ANIMAL DRUGS AND FEEDS

(Dollars in Thousands)	FY 2016 Final	FY 2016 Actuals	FY 2017 Annualized CR	FY 2018 President's Budget	FY 2018 President's Budget +/- FY 2017 CR
Animal Drugs and Feed	**188,615**	**188,042**	**190,540**	**183,280**	**-7,260**
Budget Authority	***158,635***	***158,629***	***158,333***	***107,606***	***-50,727***
User Fees	***29,980***	***29,413***	***32,207***	***75,674***	***43,467***
Center	122,508	122,848	124,497	121,749	-2,748
Budget Authority	94,005	94,001	93,826	49,117	-44,709
User Fees	28,503	28,847	30,671	72,632	41,961
Animal Drug (ADUFA)	*20,125*	*20,459*	20,879	*57,775*	*36,896*
Animal Generic Drug (AGDUFA)	*8,378*	*8,388*	9,792	*14,857*	*5,065*
Field	66,107	65,194	66,043	61,531	-4,512
Budget Authority	64,630	64,628	64,507	58,489	-6,018
User Fees	1,477	566	1,536	3,042	1,506
Animal Drug (ADUFA)	*411*	*378*	427	*1,665*	*1,238*
Animal Generic Drug (AGDUFA)	*259*	*188*	302	*570*	*268*
Food and Feed Recall	---	---	---	---	---
Food Reinspection	*807*	---	807	*807*	---
FTE	**925**	**925**	**948**	**920**	**-28**

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

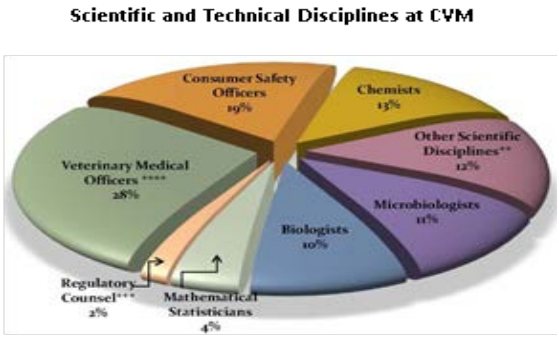
The Center for Veterinary Medicine (CVM) is a scientific and regulatory organization and one component under the Foods and Veterinary Medicine (FVM) Program that works to fulfill the U.S. Food and Drug Administration's (FDA) public health mission. The other component, the Foods Program, described in another section, is administered by the Center for Food Safety and Applied Nutrition (CFSAN). These two component programs collaborate with the Office of Regulatory Affairs (ORA), which performs field activities, including inspections, sample collections, and import exams. The Office of Foods and Veterinary Medicine provides leadership and strategic direction to the FVM Program.

The Animal Drugs and Feeds Program fosters human and animal health by evaluating animal products for safety and efficacy and by enforcing applicable provisions of the Federal Food, Drug, and Cosmetic Act and other legal authorities. These include animals from which human foods are derived, and pet (or companion) animals.

The Animal Drugs and Feeds Program reviews animal drug applications for safety and effectiveness, monitors animal drugs, animal foods, and devices on the market, reviews food additives for safety and utility, and conducts research that helps FDA ensure the safety of animal drugs, food for animals, and food products made from animals. The Animal Drugs and Feeds Program also helps to make more animal drugs legally available for minor species, such as fish, pet rodents, and birds, and for minor (infrequent and limited) uses in major species, such as cattle, turkeys, and dogs.

Congress recognized the unique challenges FDA faces in the area of food safety in the 21st Century and gave FDA a 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 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.

FDA's FVM Program Strategic Plan[31] provides a framework for implementing FSMA. The plan places a high priority on preventing foodborne illness of known and unknown origins. 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 for food safety, nutrition, animal health, and organizational excellence.



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 unapproved and compounded drugs,
- prevention of marketing of unsafe products, and
- compliance and enforcement actions to remove unsafe products from market.

Appropriations and user fee programs fund the regulatory process to ensure 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).

ADUFA and AGDUFA supplement the appropriated portion of the animal drug review processes. By supplementing funding for the animal drug review processes, ADUFA and AGDUFA support the quality and timeliness of new (pioneer) and generic animal drug reviews.

[31] The strategic plan can be found at: http://www.fda.gov/aboutfda/centersoffices/officeoffoods/ucm273269.htm.

The Export Certificate program helps international trade and promotes the export of U.S.-made products by assuring that exported products can be marketed in the U.S., or meet specific U.S. regulations.

The following selected accomplishments demonstrate the Animal Drugs and Feeds Program's delivery of its regulatory and public health responsibilities within current priorities.[32]

Improve and Safeguard Access

The Animal Drugs and Feeds Program regulates animal drugs and feeds. Premarket responsibilities include ensuring the effectiveness and efficiency of the product review process; 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
- Globalization.

Animal Drug Review

The Animal Drugs and Feeds Program increases the availability and variety of safe and effective products, including antimicrobials, to relieve animal pain and suffering and to support their health. The animal drug user fee acts require FDA to meet timeframes for review and action on 90 percent of new animal drug applications each fiscal year.

In FY 2016, FDA exceeded all animal drug review performance goals. FDA completed the review and action on 99.8 percent of original New Animal Drug Applications (NADAs) and other ADUFA sentinel submissions within timeframes specified by ADUFA. FDA also exceeded the animal drug review performance goals and completed the review and action on 100 percent of original Abbreviated New Animal Drugs Applications (ANADAs) for generic drugs, Reactivations (resubmissions), and other AGDUFA sentinel submissions within the timeframes for applications received and reviewed in FY 2016.

Selected Product Approvals in 2016

Below are the most recent Animal Drugs and Feeds Program significant product approvals during calendar year 2016. The term "Significant Approvals" means the approval of an original or supplemental NADA or ANADA that required FDA'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, and
- a new tolerance or withdrawal period.

This list does not represent any degree of importance or priority ranking of products.[33]

[32] Please visit https://www.fda.gov/AnimalVeterinary/default.htm for additional program information and detailed news items.
[33] For more information on product approvals and designations visit http://www.fda.gov/NewsEvents/ProductsApprovals/.

Date	Product Name	Purpose or Benefit
Sep 2016	Amoxicillin Trihydrate and Clavulanate Potassium Tablets	Indicated in the treatment of: **Dogs:** Skin and soft tissue infections and canine periodontal disease. **Cats:** Skin and soft tissue infections and urinary tract infections.
Jul 2016	BRAVECTO	For the treatment and prevention of flea infestations and the treatment and control of tick infestations for dogs.
Mar 2016	GALLIPRANT	For the control of pain and inflammation associated with osteoarthritis in dogs.
Mar 2016	Imrestor	For reduction in incidence of clinical mastitis in first 30 days of lactation in dairy cows and replacement dairy heifers that recently birthed a calf.
Jan 2016	Thyro-Tabs Canine	For replacement therapy for diminished thyroid function in dogs.

Genetic Engineering

In January 2017, FDA released *Draft Guidance for Industry #236, Regulation of Mosquito-Related Products*, which clarifies which mosquito-related products FDA regulates and which such products EPA regulates. FDA is accepting public comments through June 19, 2017. This draft guidance is consistent with the FDA's commitments outlined in the *National Strategy for Modernizing the Regulatory System for Biotechnology Products*, which sets forth a vision for ensuring that the federal regulatory system is equipped to assess efficiently the risks, if any, associated with future products of biotechnology. FDA is reviewing information in an Investigational New Animal Drug (INAD) file involving a genetically-engineered (GE) mosquito designed to reduce disease-transmitting mosquito populations. The *Aedes aegypti* species of mosquito is common in southern U.S. States and known to transmit potentially debilitating human viral diseases, including Zika, dengue, yellow fever, and chikungunya. As part of the INAD file review, in August 2016, the FDA completed an environmental review for a proposed field trial in Key Haven, Florida. Based on the results of a public referendum held in November 2016, the Florida Keys Mosquito Control District decided not to move forward with the trial in Key Haven. The sponsor of the GE mosquito will need to submit to FDA an environmental assessment for the new trial location.

CVM reviews applications related to GE animals as described in Guidance for Industry #187, *Regulation of Intentionally Altered Genomic DNA in Animals*. Applicants must demonstrate safety to the target animal and the lineage derived from it, food safety if the animal is from a food-producing species, and that the intended change is as claimed, such as effectiveness. With regard to animals that result from genome editing, FDA recently issued a draft revised version of its Guidance #187 that expands the scope of that guidance to include animals developed using that technology. The comment period on that guidance document is open until June 19, 2017.

In December 2015, FDA approved Kanuma (sebelipase alfa) – the first treatment for humans with a rare disease known as lysosomal acid lipase (LAL) deficiency. This drug comes from contained GE chickens. Patients with LAL deficiency have no or little LAL enzyme activity.

This results in a build-up of fats within the tissue cells and can lead to liver disease, cardiovascular disease, and other complications. The approval of Kanuma resulted from collaboration between FDA's CVM and FDA's Center for Drug Evaluation and Research (CDER).

In November 2015, FDA approved an application for AquAdvantage Salmon, an Atlantic salmon for human consumption that is genetically-engineered to grow faster than its non-GE counterpart. FDA regulates GE animals under the new animal drug provisions of the FD&C Act. This is because the recombinant DNA (rDNA) construct transplanted into the animal meets the definition of a drug.[34] 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.

Selected Guidances Issued 2016

Below are final guidances issued by the Animal Drugs and Feeds Program in 2016. These guidances help address various issues. This list does not represent any degree of importance or priority ranking among the published guidances.[35]

Date Issued	#	Title	Description
Jun 2016	FDA-2015-N-4563	Modified Release Veterinary Parenteral Dosage Forms: Development, Evaluation, and Establishment of Specifications	Recommendations on submission of chemistry, manufacturing, and controls, pharmacokinetic information, and procedures, for approval of modified release parenteral drug products for use in veterinary species.
Apr 2016	FDA-2003D-0061	Comparability Protocols - Chemistry, Manufacturing, and Controls Information for New Animal Drugs	Recommendation for preparing and using comparability protocols for post-approval changes in chemistry, manufacturing, and controls of both NADAs and ANADAs.

Animal Drug Inspections

FDA's field force conducts preapproval inspections to support the review of premarket applications for pioneer and generic animal drugs. To help ensure the integrity of scientific testing and the reliability of test data, FDA also conducts bioresearch monitoring (BIMO) inspections of study facilities, clinical investigators, institutional review boards, or contract research organizations that submit data to FDA.

After animal drug products are on the market, the field continues to inspect manufacturing establishments to determine their ability to manufacture products to the specifications stated in their applications, and to ensure product quality.

[34] A DNA construct is an artificially constructed segment of nucleic acid that is intended to be "transplanted" into a target tissue or cell.
[35] For more information on guidance please visit http://www.fda.gov/RegulatoryInformation/Guidances/.

FDA also inspects non-clinical laboratories that collect 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

The Minor Use and Minor Species (MUMS) Animal Health Act, passed in 2004, helps FDA ensure that innovative treatments are available for small populations of animals. This law helps to increase the availability of drugs for minor species, such as ferrets and fish, and for minor uses in a major species, such as to treat certain types of cancer in dogs. Greater access to these "MUMS drugs" gives veterinarians more options in treating unique species and uncommon conditions.

One main provision created a new pathway called conditional approval to bring MUMS drugs to the marketplace faster. The conditional approval is valid for one year (and renewable for another four, for a total of five years of conditional approval) and allows the drug company to legally sell the animal drug before proving it meets the "substantial evidence" standard of effectiveness for full approval. Before conditional approval is granted, a sponsor can apply for Designation status for MUMS drugs, which is a status similar to "orphan drug" status for human drugs. As of November 25, 2016, FDA granted 137 MUMS drug designations.

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 1, 2016, FDA had a total of 13 animal drugs on the Index.

FDA published a direct final rule effective December 1, 2016 to ensure that drugs used in animal feed remain available for therapeutic purposes in food-producing minor species after changes are made to remove the production claims from these drugs. This direct final rule will ensure that these drugs can still be produced by both licensed and unlicensed feed mills.

International Activities

The Animal Drugs and Feeds Program engages in international partnerships that promote and protect animals, as well as the humans who are exposed to them, and develops 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 also partners with Health Canada through the U.S.- Canada Regulatory Cooperation Council (RCC), a council that works to reduce unnecessary regulatory differences. In FY 2016, CVM and RCC have simultaneously reviewed and approved four applications under the RCC program.

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.

In FY 2016 import field investigators performed more than 7,935 field and label examinations on entry lines of animal drugs and feeds. These activities were performed to identify violations, such as the product not matching the information transmitted electronically, or the product labeling not meeting applicable compliance requirements.

Enhance Oversight

The Animal Drugs and Feeds 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
- Regulatory Science.

Selected Rules Published 2016

Below are rules published by the Animal Drugs and Feeds Program in 2016. These rules help address various issues and are further described in the attached links and narratives in this section. This list does not represent any degree of importance or priority ranking among the published rules.[36]

Date Issued	#	Title	Purpose or Benefit
Dec 2016	FDA-2016-N-1896	New Animal Drugs for Use in Animal Feed; Category Definitions (Direct final rule)	Revising definitions of two categories of new animal drugs used in medicated feeds to base category assignment only on approved uses in major animal species.
Nov 2016	FDA-2016-N-1487	Submission of Food and Drug Administration Import Data in the Automated Commercial Environment (Final Rule)	Establish requirements for electronic filing of entries of FDA-regulated products in electronic system authorized by U.S. CBP, to help FDA in determining admissibility of product.
Aug 2016	FDA-2016-19164	Substances Generally Recognized as Safe (Final rule)	Clarifies criteria for when use of substance in food not subject to premarket approval requirements because generally recognized as safe under conditions of intended use.

[36] For more information on FDA rules please visit http://www.fda.gov/RegulatoryInformation/RulesRegulations/default.htm.

Aug 2016	FDA-2011-N-0079	Disqualification of a Clinical Investigator (Final rule)	Amend regulations for new animal drugs for investigational use to expand scope of clinical investigator disqualification to include ineligibility to conduct nonclinical laboratory studies.
May 2016	FDA-2012-N-0447	FDA issues rule for data collection of antimicrobial sales and distribution by animal species	Revises FDA's annual reporting requirements for drug sponsors of all antimicrobials sold or distributed for use in animals intended for human consumption or food-producing animals.

Additional rules address the critical need to establish preventative controls for Animal Food, promote safety standards for industry, and combat antimicrobial resistance.

Preventive Controls for Animal Food

The FSMA final rule on "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals" published in September 2015 is foundational to implementing the modern prevention-focused food safety mandate granted to FDA under FSMA. 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.

In May 2016, FDA issued draft guidance to allow qualified facilities, such as small businesses, to comply with a set of modified requirements of the FSMA Preventive Controls rule. In July 2016, FDA finalized a rule to improve the accuracy of the food facility registration database. This final rule will support the FDA's efforts to act quickly in response to food-related emergencies and will help the FDA to use its inspectional resources more efficiently.

Safety Standards

FDA 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 human food or animal 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. In August 2016, FDA issued draft Guidance for Industry (GFI) #235, "*Current Good Manufacturing Practice (CGMP) Requirements for Food for Animals*," that provides information on complying with CGMP in areas throughout the facility (i.e., sanitation and water safety), and draft GFI #239, "Human Food By-Products for Use as Animal Food," that provides guidance on determining what requirements in the Preventive Controls for Animal Food rule apply to human food by-products for use as animal food. In April 2016, FDA finalized a food safety rule under FSMA that will help to prevent food contamination during transportation.

Antimicrobial Resistance

The Animal Drugs and Feeds Program continues to take important steps to support antimicrobial stewardship and address public health concerns associated with antimicrobial resistance and the use of antimicrobial drugs in animals.

FDA's judicious use strategy is intended to curb the emergence of antimicrobial resistance associated with the use of antimicrobial drugs in veterinary settings. The strategy includes GFI #209, which established a framework for ending production uses (e.g., growth promotion) of medically important antimicrobials and bringing the remaining therapeutic uses of such drugs in food-producing animals under veterinary oversight. It also includes GFI #213, which provided detailed guidance to drug sponsors for voluntarily removing production claims for medically

important antimicrobials. In January 2017, FDA announced the successful completion of the 3-year plan (outlined in GFI #213) to transition the use of medically important antimicrobial drugs in the feed or drinking water of food-producing animals to veterinary oversight and eliminate their use for production (e.g. growth promotion) purposes. There are 292 affected applications. Judicious use limits antimicrobial drugs used in food-producing animals to those necessary for the animal's health and are administered under the oversight or consultation of veterinarians.[37]

FDA published the Veterinary Feed Directive (VFD) final rule in June 2015[38] and issued revised GFI #120 in September 2015, two critical pieces of the overall strategy to promote the judicious use of antimicrobials in food producing animals, bringing the use of medically important antimicrobials in feed under veterinary supervision. 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.

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 2016, FDA published its seventh annual report under Section 105 providing a summary of sales and distribution data for 2015.[39]

In May 2016, FDA released a final rule that established a new requirement for animal drug sponsors to provide species-specific antimicrobial drug sales estimates for the major food-producing species - cattle, swine, chickens, and turkeys. The additional data will 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.

In September 2016, FDA announced it was entering the next phase of its efforts to mitigate antimicrobial resistance by focusing for the first time on medically important antimicrobials (i.e., those important for treating human disease) used in animal feed or water that have at least one therapeutic indication without a defined duration of use.

National Antimicrobial Resistance Monitoring System (NARMS)

The Animal Drugs and Feeds Program monitors antimicrobial resistance among enteric (intestinal) bacteria via NARMS. FDA uses data from NARMS and other sources to reach an overall risk estimation for the proposed use of an antimicrobial drug in food-producing animals. This risk estimation is used to guide FDA's decision to approve or deny the use of an antimicrobial drug in food-producing animals. FDA may also limit a drug's conditions of use based on this risk estimation to lessen the risk of antimicrobial resistance development. This risk estimation is used to guide FDA's decision to approve or deny the use of an antimicrobial drug in food-producing animals. FDA may also limit a drug's conditions of use based on this risk

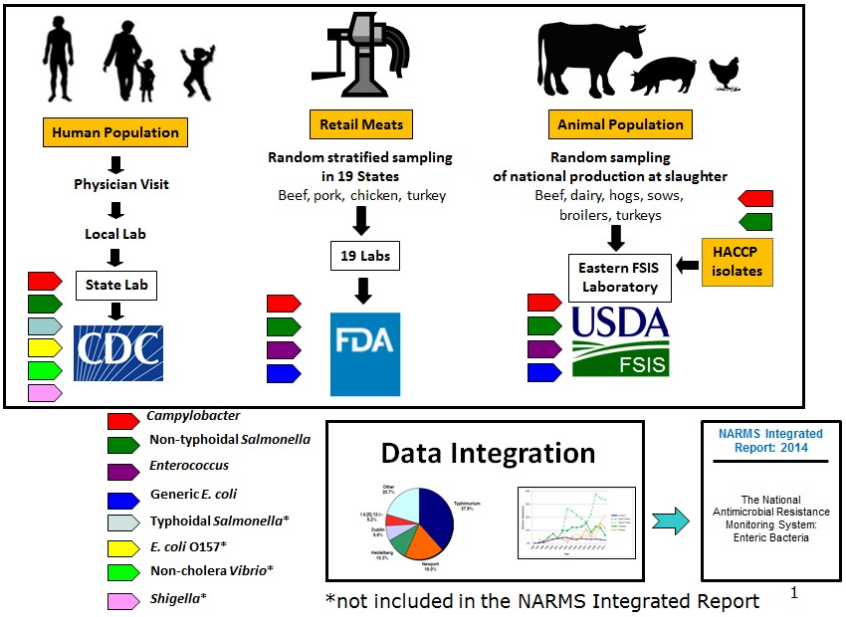
[37] FDA's judicious use strategy includes GFI #209, which established a framework for ending production uses (e.g., increased rate of weight gain and improved feed efficiency) of medically important antimicrobials and bringing the remaining therapeutic uses of such drugs in food-producing animals under veterinary oversight. It also includes GFI #213, which provided detailed guidance to drug sponsors for removing production claims for medically important antimicrobials and established an implementation timeline

[38] The veterinary feed directive final rule can be found at: http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm482110.htm

[39] The 2015 Sales and Distribution Data Report can be found at: https://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM534243.pdf

estimation to lessen the risk of antimicrobial resistance development. 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.

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.



In March 2016, FDA won a U.S. Department of Health and Human Services Ventures Program Award to design a public health surveillance mobile application that will improve the collection of retail food surveillance data that are used for resistance monitoring. The mobile application will advance the collection, management, and transfer of NARMS retail meat sample data collected in the field by creating an electronic system. The mobile app will allow partners to report surveillance data to FDA faster to support time-sensitive regulatory decision-making and provide information needed to address food related outbreaks.

In November 2016, FDA published the 2014 NARMS Integrated Report.[40] The report highlights antimicrobial resistance patterns in bacteria isolated from humans, retail meats, and animals at slaughter. The Integrated Report now has interactive data displays online to allow users to explore trends in resistance to antimicrobial agents by various factors and, for the first time, it includes Whole Genome Sequencing (WGS) data. This WGS data provides definitive information on the nature, origin, and spread of resistant bacteria in foods.

In April 2016, FDA published the 2014-2015 NARMS Retail Meat Interim Report.[41] These reports measure antimicrobial resistance in certain bacteria isolated from raw meat and poultry collected through NARMS.

[40] The NARMS 2014 Integrated Report can be found at: http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/UCM528861.pdf
[41] The NARMS 2014-2015 Retail Meat Interim Report can be found at: http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/UCM498134.pdf

In August 2015, FDA published online, for the first time, raw NARMS data collected over the past 18 years, enabling the scientific community to contribute ideas and expertise about combating antibiotic-resistant bacteria.

Research Studies Encompassing Microorganisms

FDA provides scientific research solutions that ensure the safety of human and animal health. Whole Genome Sequencing (WGS) is a critical tool that helps FDA to provide such solutions. The high capacity and low costs of rapid DNA sequencing technology and advances in analysis software have made it affordable and easier to routinely determine and interpret the complete DNA sequence obtained from microorganisms. Advancements in 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 2015, FDA sequenced 5,100 isolates and, in the first half of FY 2016, sequenced an additional 918 isolates of *Salmonella* sp. and *Campylobacter* sp. These numbers include the 2013 NARMS Campylobacter isolates recovered from retail meat and about 2,500 sequences from various pilot projects for *Escherichia coli*, *Salmonella* sp., and *Campylobacter* sp. that have been submitted to the National Institutes of Health's National Center for Biotechnology Information (NCBI) and are available to the public. The data from the Salmonella isolates are publically available via the NARMS interim report for Salmonella and NCBI.

FDA continues to work with scientists at the University of Georgia to improve the accuracy of serotyping Salmonella via the use of WGS data. FDA is providing sequence data derived from rare Salmonella serotypes to improve the serotyping algorithm for Salmonella.

Selected Guidances Issued 2016

Below are guidances issued by the Animal Drugs and Feeds Program in 2016. These guidances help address various issues and can be further described in the attached links and narratives in this section. This list does not represent any degree of importance or priority ranking among the published guidances.[42]

Date Issued	#	Title	Description
Nov 2016	FDA-2011-N-0922	Small Entity Compliance Guide - Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals	To inform domestic and foreign animal food facilities about the PCAF regulations and enable them to better understand the requirements of the rule.
Sep 2016	FDA-2010-N-0155	Veterinary Feed Directive Common Format Questions and Answers	Following comments on the VFD Q&A (GFI #120), FDA is issuing guidance to recommend a common VFD format.

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

Date Issued	#	Title	Description
Mar 2016	FDA-2003-D-0432	Use of Material from Deer and Elk in Animal Feed	FDA's recommendations regarding use in animal feed of material from deer and elk that are positive or at high risk for Chronic Wasting Disease (CWD).
Mar 2016	FDA-2014-D-1180	Ensuring Safety of Animal Feed Maintained and Fed On-Farm	To help animal producers develop procedures and practices to ensure the use of safe feed in animal production. Applies to all feed for farm animals.

Unapproved and Compounded Animal Drug Products

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

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.[43] FDA is working to reduce the risk of harm to humans and animals from substandard or illegally marketed animal drugs.

Medicated Feed Drugs

In November 2016, FDA finalized its report on proposed changes to improve the efficiency of approvals for the use of multiple new animal drugs in combination drug medicated feeds, while still protecting public health. This report is consistent with a performance goal in the Animal Drug User Fee Amendments of 2013 (ADUFA III) goals letter and are based on public comment. This report will be used in discussions concerning the reauthorization of the animal drug user fee program for FY 2019 – FY 2023 (ADUFA IV).

Postmarket Animal Drug Safety

In April 2016, FDA proposed to withdraw approval of all new animal drug applications (NADAs) providing for use of carbadox in medicated swine feed, based on FDA's determination that the approved use of carbadox results in residues of carcinogenic concern in the edible tissues of treated swine. Currently, there are three approved NADAs for use of carbadox in medicated swine feed, either by itself or in combination with other approved new animal drugs.

FDA believes that continued approval of carbadox would expose humans to concentrations of total residues of carcinogenic concern that are between 11 to 30 times higher than the allowed concentration of total residues that are considered safe.

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

[43] The webpage can be accessed at: http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/UnapprovedAnimalDrugs/ucm417562.htm

of marketed products. FDA identified and addressed policy and process changes to implement an inspection program that targets high-risk food and feed establishments and products.

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 59 warning letters in FY 2016 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 2016, FDA classified 73 Class I (most serious), 35 Class II, and 13 Class III recalls of regulated animal products.

Adverse Drug Review
The Animal Drugs and Feeds Program received approximately 99,000 Adverse Drug Experience (ADE) reports for FY 2016.

The Program has the largest regulatory agency animal drug ADE database in the world, with over 694,000 cases. The effort to increase the functionality, utilization, and analysis of this pharmacovigilance database has improved animal drug safety. 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 99 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. Signal detection and signal management strategies are under development to assist with early identification of potential safety and effectiveness issues. ADE data summary reviews for newly marketed products are developed that describe the postmarket product safety profiles.

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 enhances the prevention for entry of adulterated, misbranded, or otherwise violative goods and expedites the entry of non-violative goods. 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.

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 2016, FDA continued to work on pet illnesses related to jerky-type pet treats by posting updates to the investigation results on the FDA website. 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.

Food Additive Petition
FDA reviews 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.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
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 Actuals	$188,042,000	$158,629,000	$29,413,000
FY 2017 Annualized CR	$190,540,000	$158,333,000	$32,207,000
FY 2018 President's Budget	$183,280,000	$107,606,000	$75,674,000

BUDGET REQUEST

The FY 2018 Budget Request for the Animal Drugs and Feeds Program is $183,280,000, of which $107,606,000 is budget authority and $75,674,000 is user fees. Budget authority decreases by $50,727,000 to the FY 2017 Annualized CR level and user fees increase by $43,467,000. The Center for Veterinary Medicine (CVM) amount in this request is $121,749,000. The Office of Regulatory Affairs amount is $61,531,000.

The Animal Drugs and Feeds Program will strive to uphold its pre-approval activities by continuing to enhance the availability and diversity of safe and effective products that relieve animal pain and suffering, sustain their health, and not compromise human health. These activities include conducting preapproval inspections, ensuring safety and effectiveness of an animal drug before approval, reviewing feed additives for safety and effectiveness, and ensuring food for animals is safe, made under sanitary conditions, and properly labeled. The Animal Drugs and Feeds Program will continue to support the evolving regulatory framework for emerging technologies by clarifying the process for evaluating Genetically Engineered (GE) animals.

In addition, the Animal Drugs and Feeds Program will strive to continue the most critical postmarket efforts to protect human and animal health such as monitoring the safety and effectiveness of animal drugs on the market, reviewing Adverse Drug Experience reports, monitoring the safety of animal devices, investigating pet illnesses, enforcing compliance actions, and ongoing efforts to reduce the availability of illegally marketed unapproved animal

drugs, including compounded animal drugs. Unapproved animal drugs pose a public health risk because they may not meet the agency's strict standards for safety and effectiveness and may not be properly manufactured or labeled.

The Animal Drugs and Feeds Program will continue the Food Safety Modernization Act (FSMA) efforts by implementing a modern, prevention-focused, science- and risk-based food and feed safety system.

The Animal Drugs and Feeds Program will continue surveillance efforts such as monitoring antimicrobial resistance among enteric (intestinal) bacteria via the National Antimicrobial Resistance Monitoring System (NARMS). Response efforts will also continue such as utilizing laboratory capacity via the Veterinary Laboratory Investigation and Response Network (Vet-LIRN) to assist FDA with investigations into potential problems with animal feeds, including pet foods, and animal drugs.

The Animal Drugs and Feeds Program will also conduct field inspections, investigations, and enforcement activities to ensure the adherence of laws to protect and advance human and animal health.

These activities in the FY 2018 President's Budget Request support mission critical program activities and Presidential, HHS, and FDA human and animal health priorities.

BUDGET AUTHORITY

Reductions (-$8.4 million)

Food Safety: -$6.6 million
Center: -$2.1 million
CVM will reduce FTE through attrition. Not back-filling critical positions will require FDA to reprioritize to ensure that the most essential issues of post-market animal food and feed safety, including surveillance and response are addressed. These reductions will require FDA to reevaluate how the agency responds to food and feed outbreaks affecting companion and food animals. Reductions could impact applied research, investments related to information technology and the level of engagement in international activities. FDA's goal is to minimize the impact of these reductions on FDA's core mission activities.

Field: -$4.5 million
In order to continue operations under the FY 2018 request level, ORA will apply the necessary program reductions to areas such as partnerships, training, IT and lab equipment, and across all program office operating budgets. While protecting resources for inspections and compliance activities will be the priority, some reductions will occur due solely to reduced staff. ORA will reduce existing workforce levels through attrition, which may result in fewer staff conducting field exams, import entry review, investigations, sample analysis, and inspections for surveillance, compliance, and follow up activities, both domestically and abroad.

These reductions are targeted to investments in IT and lab equipment, and its related maintenance and operating expenses. In addition, there will be decreased investments in partnerships and training.

ORA will also have to reduce cooperative agreements supporting the Animal Feed Regulatory Program Standards (AFRPS).

Medical Product Safety & Availability: -$1.7 million
Center: -$1.7 million
CVM will reduce FTE through attrition, which will require FDA to reprioritize activities related to post-market veterinary medical product safety, including surveillance and the ability to respond to Adverse Experience Reports; research used to make evidence-based regulatory decision; combatting antimicrobial resistance; and international standards harmonization. FDA's goal is to minimize the impact of these reductions to FDA's core mission activities.

CVM will reprioritize to ensure that approved therapeutic uses of medically important antimicrobials in food animals are consistent with the principles of judicious use, including being labeled for an appropriately defined duration of use. FDA published a request seeking information on how to better target such antimicrobial use to address various diseases in livestock as well as on strategies for updating affected product labels. This effort represents an important next step in FDA's ongoing strategy to mitigate antimicrobial resistance by ensuring the judicious use of antimicrobials in food-producing animals. CVM will continue to prioritize this work to fight against antimicrobial resistance.

CVM will reduce minor use minor species (MUMS) grants distributed to support innovation and the development of new animal drugs intended for minor species or minor uses in major species. These grants are included as a provision in the MUMS Animal Health Act of 2004 and are leveraged to support safety and effectiveness testing for Designation status, similar to the "orphan drug" status for human drugs.

Medical Product Budget Authority Recalibration (-$42.4 million)

Center: -$40.9 million / Field: -$1.5 million
The FY 2018 President's Budget recalibrates FDA funding for medical product review and approval processes from budget authority to user fees.

USER FEES

Medical Product User Fee Recalibration (+$43.4 million)

Center: +$42.0 million / Field: +$1.5 million
The FY 2018 President's Budget recalibrates FDA funding for medical product review and approval processes from budget authority to user fees. As user fees are replacing budget authority, which supports both medical product and food safety, such as evaluating the human food safety aspect of animal drugs used in food producing animals, for the Animal Drugs and Feeds Program, the fee increases proposed in the final year of authorization for the Animal Drugs and Animal Generics programs will support both medical product and food safety.

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 2017 Target	FY 2018 Target	FY 2018 +/- FY 2017
243201: Complete review and action on original New Animal Drug Applications (NADAs) and reactivations of such applications received during the fiscal year. *(Output)*	FY 2016: 99.8% 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 2016: 100% w/in 270 days Target: 90% w/in 270 days (Target Exceeded)	90% w/in 270 days	90% w/in 270 days	Maintain
244212: Percentage of domestic and foreign high-risk animal drug and feed inventory inspected (approximately 225 in total). *(Output)*	FY 2016: 248 Target: 225 (Target Exceeded)	99%	99%	Maintain
244203: Percentage of planned targeted prohibited material BSE inspections. *(Output)*	FY 2016: 100% Target: 100% (Target Met)	99%	99%	Maintain
244204: Complete review and action on warning letters received to better safeguard our food supply by alerting firms to identified deviations in order to become compliant. *(Output)*	FY 2016: 42% w/in 15 working days Target: 60% w/in 15 working days (Target Not Met)	50% w/in 25 working days	50% w/in 25 working days	Maintain

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2017 Target	FY 2018 Target	FY 2018 +/- FY 2017
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 2016: 38 Target: 36 (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 eleven out of twelve years. Additionally, CVM exceeded AGDUFA performance goals, except for one submission, in six out of seven years. CVM completed review and action on 99.8 percent of original NADAs as well as other ADUFA sentinel submissions within the timeframes specified during FY 2016. 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 2016.

Warning Letter Review

In FY 2016, CVM saw an increase in both the volume and complexity of warning letters, while also accommodating a reduction in subject-matter experts. Each warning letter requires a case-by-case development of enforcement policies, in-depth scrutiny, and collaboration with field inspectors. These factors contributed to CVM missing the performance target to complete review and action on 50 percent of warning letter packages within 15 days by eight percent and influenced the decision to adjust the targets for FY 2017 and FY 2018.

PROGRAM ACTIVITY DATA TABLES

Animal Drugs & Feeds Program Activity Data (PAD)

CVM Workload and Outputs	FY 2016 Actual	FY 2017 Annualized CR	FY 2018 President's Budget
New Animal Drug Applications (NADAs) [1]			
Received	30	31	31
Completed	20	20	20
Approved	16	16	16
Pending [2]	13	24	35
New Animal Drug Application Supplements [1, 3]			
Received	544	675	625
Completed	443	550	475
Approved	333	400	400
Pending [2]	217	342	492
Abbreviated New Animal Drug Applications (ANADAs) [1]			
Received	22	50	60
Completed	23	45	32
Approved	20	20	20
Pending [2]	9	14	42
Abbreviated New Animal Drug Application Supplements [1, 3]			
Received	227	340	425
Completed	204	300	325
Approved	123	200	160
Pending [2]	189	229	329
Investigational New Animal Drug (INAD) Files [4]			
Received	3,198	3,500	3,600
Completed	3,156	3,250	3,250
Pending [2]	627	877	1,227
Generic Investigational New Animal Drug (JINAD) Files [4]			
Received	502	750	800
Completed	469	675	700
Pending [2]	476	551	651
Food (Animal) Additive Petitions Completed	101	100	100
Investigational Food Additive Petitions Completed	90	120	120
Adverse Drug Event (ADE) [5]			
ADE Reports Received	98,679	90,000	90,000
Post-Approval ADE Data Reviews	139	175	185

[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.

Field Animal Drugs & Feeds Program Activity Data (PAD)

Field Animal Drugs and Feeds Program Workload and Outputs	FY 2016 Actuals			FY 2017 Annualized CR			FY 2018 President's Budget		
	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	***1,822***	***255***	***1,589***	***1,664***	***298***	***1,398***	***1,664***	***298***	***1,398***
Pre-Approval /BIMO Inspections	39	39	0	79	79	0	79	79	0
Drug Process and New ADF Program Inspections	221	221	0	175	175	0	175	175	0
BSE Inspections	1,341	0	1,341	1,205	0	1,205	1,205	0	1,205
Feed Contaminant Inspections	13	0	13	25	0	25	25	0	25
Illegal Residue Program Inspections	397	0	397	450	0	450	450	0	450
Feed Manufacturing Program Inspections	250	0	250	200	0	200	200	0	200
Domestic Laboratory Samples Analyzed	1,555	8	1,547	1,560	20	1,540	1,560	20	1,540
FOREIGN INSPECTIONS									
UNIQUE COUNT OF FDA FOREIGN ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***126***	***118***	***8***	***76***	***71***	***5***	***76***	***71***	***5***
Foreign Pre-Approval/Bioresearch Monitoring Program Inspections	13	13	0	40	40	0	40	40	0
Foreign Drug Processing and New ADF Program Inspections	109	109	0	33	33	0	33	33	0
Foreign Feed Inspections	7	0	7	5	0	5	5	0	5
BSE Inspections	5	0	5	0	0	0	0	0	0
TOTAL UNIQUE COUNT OF FDA ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***1,948***	***373***	***1,597***	***1,740***	***369***	***1,403***	***1,740***	***369***	***1,403***
IMPORTS									
Import Field Exams/Tests	7,935	796	7,139	3,795	495	3,300	3,300	495	3,300
Import Laboratory Samples Analyzed	894	4	890	867	2	865	867	2	865
Import Physical Exam Subtotal	**8,829**	**800**	**8,029**	**4,662**	**497**	**4,165**	**4,167**	**497**	**4,165**
Import Line Decisions	446,903	48,661	385,723	469,248			492,711		
Percent of Import Lines Physically Examined	1.98%	1.64%	2.08%	0.99%			0.85%		
STATE WORK									
UNIQUE COUNT OF STATE CONTRACT ANIMAL FEEDS ESTABLISHMENT INSPECTIONS	***3,702***	***0***	***3,702***	***3,832***	***0***	***3,832***	***3,832***	***0***	***3,832***
UNIQUE COUNT OF STATE PARTNERSHIPS ANIMAL FEEDS ESTABLISHMENT INSPECTIONS [1]	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***
UNIQUE COUNT OF STATE COOPERATIVE AGREEMENT ANIMAL FEEDS ESTABLISHMENT INSPECTIONS [2]	***2***	***0***	***2***	***0***	***0***	***0***	***0***	***0***	***0***
State Contract Inspections: BSE	3,694	0	3,694	3,500	0	3,500	3,500	0	3,500
State Contract Inspections: Feed Manufacturers	623	0	623	620	0	620	620	0	620
State Contract Inspections: Illegal Tissue Residue	134	0	134	130	0	130	130	0	130
State Partnership Inspections: BSE and Other	0	0	0	0	0	0	0	0	0
State Cooperative Agreement BSE Inspections	2	0	2	0	0	0	0	0	0
State Contract Animal Drugs/Feeds Funding	$3,073,399	0	$3,073,399	$3,165,601	0	$3,165,601	$3,260,569	0	$3,260,569
BSE Cooperative Agreement Funding	$0	0	$0	$0	0	$0	$0	0	$0
State Contract Tissue Residue Funding	$456,317	0	$456,317	$442,627	0	$442,627	$429,348	0	$429,348
Total State Funding	**$3,529,716**	**$0**	**$3,529,716**	**$3,608,228**	**$0**	**$3,608,228**	**$3,689,917**	**$0**	**$3,689,917**
GRAND TOTAL ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***5,652***	***373***	***5,301***	***5,572***	***369***	***5,235***	***5,572***	***369***	***5,235***

[1] The FY 2016 actual unique count of foreign inspections includes 12 OIP inspections (11 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.