensive report by product of multiple ADE reports (in some cases this could be hundreds or thousands of individual reports).

Field Animal Drugs & Feeds Program Activity Data (PAD)

Field Animal Drugs and Feeds Program Workload and Outputs	FY 2015 Actuals			FY 2016 Estimate			FY 2017 Estimate		
	Total	Animal Drugs	Feeds	Total	Animal Drugs	Feeds	Total	Animal Drugs	Feeds
FDA WORK									
DOMESTIC INSPECTIONS									
UNIQUE COUNT OF FDA DOMESTIC ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***1,565***	***226***	***1,356***	***1,565***	***299***	***1,524***	***1,565***	***299***	***1,524***
Pre-Approval /BIMO Inspections	39	39	0	79	79	0	79	79	0
Drug Process and New ADF Program Inspections	189	189	0	222	222	0	222	222	0
BSE Inspections	1,163	0	1,163	1,205	0	1,205	1,205	0	1,205
Feed Contaminant Inspections	24	0	24	25	0	25	25	0	25
Illegal Residue Program Inspections	424	0	424	473	0	473	473	0	473
Feed Manufacturing Program Inspections	178	0	178	141	0	141	141	0	141
Domestic Laboratory Samples Analyzed	1,650	4	1,646	2,458	26	2,432	2,458	26	2,432
FOREIGN INSPECTIONS									
UNIQUE COUNT OF FDA FOREIGN ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS [1]	***98***	***83***	***15***	***75***	***69***	***6***	***75***	***69***	***6***
Foreign Pre-Approval/Bioresearch Monitoring Program Inspections	35	35	0	45	45	0	45	45	0
Foreign Drug Processing and New ADF Program Inspections	70	70	0	33	33	0	33	33	0
Foreign Feed Inspections	8	0	8	7	0	7	7	0	7
BSE Inspections	10	0	10	0	0	0	0	0	0
TOTAL UNIQUE COUNT OF FDA ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***1,663***	***309***	***1,371***	***1,640***	***368***	***1,530***	***1,640***	***368***	***1,530***
IMPORTS									
Import Field Exams/Tests	7,311	1,708	5,603	3,600	185	3,415	3,600	185	3,415
Import Laboratory Samples Analyzed	931	1	930	750	2	748	750	2	748
Import Physical Exam Subtotal	**8,242**	**1,709**	**6,533**	**4,350**	**187**	**4,163**	**4,350**	**187**	**4,163**
Import Line Decisions	416,860			446,903			479,111		
Percent of Import Lines Physically Examined	1.98%			0.97%			0.91%		
STATE WORK									
UNIQUE COUNT OF STATE CONTRACT ANIMAL FEEDS ESTABLISHMENT INSPECTIONS	***4,426***	***0***	***4,426***	***5,045***	***0***	***5,045***	***5,045***	***0***	***5,045***
UNIQUE COUNT OF STATE PARTNERSHIPS ANIMAL FEEDS ESTABLISHMENT INSPECTIONS [2]	***6***	***0***	***6***	***0***	***0***	***0***	***0***	***0***	***0***
UNIQUE COUNT OF STATE COOPERATIVE AGREEMENT ANIMAL FEEDS ESTABLISHMENT INSPECTIONS [3]	***306***	***0***	***306***	***0***	***0***	***0***	***0***	***0***	***0***
State Contract Inspections: BSE	4,105	0	4,105	5,000	0	5,000	5,000	0	5,000
State Contract Inspections: Feed Manufacturers	741	0	741	320	0	320	320	0	320
State Contract Inspections: Illegal Tissue Residue	276	0	276	412	0	412	412	0	412
State Partnership Inspections: BSE and Other	6	0	6	0	0	0	0	0	0
State Cooperative Agreement BSE Inspections	306	0	306	0	0	0	0	0	0
State Contract Animal Drugs/Feeds Funding	$2,917,129	0	$2,917,129	$3,004,643	0	$3,004,643	$3,094,782	0	$3,094,782
BSE Cooperative Agreement Funding	$0	0	$0	$0	0	$0	$0	0	$0
State Contract Tissue Residue Funding	$469,072	0	$469,072	$483,144	0	$483,144	$497,638	0	$497,638
Total State Funding	**$3,386,201**	**$0**	**$3,386,201**	**$3,487,787**	**$0**	**$3,487,787**	**$3,592,420**	**$0**	**$3,592,420**
GRAND TOTAL ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***6,401***	***309***	***6,109***	***6,685***	***368***	***6,575***	***6,685***	***368***	***6,575***

[1] The FY 2015 actual unique count of foreign inspections includes 7 OIP inspections (7 for China).

[2] The State inspections that are funded by the FDA are now being obligated via formal contract funding vehicles and this number is expected to decrease in the future until there are no planned State Partnership inspections.

[3] The State cooperative agreement BSE inspections that are funded by the FDA are now being obligated via formal contract funding vehicles and this number along with the funding for these inspections are expected to decrease in the future until there are no planned State Cooperative Agreement BSE inspections.