

Food and Drug Administration
FY 2012 Congressional Budget Request
Table of Contents

	<u>Page</u>
<u>Narrative by Activity:</u>	
FDA Program Resources Table	216
Program Description and Accomplishments	217
Five Year Funding Table	242
Summary of the Budget Request	243
Program Activity Data	251

ANIMAL DRUGS AND FEEDS

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2010 through FY 2012.

**FDA Program Resources Table
(Dollars in Thousands)**

	FY 2010 Enacted	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
Program Level	\$154,863	\$153,919	\$154,863	\$176,458	\$21,595
Center	\$101,652	\$100,787	\$101,652	\$117,009	\$15,357
FTE	447	488	488	487	40
Field	\$53,211	\$53,132	\$53,211	\$59,449	\$6,238
FTE	278	279	279	307	29
Program Level FTE	725	767	767	794	69
Budget Authority	\$134,798	\$134,360	\$134,798	\$147,898	\$13,100
Center	\$81,980	\$81,918	\$81,980	\$92,247	\$10,267
Field	\$52,818	\$52,442	\$52,818	\$55,651	\$2,833
<i>Pay Increase (non add)</i>				\$309	\$309
<i>Transforming Food Safety and Nutrition (non-add)</i>				\$11,214	\$11,214
<i>Protecting Patients (non-add)</i>				\$684	\$684
<i>FDA Regulatory Science and Facilities (non-add)</i>				\$2,150	\$2,150
<i>Administrative and Contract Savings (non-add)</i>				-\$1,257	-\$1,257
Budget Authority FTE	636	677	677	682	46
Center	361	401	401	399	38
Field	275	276	276	283	8
User Fees	\$20,065	\$19,559	\$20,065	\$28,560	\$8,495
Center ADUFA	\$15,290	\$14,644	\$15,290	\$19,261	\$3,971
FTE	66	65	65	66	0
Field ADUFA	\$250	\$546	\$250	\$315	\$65
FTE	2	2	2	2	0
Center AGDUFA	\$4,382	\$4,225	\$4,382	\$4,898	\$516
FTE	20	22	22	20	0
Field AGDUFA	\$143	\$144	\$143	\$160	\$17
FTE	1	1	1	1	0
Field Food Reinspection				\$2,550	\$2,550
FTE				18	18
Field Medical Products Reinspection				\$134	\$134
FTE				1	1
Center Export Certification				\$82	\$82
FTE				0	0
Recall User Fee				\$1,160	\$1,160
Center				\$521	\$521
FTE				2	2
Field				\$639	\$639
FTE				2	2
User Fees FTE	89	90	90	112	23

FDA Animal Drugs and Feeds Program operate under the following legal authorities:

Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 321-399)

Public Health Service Act (1944) (42 U.S.C. 264, 271)

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*
Food and Drug Administration Modernization Act of 1997*
Public Health Security and Bioterrorism Preparedness 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*
Food and Drug Administration Amendments Act of 2007 (FDAAA)*
Animal Drug User Fee Amendments of 2008 (P.L. 110-316)
Animal Generic Drug User Fee Act of 2008 (P.L. 110-316)
FDA Food Safety Modernization Act (P.L. 111-353)
Protecting Patients and Affordable Care Act of 2010*

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

Program Description and Accomplishments

The Center for Veterinary Medicine (CVM) is a consumer protection organization. CVM fosters public and animal health by approving safe and effective products for animals and by enforcing applicable provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and other authorities. CVM is responsible for regulating drugs, devices and food additives used in animals — approximately 8.5 billion chickens and turkeys, 160 million cattle and pigs, 11 million sheep and goats, 65 million dogs, 75 million cats, 9.5 million horses — and minor animal species that include all animals other than cattle, swine, chickens, turkeys, horses, dogs and cats.

The Animal Drugs and Feeds Program is responsible for ensuring that animal drugs and feeds used for food-producing animals do not result in unsafe residues in the food supply and that food from treated animals is safe. The Animal Drugs and Feeds Program also protects the health of companion animals and addresses zoonotic diseases — animal diseases that can be transmitted to humans. The Program accomplishes its responsibilities through premarket review of animal drug submissions. The Program also conducts surveillance and compliance activities to prevent marketing of unsafe products, and coordinates enforcement actions against unsafe products.

The authority to regulate animal drugs and medicated feeds derives from the FD&C Act, which Congress amended in 1968 to include new authorities for animal drugs. In December 2010, the President signed The Food Safety Modernization Act into law. The law gives FDA the power to directly issue a food recall. Previously, FDA had to arrange a voluntary recall with the company in question. Food and feed production facilities must also alert the FDA, through writing, of all identified hazardous practices currently in place and their plans to implement preventive measures going forward. The Animal Drugs and Feeds Program is funded through appropriations and user fees. The Animal Drug User Fee Act (ADUFA) was enacted in FY 2003 (FY 2004 – FY 2008) and

* Authorities under this act do not appear in sequence in the U.S. Code. The authorities are codified as amended in scattered sections of 21 U.S.C.

reauthorized in FY 2008 (FY 2009 – FY 2013). The new Animal Generic Drug User Fee Act (AGDUFA) was enacted in FY 2008. With the new Minor Use and Minor Species Grant Program initiated in FY 2009, CVM provides funding for the development of new animal drugs intended for minor species or minor uses in major species to defray the costs of qualified safety and effectiveness testing expenses incurred in connection with the development of designated new animal drugs.

CVM conducts the activities of the Animal Drugs and Feeds program with assistance from the Office of Regulatory Affairs (ORA). ORA supports the Animal Drugs and Feeds Program activities by assessing industry compliance with the applicable regulations to protect the public health. ORA achieves this assessment by conducting pre- and post-market risk-based inspections of domestic and foreign establishments to determine the safety of manufactured products. ORA monitors and samples imports to ensure the:

- safety of the animal drug supply
- safety of biosecurity of the feeds supply
- compliance with recalls of violative products.

In instances of criminal activity, ORA's Office of Criminal Investigations (OCI) complements the enforcement activities of the regular Field force. The Field Animal Drugs and Feeds Program is funded by appropriated dollars and user fee revenues from ADUFA and AGDUFA.

The Animal Drugs and Feeds Program executes its public health responsibilities in two major areas: food safety and medical product safety. Foods safety focuses on four strategic areas to ensure the safety of the human and animal food supply (pre and post market):

- prioritizing prevention
- strengthening surveillance
- strengthening enforcement
- improving response and recovery

Medical product safety focuses on pre- and post-market safety and compliance for companion animals and exotic animals that can transmit disease from animals to humans.

Prioritizing Prevention - Center Activities

Base Amount: \$35,503,000 (BA: \$23,700,000 / UF: \$11,803,000)

Public Health Focus

Prevention is the cornerstone of an effective, proactive food safety strategy. Prevention allows FDA to protect consumers and animal populations with the use of scientific and analytical tools to better identify food safety risks, effective control measures, and food safety standards.

Public Health Outcome

CVM reviews animal drug applications, establishes standards for feed contaminants, approves safe food additives, and manages FDA's medicated feed and pet food programs. CVM works with all stakeholders to promote corporate responsibility through the identification and implementation of new regulations to further support the production of safe feed for all animals.

CVM reviews new and generic animal drug applications not only for the effect on the targeted animal users, but also the human users who may consume food produced from the animal. CVM works to bring animal drugs to market more quickly, including products developed using new technologies such as biotechnology — genetically engineered animals and cloning. Bringing animal drugs to the market quickly helps to ensure that the public has access to safe and effective drugs on a timely basis. This access to safe and effective drugs protects public health by reducing the use of unapproved — illegally compounded animal drugs — and improperly labeled drugs used to treat animal diseases and for growth promotion.

In March 2010, CVM approved the generic new animal drug, FLUNAZINE -S, for the control of fever associated with swine respiratory disease. In addition, in November 2009, CVM approved the new animal drug, Resflor Gold, for the treatment of bovine respiratory disease (BRD) and control of BRD-associated fever in beef and non-lactating dairy cattle. In October 2009, CVM approved the new animal drug, EAZI-BREED CIDR Sheep and Goat Insert. This progesterone Controlled Intravaginal Drug Release (CIDR) is a steroid hormone that allows out-of-season breeding in sheep.

In January 2010, CVM issued a revised Animal Feed Safety System (AFSS) Framework Document comprised of components that cover the processes FDA used to ensure that ingredients used in animal feeds are safe, the methods used in making feeds result in safe products, and regulatory oversight is present at levels commensurate with risk to human and animal health. AFSS is a comprehensive, risk-based, preventive system that minimizes or eliminates the risks to animal and human health that can arise from animal feed. The AFSS covers regulation of the labeling, production and distribution of all feed ingredients and mixed feeds at all stages of manufacture, distribution and use. An integral part of a safe animal feed system effort is the development of a relative-risk ranking model for potentially toxic or deleterious biological, chemical and physical hazards in animal feed.

One of the developments addressed in the revised AFSS Framework Document is the policy announcement about a pilot program concerning Generally Recognized As Safe (GRAS) notifications for feed ingredients. CVM implemented this voluntary pilot program to accept submission of notices of claims that a particular use of a substance in food for animals is exempt from the statutory premarket approval requirements based on the individual's determination that such use is GRAS. The pilot program facilitates industry submissions of high quality GRAS food additive petitions and reduces the time to approval for new ingredients thereby increasing the number of ingredients that are

approved for use in animal food. The new AFSS Framework Document also discusses the Reportable Food Registry rule, which states industry must, and public health officials may, report when there is a reasonable probability that an article of human food or animal food/feed will cause serious adverse health consequences or death to humans or animals.

In an effort to improve the public awareness of animal and human health issues, CVM developed the Animal Health Literacy Campaign. The campaign is geared towards using social media to connect with consumers, veterinarians, and industry to share important animal health and safety tips, public health updates, and product recalls. Information is disseminated to consumers through a variety of methods, such as articles, brochures, and posters. As a compliment to the Animal Health Literacy Campaign, CVM launched its Pet Health and Safety Widget and Animal Health Twitter account to provide real time updates on important public health issues. The Pet Health and Safety Widget went live in December 2009, displaying content featured on CVM's Web site for consumers and other stakeholders to place on their own Internet sites or blogs. As a result, visitors to these sites have instant access to CVM Updates, and animal health and safety tips. Shortly after the widget launch, the first tweet further opened the doors of communication between FDA and the public in February 2010. Twitter is a free social media marketing tool that allows CVM to connect and keep in touch with our user base through the exchange of quick, frequent answers to one simple question: What's happening in the world of CVM and animal health?

Promoting Efficiency

CVM continues to exceed all user fee performance goals under ADUFA. Sustaining this performance not only protects the American public as they consume products from food-producing animals, it also gives manufacturers a reliable review process and timeline for animal drug applications and reduces the cost of product development. The following enhancements to the review process are efficiencies that CVM will sustain with the resources in this subprogram:

- An electronic tool for submitting industry applications that transforms the receipt and review of applications through a modern web-friendly environment. The electronic tool increases efficiency and decreases administrative costs to industry and government.
- A process to improve the timeliness, scheduling and predictability of Foreign preapproval inspections. This improvement supports the timely approval of animal drug applications submitted by manufacturers.
- A process to address End-Review Amendments (ERA). This process allows CVM to achieve a complete review decision sooner on applications and reduce the number of review cycles. CVM used the ERA process to request additional information on 153 applications and other animal drug submissions during FY 2009 and FY 2010. Manufacturers used the ERA process for 93 percent of these submissions. CVM completed reviews for 88 percent of these applications and submissions in only one review cycle.

CVM implemented the first generic drug user fee program and established performance goals for review of generic drugs, allowing the faster approval of lower cost generic drugs. CVM instituted business reengineering procedures for generic animal drug review that eliminated a backlog of more than 150 generic new animal drug submissions. This efficiency supports the review of current generic applications bringing safe and effective products to the market more efficiently and allows CVM to successfully meet performance goals.

CVM established a pilot program to find an effective mechanism to further strengthen the animal biotechnology program in an efficient and proactive manner. The objective of this program is to maximize available resources and expertise across CVM by engaging professionals of the appropriate expertise – regardless of their organizational unit. This pilot matrix program enhances the continuity of pre- and postmarket animal drug activities and provides internal peer-review of CVM's assessments and actions. In summary, the pilot is a program grounded in risk-based, full lifecycle regulatory oversight and a team-based review process to further strengthen the animal biotechnology program. CVM is conducting quarterly assessments to affirm the progress and benefits of the pilot program.

Prioritizing Prevention - Field Activities

Base Amount: \$12,372,000 (All BA)

Public Health Focus

To advance public health and protect consumers, ORA focus on prevention through outreach coordination and technical assistance. To gain expertise and encourage collaboration with external stakeholders, internal and external training remains a top priority of the Field.

Public Health Outcome

ORA views state-based grant programs such as the Small Scientific Conference (SSC) and Food Protection Task Force grants (FPTF) as an important mechanism for providing feed safety and feed defense program coordination. SSC and FPTF grants foster communication, cooperation, and collaboration within the states and among State, local, and tribal food protection, public health, agriculture, and regulatory agencies, enabling states to strengthen food protection systems.

ORA's focus on prevention includes non-research international harmonization activities. ORA's work with FDA's Office of International Programs (OIP) Beyond our Borders offices in China, India and Latin American enables cooperation between FDA and its counterpart regulatory authorities. This cooperation improves the safety and quality of animal feed and other FDA regulated products exported to the United States, and enhances the level of feed safety and public health protection provided to consumers in the United States.

In FY 2010, ORA awarded five associations with SSC grants and 27 state/local groups FPTF grants. These grants supported an enhanced focus on topics of intervention and prevention by reviewing feed supply vulnerabilities, performing risk-based inspections, sampling, and surveillance as a means of enhancing an integrated feed safety system.

ORA continues its outreach efforts to ensure up-to-date communication of emerging issues and advance FDA policies and FDA initiatives to internal and external stakeholders. ORA participated in more than 50 outreach events at a variety of symposiums and conferences attended by regulated industry, other government agencies and foreign regulatory bodies.

ORA awarded contracts to 36 states under the Feed Safety BSE Contract program in FY 2010. These contracts aid FDA in establishing an expanded level of inspection coverage as well as surveillance and public and industry education, greatly enhancing regulatory oversight of medicated feed facilities and those feed facilities subject to the BSE rule.

Promoting Efficiency

The use of grant and contract programs allows ORA to increase its focus on prevention. Through these efforts, ORA is enhancing the evaluation of feed supply vulnerabilities, risk-based inspections, sampling, and surveillance and bolster an integrated feed safety system and U.S. feed defense efforts.

ORA was recently accepted into the Pharmaceutical Inspection Co-operation Scheme. This will promote a more efficient use of inspection resources through the sharing of Good Manufacturing Practices (GMP) inspection reports with 37 participating global authorities, as well as the development and promotion of harmonized GMP standards and guidance documents and training of competent authorities.

ORA continues to provide state partners with training on the latest risks facing feed safety and BSE prevention to support ORA's efforts of protecting public health through public and industry education.

ORA outreach provides FDA with the opportunity to ensure transparency, open communication and sharing of information and ideas with consumers, regulated industry and the import trade community. Through this outreach, ORA is able to identify areas where regulated industry can work as partners to more efficiently protect the public health. These efforts also create a sense of ownership of the important role the import trade community and regulated industry play in ensuring safe and secure products for U.S consumers.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
<u>243201</u> : Complete review and action on original New Animal Drug Applications (NADAs) and reactivations of such applications received during the fiscal year. <i>(Output)</i>	FY 2009: 100% of 5 w/in 180 days; (Target Exceeded)	90% w/in 180 days	90% w/in 180 days	Maintain
<u>243202</u> : Complete review and action on Non-administrative original Abbreviated New Animal Drug Applications (ANADAs) and reactivations of such applications received during the fiscal year. <i>(Output)</i>	N/A	90% w/in 680 days	90% w/in 380 days	-300 days

Strengthening Surveillance and Enforcement - A. Strengthening Surveillance - Center Activities

Base Amount: \$13,286,000 (All BA)

Public Health Focus

New animal drug products are carefully tested before they are marketed. However, wider use of the drug products may disclose problems not evident during pre-marketing research and review. Therefore, the assessment of the safety of a new animal drug is a continuing process that takes place throughout the development and marketing of a drug. Animal drugs are used to treat and prevent illnesses in food producing animals; therefore, post-marketing surveillance is critical to ensuring the safety of our food supply. If the public health warrants, FDA may recommend withdrawal of an approved drug if it is found to be unsafe or ineffective.

Public Health Outcome

FDA reviews and analyzes information from adverse event reporting to protect consumers and animals and ensure the safety of products throughout their life cycle. CVM, in cooperation with FDA Field Offices, monitors the safety and effectiveness of approved drugs, feeds, food additives, and veterinary devices to protect public and animal health after they enter the market. In addition, CVM works with the U.S. Department of Agriculture (USDA) and state agencies to monitor unsafe drug residues in meat and poultry products and to conduct educational and enforcement activities. CVM also conducts surveillance to protect animal feed from contamination by toxic materials such as mycotoxins, pesticides, heavy metals, and industrial chemicals.

CVM utilizes an existing early warning surveillance system as a mechanism for notifying the public of recalls involving contaminated animal feed. With this system, CVM can

analyze and administer the data to identify adulterated food and feed products and outbreaks of illness that will be collected and provide notice to veterinarians and stakeholders during recalls. The early warning surveillance system continues to be refined and will be used in addition to MedWatch Plus. As a component of the early warning surveillance system, the Pet Event Tracking Network (PETNet) is an additional surveillance tool that provides secure reporting/ notification, only accessible by state/federal government officials, for the exchange of early information on outbreaks of illnesses associated with adulterated food and feed. These systems improve detection of food system “signals” that enable FDA and regulatory partners to respond rapidly to either prevent or quickly limit the adverse events caused by adulterated food and feed.

In regulatory research, CVM protects public health by monitoring antimicrobial drugs used in food-producing animals to identify the development of resistance among bacterial foodborne pathogens. CVM, in collaboration with the Centers for Disease Control and the United States Department of Agriculture, leads the National Antimicrobial Resistance Monitoring System program (NARMS). NARMS monitors changes in susceptibility or resistance of select zoonotic bacterial organisms recovered from animals, humans, and retail meats. NARMS helps provide important information on antimicrobial resistance in humans due to consuming food producing animals that are given antimicrobial drugs. In May 2010, CVM reported on *Salmonella*, *Campylobacter* and *Escherichia coli* in the NARMS 2007 Executive Report . This report summarizes data on isolates recovered from food animals at federally inspected plants, retail meats, chickens, and humans. In addition, in December 2010, CVM reported on identifying and analyzing trends in antimicrobial resistance in the 2008 NARMS Retail Meat Annual Report .

In June 2010, CVM issued a draft guidance document on the judicious use of medically important antimicrobials in food-producing animals. The intent of the draft guidance is to provide information on how to reduce the development of resistance to medically important antimicrobial drugs used in food-producing animals. FDA acknowledged the efforts to date by various veterinary and animal producer organizations to institute guidelines for the judicious use of antimicrobial drugs, but FDA believes additional steps are needed.

In December 2010, as mandated by ADUFA II, CVM published its first annual report summarizing sales and distribution data of antimicrobial drugs approved for food-producing animals. The collection of data on antimicrobial drugs, such as sales and distribution information, assists FDA’s evaluation of antimicrobial resistance trends as well as its analysis of other issues that may arise relating to the safety and effectiveness of antimicrobial drugs approved for use in food-producing animals, such as cattle, swine, and poultry.

CVM is working closely with the World Health Organization (WHO) Advisory Group for Integrated Surveillance of Antimicrobial Resistance (AGISAR) to help outline FDA priorities, identify regional pilot projects and special research studies, and prioritize regions for laboratory capacity building exercises in 2010. As a result, FDA will be

supplied with the vital data necessary to inform and prioritize science based approaches to assuring food safety and to minimize public health concerns with regards to antimicrobial use in food producing animals.

Promoting Efficiency

In this subprogram, the introduction of the field of social science helps CVM provide better, more targeted communications to various stakeholders. CVM has recently integrated the use of social science into some of its key program areas. For example, CVM is conducting a “mental modeling” study designed to identify factors that influence dairy farmers' ability to avoid tissue residues. Dairy cattle represent approximately seven percent of the U.S. beef sold, yet they contribute to approximately 80 percent of the drug tissue residues identified by the USDA.

CVM conducted an expert workshop with key players in the dairy industry such as producers, veterinarians, packers, and regulators. The experts provided input on the dairy farmers' experiences, where they obtain information, who they trust, and what influences their decisions. This input will be used to create a "mental model" map which can help CVM better understand how to best communicate the need to protect consumers and public health by avoiding tissue residues associated with animal drugs.

CVM conducts studies with food-producing animals in a production-like environment to provide other regulatory scientists, reviewers, and regulators with the tools to address drug residue and withdrawal-time issues for animal drugs. Developing new methods through these studies has generated efficiencies for industry through the availability of additional tools that industry uses in surveillance of their own products. These new methods also support the development of methods that benefit regulated industry during the pre-approval or post-market phases of the product lifecycle. In turn, governmental agencies have been able to implement better and more cost-efficient surveillance programs for veterinary drug residues in foods. The methods also give FDA the means of more rapidly responding and assessing specific food-related hazards.

The information generated through the National Antimicrobial Resistance Monitoring System (NARMS) that supports the judicious use of antimicrobials by industry reduces governmental oversight and regulatory costs. It also reduces the threat and health care costs associated with antimicrobial resistance among the American public. CVM and its partners have automated NARMS data processing to speed the preparation of large data blocks for uploading into the NARMS database. The process of collecting data from NARMS partners at CDC and USDA has been simplified and sped up by creating a new process known as extract, transform, and load. CVM is analyzing improvements such as this in the workflow and dataflow in the NARMS laboratory to streamline processes and shorten the time from data acquisition to reporting.

Strengthening Surveillance and Enforcement - A. Strengthening Surveillance - Field Activities

Base Amount: \$13,843,000 (All BA)

Public Health Focus

To strengthen bio-security, surveillance and risk analysis, ORA conducts:

- import prior notice and entry reviews
- import field exams
- import sample collections
- laboratory analyses.

Laboratory analyses activities include sample analysis, product testing and methods development to enable FDA to develop solutions for specific regulatory problems. ORA applies risk based principles to the life cycle of ORA scientific operations — including sample collection, sample analysis, data reporting, and data analysis.

Public Health Outcome

ORA uses a combination of techniques to perform import surveillance:

- electronic information technology for risk-based screening
- intensive ORA staff surveillance
- physical exams
- laboratory analysis.

Because the number and complexity of FDA-regulated imported products is increasing exponentially, ORA increased its efforts to strengthen surveillance and risk analysis.

During FY 2010, ORA issued several notices identifying modifications to animal feed and drug related Import Alerts encompassing various animal feed and drug commodities and manufacturers. These actions were a result of ORA import surveillance activities of regulated products at the time they were offered for import into the U.S., as well as for-cause sampling of imported products based on ORA findings of violations during inspections of foreign manufacturers.

In FY 2010, ORA began staffing the Commercial Targeting and Analysis Center (CTAC), a facility designed to leverage numerous government agencies in information sharing and data analysis to identify safety risks in imported products. Once the risks are identified, the appropriate agencies work together to minimize the risk. ORA

personnel are working closely with other government agencies on several ongoing cases including products in the animal feed and animal drug program.

ORA continues to conduct routine surveillance examinations, sampling, and analysis to ensure the compliance, safety and security of animal feeds. In January 2010, FDA issued a press release warning consumers not to use a packaged dog treat product due

to concerns that the product had been contaminated with Salmonella. FDA became aware of the issue when routine surveillance sample collection and analyses found the product to be contaminated.

Due to an unusually wet and cool growing season on the east coast and in the Midwest in 2009, high levels of the mycotoxin Deoxynivalenol (DON), also known as vomitoxin, were detected in wheat, corn and other grains harvested from that growing season. In FY 2010, ORA worked with the states to accomplish a comprehensive sampling and analytical effort in affected areas.

The joint effort called for ORA and state sampling of grain by-products intended for use in animal feed to determine the levels of DON present. Products that exceeded FDA advisory levels led to follow-up with sampling of finished feeds manufactured using the milled wheat products, grains or grain by-products that exceeded FDA advisory levels.

FDA took regulatory action as appropriate. Additionally, FDA developed multi-residue mycotoxin testing methods, consolidating into a single test the previous testing process comprised of an initial test to determine the presence of mycotoxins and the confirmation test for regulatory determination and action. These efforts increased ORA analytical efficiencies.

ORA continues to award contracts and grants to the states to increase collaborative efforts, leverage existing resources and continue to bolster an integrated feed safety system. In FY 2010, ORA-awarded contracts included:

- 19 Tissue Residue program contracts to states to provide for completion of 260 tissue residue inspections by state inspectors
- 27 FPTF grants to state and local groups
- SSC grants to five associations allowing for increased interactions at operational levels to assure uniformity and consistency in enforcement activities.
- contracts awarded to 36 states under the Feed Safety BSE Contract program. These contracts aid FDA in establishing an expanded level of inspection coverage as well as surveillance and public and industry education, greatly enhancing regulatory oversight of medicated feed facilities and those feed facilities subject to the BSE rule.

In FY 2010, ORA initiated a nationwide investigation to collect and analyze samples of import and domestic distiller grain samples for the presence of antibiotic residues. ORA also developed a new analytical method to allow for the confirmation of residues and determination of residue levels using a single method to screen for 21 drugs. Additionally, ORA purchased and outfitted two ORA field laboratories with new equipment to complete this testing, expanding the available ORA laboratory resource network.

Promoting Efficiency

ORA is increasing efficiencies by reviewing import entries through the implementation of PREDICT (Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting). PREDICT gathers intelligence from various sources to allow for a more informed review of specific product entries. With data that supports ORA's ability to confirm that an imported product complies with import standards, ORA will more quickly process and release those entries; data indicative of concerns or violations will result in entries being flagged for additional scrutiny by ORA investigators. PREDICT allows ORA to target its resources in a more strategic manner. PREDICT expedites clearance of low risk products while allowing ORA to focus examination and sample collection resources on higher risk animal feed and drug products.

ORA implemented the Analytical Tools Initiative to assess tools for the investigator toolbox. This initiative includes the evaluation of field deployable kits and instruments to enhance an investigator's ability to quickly test and assess products in the field for potential public health risks. This initiative also supports the evaluation of additional instruments for laboratory use that will enhance laboratory capacity and capability.

ORA continues to evaluate violations identified during inspections of foreign facilities to establish pre-emptive import controls. ORA increases exams and sampling of products manufactured where violations are likely to ensure a high level of scrutiny when those products are offered for import into the United States.

ORA oversight of grants and cooperative agreements with the states has enhanced and developed programs to safeguard products intended for animal use and furthered the development of an integrated feed safety system. Using these grants and cooperative agreement funds, ORA has increased integrated feed safety system by assuring better trained state inspectors, increasing state capabilities to respond to feed incidents and outbreaks.

ORA achieves efficiencies by leveraging resources with our state Tissue Residue Inspection partners by identifying the causes of illegal drug residues and obtaining compliance through voluntary or regulatory actions. Additionally, ORA strengthens surveillance and risk analysis activities by using experienced state-employed veterinarians to investigate animal producers that the USDA Food Safety and Inspection Service identifies as firms with tissue residue violations. ORA identifies the causes of the residues and pursues appropriate enforcement actions.

ORA's expansion of prior notice bio-security targeting capabilities and intelligence data mining have allowed ORA to provide an increased focus on import shipments that pose the highest risk of an intentional act of bio-terrorism. These advances have increased bio-security review efficiency and increase FDA's ability to detect and prevent high risk feed shipments that pose a bio-security threat from reaching domestic distribution chains.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
242201: Review adverse experience reports to detect animal product hazards early. (Output)	FY 2010: 22% (Target Not Met)	50%	55%	+5%

Strengthening Surveillance and Enforcement - B. Strengthening Enforcement - Center Activities

Base Amount: \$8,858,000 (All BA)

Public Health Focus

Appropriate enforcement strategies and regulatory decisions need to be in place to ensure the compliance of marketed products. Inspections serve as a foundation to ensure products are manufactured according to good manufacturing practices. Working with our state counterparts, the Animal Drugs and Feeds Program conducts high-quality targeted, risk-based interventions with emphasis on the points of manufacture and distribution to prevent contaminated food/feed from entering the food supply.

Public Health Outcome

CVM developed risk based inspection criteria for the bovine spongiform encephalopathy (BSE), tissue residue, medicated feeds and animal drug inspection programs. These criteria allow CVM, in collaboration with ORA, to prioritize inspection workload based on risk. As a result of these risk-based inspections, CVM effectively and efficiently manages compliance programs to protect animal feed from contamination by toxic materials such as mycotoxins, pesticides, heavy metals, and industrial chemicals, and to prevent the establishment and amplification of BSE through feed.

In addition, CVM developed the Polymerase Chain Reaction (PCR)-based method for testing animal feed for prohibited materials. As the new PCR-based method is routinely used, it will enhance FDA's ability to make sure animal feed is safe and free of prohibited materials that may spread the agent thought to cause BSE. In less than 2.5 hours, the new real-time PCR-based method can detect processed materials from cattle, sheep, and goats, as well as a select set of processed materials from chickens, turkeys, and geese. This method not only detects animal materials that have been processed in North America, but also animal materials processed in the European Union, which are more difficult to detect due to a different processing method.

CVM conducts the activities of the Animal Drugs and Feeds program with assistance from ORA. ORA provides FDA leadership on enforcement, foreign and domestic inspections, and laboratory analysis.

Promoting Efficiency

To promote efficiency and improve public health in the Strengthening Enforcement subprogram, CVM has written a draft Compliance Policy Guide to focus the regulatory response to the classes of feeds and Salmonella serotypes that have shown the highest risk of causing human or animal illness. Previously, without a policy to prioritize Salmonella serotypes of greatest significance, all Salmonella events were treated equally. This efficient, risk-based decision tool allows FDA and others to focus resources on Salmonella serotypes of human and animal health concern for the prevention of and response to Salmonella events.

CVM is also promoting efficiency by continuously working with feed and food industries to ensure safe uses of products that would otherwise be considered adulterated. These efficiency efforts maximize the availability of feed ingredients while still protecting animal and human health. Examples include reconditioning of Salmonella-contaminated feeds, and diverting mycotoxin-contaminated feeds from use in highly sensitive animal species to use in species that would not be affected. Additionally, CVM has established safeguards to identify the conditions for the safe use of products such as sugarcane, which was contaminated by an oil well blowout.

Strengthening Surveillance and Enforcement - B. Strengthening Enforcement - Field Activities

Base Amount: \$12,087,000 (All BA)

Public Health Focus

One of ORA's main feed protection duties is to conduct risk-based inspections and enforcement activities. ORA investigators conduct physical inspections of regulated domestic and foreign feed establishments and conduct follow-up investigations on reports of tissue residues.

Public Health Outcome

Currently the best approach to improving the safety and security of feed is to utilize resources to expand targeting and follow through on potentially high-risk areas.

ORA and experts from the Center for Veterinary Medicine (CVM) review risk-based scenarios of bioterrorism and develop criteria that targets animal feed and feed ingredients that pose an increased risk for intentional contamination. ORA implemented this science and risk-based screening criteria, thereby strengthening FDA's defense of the animal feed industry.

Submission of accurate prior notice data for imported animal food and feed shipments ensures that ORA can complete meaningful bio-security risk assessments. To continue to ensure compliance, ORA made more than 800 informed compliance calls to the import trade community and regulated industry in FY 2010 to obtain accurate prior

notice data and inform the trade community of the existing requirements. In conjunction with CBP, ORA executed compliance enforcement actions against more than 1,300 imported food and feed shipments where the inadequate prior notice data was so egregious that it restricted ORA's ability to perform meaningful bio-security risk assessments. The actions required resubmission of accurate prior notice data before the imported food and feed shipments were allowed to enter the U.S.

ORA's Ruminant Feed Ban cooperative agreements with the states enhance an integrated feed safety system. The agreements support the development of state infrastructure, territorial and tribal animal feed safety, and BSE prevention programs, and they assure a broader regulatory framework for the U.S. feed supply.

In FY2010, FDA classified and issued recall numbers for 40 Class I (most serious); 126 Class II; and 31 Class III recalls of animal products. In FY2010, FDA's MARCS-Compliance Management System indicated 3 approved CVM injunctions.

An OCI investigation led to a guilty plea from the owner of a veal feed business for misbranding violations under the Food, Drug and Cosmetic Act. The company owner was directing the contract farmers to use feeding protocols that included the routine addition of formaldehyde and potassium permanganate to the veal calves' feed. These are "drugs" within the meaning of the FDCA, and they are not approved for use in veal calf meat intended for human consumption. In October 2009, the company owner signed a guilty plea agreement on behalf of its company that resulted in criminal fine of \$550,000. The owner and the company were also ordered to pay special assessments.

Promoting Efficiency

OLRA revised its Regulatory Procedures Manual (RPM) to provide a process for issuing Warning or Untitled Letters based on evidence obtained by state personnel. The process allows FDA to issue Warning or Untitled Letters if the standards and criteria used by state personnel provide reliable support for regulatory action consistent with FDA's guidance on regulatory actions and laboratory procedures. This process increases the number of enforcement actions and decreases the time and resources required to prevent the continued distribution of adulterated products in U.S. commerce, resulting in greater efficiency.

Informing the import trade community of the importance of submitting accurate prior notice data via informed compliance calls, compliance actions and joint cases with CBP serves to increase the reliability and specificity of ORA bio-security assessments and targeting. These enforcement efforts have added operational efficiency to both the animal food and feed import trade community and FDA, while continuing to ensure the U.S. animal feed supply does not experience an act of bio-terrorism.

Ruminant Feed Ban contract programs enhance FDA efforts to build an integrated feed safety system by increasing ORA and state ability to locate and visit companies

involved in the manufacture, distribution, and transportation of animal feed as well as animal feed operations and to verify their compliance with the BSE/ruminant feed ban.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
244202: Number of domestic and foreign high-risk animal drug and feed inspections. <i>(Output)</i>	FY 2010: 279 (Target Exceeded)	250	250	Maintain
244203: Number of targeted prohibited material BSE inspections. <i>(Output)</i>	FY 2010: 567 (Target Exceeded)	490	490	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. <i>(Output)</i>	FY 2010: 25% w/in 15 working days (Target Not Met)	80% w/in 15 working days	50% w/in 15 working days	-30%

Improving Response and Recovery - Center Activities

Base Amount: \$2,235,000 (All BA)

Public Health Focus

Early detection of illnesses associated with food, tracing the source of the outbreak, and removing the contaminated product from the market is critical to containing potential risks to the public.

Public Health Outcome

CVM is improving on how to communicate with consumers about food-related emergencies and ensuring that communications related to food safety better meet the health and information needs of consumers. Improving safety through better risk communication ensures consumers understand what to do – and not do – in response to safety problems.

CVM, in collaboration with the Center for Food Safety and Applied Nutrition (CFSAN) and other FDA Offices, participated in the development and launching of the Reportable Food Registry to provide a reliable mechanism to track patterns of adulteration in food in order to support FDA's efforts to target limited inspection resources to protect the public health.

In advance of foodborne illness events, CVM reviews and improves the protocol and roles and responsibilities for emergency coordination. CVM now has full-time

emergency and complaint response coordinators and other staff members dedicated solely to monitoring and responding, in real-time, to situations involving contaminated food and feed. CVM is able to initiate a rapid Agency response upon detection and identification of an animal disease outbreak associated with pet food products. CVM has participated in review and updating of the FDA Emergency Operations Plan (EOP) to include a strategic plan for rapid response to import-safety incidents and to reflect changes to the National Response Framework.

Promoting Efficiency

CVM is developing the Veterinary Laboratory Response Network (Vet-LRN), a system that is “proactive” in a “reactive” situation. This network will provide the means for rapid response to report animal injury and will establish protocols to facilitate veterinary diagnostic reporting to FDA. Working with the Food Emergency Response Network (FERN) partners, CVM established a network of state and federal laboratories that integrate resources and expertise for timely and accurate reporting, identification, and analysis of animal feed chemical and microbiological contamination events. Upon completion, Vet-LRN will reduce duplication by coordinating resources and expertise between diagnostic laboratories thereby saving costs to both consumers and government investigators.

Coordinating intra-Agency efforts between NCTR, CFSAN and CVM has saved government resources by not duplicating, but complementing, each center’s efforts by leveraging equipment and manpower. As a recent example, CVM conducted pioneering melamine toxicity studies that were vital during FDA and WHO risk assessments for melamine during the pet food recall and infant formula events of 2007 and 2008. CVM scientists have worked with WHO and CFSAN risk assessors to provide needed data regarding melamine toxicity. Data obtained from collaborative work by CVM and industry resulted in one of the most cited papers on melamine toxicity (Dobson et al 2008). CVM studies have provided valuable insight into the mechanism of renal failure caused by melamine related compounds. This information was extremely important during the infant formula recall and subsequent contamination events. CVM’s method development work has helped industry develop new methods to detect melamine and related compounds.

Improving Response and Recovery - Field Activities

Base Amount: \$9,832,000 (All BA)

Public Health Focus

With the integrated food supply chain, it is more important than ever for ORA to work with its regulatory partners, specifically its Federal, State, local, tribal and territorial partners, in order to protect the nation’s food supply.

The globalization of the U.S. food supply, rapid and widespread distribution of food, and changes in consumer expectations create the need for a framework for food protection.

Protecting the U.S. food supply requires an integrated approach for recognizing, investigating, and responding to foodborne illnesses. ORA continues to work with the states to establish new and develop further existing rapid response teams (RRTs), comprised of both ORA and state inspectors.

The Reportable Food Registry (RFR) is an electronic portal to which industry, public health officials and consumers can report when there is a reasonable probability that an article of animal food and feed will cause serious adverse health consequences or death to animals. RFRs provide regulated industry and consumers with an immediate reporting mechanism into FDA and also supply key information that is vital for effective FDA follow up activities.

Public Health Outcome

To rapidly respond to outbreaks and facility recovery, ORA leverages its regulatory partnerships. Examples of these partnerships include State contracts, FERN laboratories, rapid response and state lab cooperative agreements, BSE contracts, and 50-State Meetings. ORA developed and supports FERN, a network of State and local labs that perform laboratory analysis for FDA in the event of a public health emergency. FERN laboratories provide critical analytical surge capacity during food emergency events. The ability to rapidly test large numbers of samples of potentially contaminated food products is a critical component of controlling threats from deliberate foodborne contamination.

Currently ORA has developed nine RRTs through the use of cooperative agreements and continues to develop the existing teams while working to enroll remaining states in the program. The established teams continue to work with Federal and local partners (including 10 ORA districts) to explore, develop, implement, and share best practices. This work enables Federal and state partners to improve their systems to more quickly and effectively stop an outbreak; mitigate the concern; and when possible and appropriate, identify sources of contamination and contributing factors for the outbreak and reach conclusions and possible interventions for the prevention of future cases. The RRTs have developed tools and guidance to share and facilitate improvement on key capabilities that are essential for effective responses to emergencies. ORA responded to numerous pet foods and animal feed RFRs in FY 2010. Significant resources were expended into nationwide investigations, sample collections and analyses of a variety of products for various contamination concerns including animal feed contamination leading to animal death and Salmonella contamination of pet treats,

Promoting Efficiency

Improving the coordinated, rapid response of federal, state, and local partners to feed related emergencies through the use of RRTs helps to minimize the public health consequences of an incident while diminishing unnecessary costs at the federal, state, and local levels resulting from poor response coordination or communication.

The RFR is an example of how FDA uses technology to prevent animal feed safety threats from resulting in consumer illness or injury, providing a reliable mechanism to track patterns of adulteration in feeds. Pre-emptive investigations into reports received assured ORA investigations were comprehensive and affected products were contained and recalled before illness or injury could occur.

ORA's continued use of grants and contracts with the states leverages working relationships with state counterparts at the local level to improve surveillance activities, enhance an integrated feed safety system and respond to public health threats in a timely and efficient manner. These programs assist FDA efforts during trace-back investigations, allowing for greater inspectional coverage for ORA and enhance feed safety and defense through increased communication and integration of key stakeholders.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
244301: Total number of collaborating laboratories that will provide coordinated response to high priority chemical and microbial animal feed contamination events. <i>(Outcome)</i>	FY 2010: 9 (Historical Actual)	2	11	+9 (Total of 11 labs)

Animal Drug Review - Center Activities

Base Amount: \$24,310,000 (BA: \$16,441,000 / UF: \$7,869,000)

Public Health Focus

The increasing companion animal population in the U.S., along with the growing affinity pet owners have for their pets — evidenced by the rising expenditures for pet care and aggressive marketing of pet products — illustrates the need for more safe and effective drugs for disease prevention, treatment, and control in companion animals. To meet this need, CVM serves public interest by increasing the availability and diversity of approved, safe and effective veterinary products which relieve the pain and suffering of pets.

Public Health Outcome

Timely review for safety and effectiveness of new animal drug products is critical to bringing innovative, high quality and safe medical products to market for companion animals. CVM reviews safety and effectiveness data submitted in premarket applications for pioneer and generic new animal drugs. In addition, under the Minor

Use and Minor Species (MUMS) Animal Health Act of 2004, CVM reviews conditional drug approval requests, indexing requests, and designation requests to increase the number of safe and effective new animal drug products for minor animal species and uncommon diseases in major animal species. CVM administers a grant program to support the development of new animal drugs intended for minor species or minor uses in major species. In March 2010, CVM issued Guidance for Industry on “Anesthetics for Companion Animals”. This guidance document makes recommendations to assist developers of general anesthetic drugs, injectable or inhalational, for use in companion animals — dogs, cats, and horses. The guidance discusses the contents of the target animal safety, effectiveness, and labeling technical sections of a new animal drug application for general anesthetics.

The support of the reauthorized Animal Drug User Fee Act (ADUFA) of 2008 and the Animal Generic Drug User Fee Act (AGDUFA) of 2008 has provided resources for sustained performance, making it possible for safe and effective drug products to reach the market sooner.

CVM employs a phased-in approach to prevent drug makers from making critical and costly mistakes that delay the review of new animal drugs, thus bringing safe and effective products to the market more efficiently. This approach encourages sponsors to submit information to support approval as it becomes available, rather than waiting until they have collected all needed information, and to maintain ongoing consultations with CVM about requirements for approval.

In November 2009, CVM approved a generic new animal drug, Sevoflurane, for the induction and maintenance of general anesthesia in dogs. In December 2010, CVM approved the first drug, Equidone Gel (domperidone), for the prevention of fescue

toxicosis, a life threatening disease that can cause serious reproductive problems in horses. Fescue, a type of grass, carries the endophytic fungus, which produces toxins that interfere with the hormones involved in pregnancy and milk production.

Promoting Efficiency

CVM began a plan in FY 2010 to encourage the development of innovative and novel new animal drugs to meet public and animal health needs. A working group of CVM scientists, the InnoVation Exploration Team (IVET), was assembled as a think tank to introduce innovative products and processes to FDA, and to increase the certainty of the regulatory pathway for innovative products. IVET works with pharmaceutical companies, engaging their leadership in discussions to better understand pressures facing the industry that impact the development of innovative products. IVET utilizes the broad expertise across the CVM and FDA in a matrix review environment.

The MUMS Designation program for animal drugs provides incentives to the pharmaceutical industry to pursue drug approval for species and diseases that represent small markets thus reducing the likelihood of unapproved drug use. When a

drug is designated for a particular intended use, the sponsor of the drug obtains seven years of exclusive marketing rights upon approval (or conditional approval) of the drug for that intended use. This program assists drug approval through grants to support safety and effectiveness testing and through exclusive marketing rights. In addition, this program supports the pharmaceutical industry in this effort through grants that pay for some required studies, thus lowering the direct cost of drug approval. It also protects the sponsor from competition following approval to further offset the company's drug development costs. These products also qualify for waivers from user fees which provides an additional incentive to the industry to seek approval.

The MUMS Indexing program benefits the regulated industry by providing a reasonable and less expensive path to legal marketing of minor species drug products. Indexing takes much less time than drug approval which allows companies to begin to recoup their investment sooner. The cost is a fraction of that of a drug approval. Inclusion in the Index is based on the evaluation of the target animal safety and effectiveness of each specific product by a panel of qualified experts. A Small Entity Compliance Guide was published recently to assist the regulated industry -- especially small businesses -- in using both the designation and indexing options. CVM carries out research with aquatic species in support of CVM, FDA, and other governmental entities to increase efficiency in approval and surveillance of products used in aquatic health and production programs. This research includes:

- drug safety and efficacy studies
- standard methods development
- aquatic species model development
- therapeutics evaluation
- support of minor species initiatives.

Research in these areas establishes models and standards that can be used in guidances for regulated industry resulting in lower resource allocation during preapproval interactions and the formal approval process.

Animal Drug Review - Field Activities

Base Amount: \$2,544,000 (BA: \$2,151,000 / UF: \$393,000)

Public Health Focus

The ORA Field supports the Animal Drugs Program by advising FDA leadership on enforcement, import, inspection, and laboratory policies. Through its Field offices nationwide, ORA supports the Animal Drugs Program by conducting premarket inspections of domestic and foreign establishments to determine the safety and effectiveness of manufactured products.

Public Health Outcome

ORA's Field force conducts preapproval inspections to support CVM's review of New Animal Drug Applications (NADA) and Abbreviated New Animal Drug Applications (ANADA). The Field inspects manufacturing establishments to determine their ability to manufacture the product to the specifications stated in their application. ORA performs inspections of non-clinical laboratories engaged in the collection of data to determine whether Good Laboratory Practices are followed. Accurate data is essential to the review and approval of new animal drugs. Inspections also help ensure that the rights and welfare of animals are protected.

Promoting Efficiency

ORA provides training in the conduct of inspections of animal drug manufacturers and non-clinical laboratories, increasing the consistency of these inspections. When significant violations are observed during inspections, ORA works collaboratively with CVM to determine and implement the appropriate follow-up regulatory actions to assure the safety of U.S. public health.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
<u>243201</u> : Complete review and action on original New Animal Drug Applications (NADAs) and reactivations of such applications received during the fiscal year. <i>(Output)</i>	FY 2009: 100% of 5 w/in 180 days; (Target Exceeded)	90% w/in 180 days	90% w/in 180 days	Maintain
<u>243202</u> : Complete review and action on Non-administrative original Abbreviated New Animal Drug Applications (ANADAs) and reactivations of such applications received during the fiscal year. <i>(Output)</i>	N/A	90% w/in 680 days	90% w/in 380 days	-300 days

Post-market Safety and Compliance - Center Activities

Base Amount: \$17,460,000 (All BA)

Public Health Focus

Monitoring the safety and effectiveness of marketed animal drugs, food additives and veterinary devices is paramount in ensuring the health and safety of our pets. Wider use of products often discloses problems not evident during the pre-market review stage. Nonetheless, our surveillance efforts enable the identification of potential harm

prior to an adverse event. In addition, CVM is responsible for controlling the spread of zoonotic diseases that can be transmitted from animals to humans by pets and exotic animals.

Public Health Outcome

As in the foods area, FDA has a similar public health objective to ensure the safety of companion animal related products throughout the life cycle. CVM utilizes and maintains an Adverse Drug Experience (ADE) database to provide a surveillance system to identify drug safety signals and effectiveness issues of concern that were not detected during pre-market testing of FDA-approved animal drugs. Though there is not mandatory ADE reporting for the manufacturers of drugs not FDA approved for animals, CVM monitors the reports that it receives for these products to identify safety and effectiveness issues of concern. CVM scientists use the ADE database to make decisions about product safety, which may include changes to the label or other regulatory action.

The constant interactions of humans, animals, and the environment have a tremendous impact on public health. There are over 200 infectious zoonotic diseases that are an important public health concern because they cause significant morbidity and mortality in the US and worldwide. Animals are the major source of the pathogens involved in zoonoses. CVM has the ability to address regulatory issues designed to prevent and control zoonotic diseases in both animal and human populations. The most current zoonotic diseases are variant Creutzfeldt-Jakob disease, West Nile virus, avian influenza, H1N1, rabies, monkeypox, and salmonellosis. Approximately 75 percent of emerging human diseases seen in the past 25 years have been zoonotic. In the area of regulatory research, CVM initiated a multi-phase study on herding dogs that are predisposed to have a genetic defect which increases their sensitivity to certain classes of drugs such as the avermectin class heart worm medication. Dogs that have this genetic defect are at risk of developing toxic reactions to what normally are therapeutic doses of the drug. These reactions can even cause the animals to die. The results of these studies will influence how veterinary clinical data are generated and evaluated, the type of preclinical data requested to support drug approval, and ultimately the product label. CVM will improve the ability to predict therapeutic effects and adverse reactions for drugs used in veterinary practice, providing better information for practitioners and their client-owners.

Promoting Efficiency

CVM developed and implemented a pharmacovigilance program that accepts reports electronically and pre-populates an adverse drug events database. The program provides significant administrative savings to industry and allows CVM to provide more real-time surveillance of adverse drug event reports so that safety signals can be identified and communicated to veterinarians and animal and pet owners. Electronic submission of adverse event information was made possible through CVM's Electronic Submissions System (ESS), which integrates with the FDA Electronic Submissions

Gateway (FDA ESG) to allow adverse drug event reports to be transmitted directly from industry to CVM – gateway-to-gateway submission. ESG allows thousands of adverse event reports to immediately enter the database for processing and analysis. The Safety Reporting Portal (SRP), implemented separately, allows individual mandatory adverse event reports for animal drugs. SRP is intended primarily to provide the electronic submission option for sponsors without sophisticated electronic pharmacovigilance programs or for those with few adverse drug event reports. This provides financial savings to those companies and ensures they provide the appropriate adverse event safety information needed to protect animals and humans.

CVM is applying lessons learned in the human drug arena and incorporating applicable methods to improve animal patient safety. Reducing and preventing medication errors has become a top priority in improving patient safety with other FDA Centers. Paralleling with CDER's efforts, in 2008, CVM began a similar patient safety initiative to prevent medication errors in animals. While early in the process, CVM has identified reports of preventable medication errors in animals that are similar to the medication errors in people, which may cause unnecessary harm and injury to animals.

Post-market Safety and Compliance (medical) - Field Activities

Base Amount: \$2,533,000 (All BA)

Public Health Focus

ORA supports the Animal Drugs Program by evaluating manufacturing practices to determine the safety and effectiveness of manufactured products. ORA also supports the Animal Drugs Program by advising FDA leadership on enforcement, import, inspection, and laboratory policies.

Public Health Outcome

Through its Field offices nationwide, ORA supports the Animal Drugs Program by conducting post-market inspections of domestic and foreign establishments to determine the safety and effectiveness of manufactured products.

ORA monitor and sample imports to ensure the safety of the animal drug supply. In instances of criminal activity, ORA's Office of Criminal Investigations (OCI) and the Forensic Chemistry Center complement the regular Field force activities.

ORA support the Center's evaluation of adverse event reports. The Field offices conduct follow-up inspections on adverse event reports when information from the manufacturer is needed to evaluate the risks involved. In addition, ORA reviews adverse event and complaint files during inspections for compliance with FDA reporting regulations. In the event of a public health incident concerning a disease from an animal, for example salmonella from pet turtles, ORA will assist CVM by conducting any appropriate investigations.

Promoting Efficiency

ORA evaluates adverse event reports in consultation with CVM and uses this information to perform targeted inspections to determine potential root causes of adverse events.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result	FY 2010 Target	FY 2012 Target	FY 2012 +/- FY 2010
242201: Review adverse experience reports to detect animal product hazards early. (Output)	FY 2010: 22% (Target Not Met)	50%	55%	+5%

Information Technology Investments – Animal Drugs and Feeds Program Activities (Base Amount displayed as a non-add item: \$23,885,000)

The ongoing modernization and enhancement of the FDA information technology (IT) infrastructure and systems is creating a robust foundation to enable interoperability of regulatory data sharing across the FDA program areas. This allows FDA to transform nearly every aspect of its operations and regulatory duties. FDA has agency-wide costs associated with the operation and maintenance of shared IT infrastructure which includes data centers, security, telecommunication networks, and help desk functions. In addition, each center and office has program specific IT systems and FDA also has a number of enterprise systems ranging from improving the pre-market review process for all regulated products to post-market surveillance, including adverse event detection and future scientific computing capabilities.

In addition to investments in IT infrastructure, unique center-specific systems, and enterprise-wide systems, the following are examples of IT development efforts related to the regulation of our nation's veterinary products and feed. FDA is committed to moving to an all electronic work environment to support the center's business process. CVM's Electronic Document Submission and Review (EDSR) project created an electronic system to receive, process, review, and respond to pre-market submissions and reviews, and will leverage these processes for post-market, product quality, administrative, drug index files, and scientific computing submissions and reviews. In addition, CVM is committed to convert its paper records into an electronic archive. CVM is also committed to expanding and to enhancing the National Antimicrobial Resistance Monitoring System (NARMS) with its external stakeholders including CDC, USDA, and state agencies to support the FDA Food Safety Initiative.

CVM will expand and enhance the electronic processing of adverse event reports, product problem reports, and both adverse event and product problem reports submitted by the regulatory industry and the public. The electronic processing capability

will be expanded to include the reporting of voluntary animal drug events, the reporting for medicated feeds, and the reporting of reportable foods, which would better allow FDA to use the information to promote and protect the public health.

Five Year Funding Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staffing levels from FY 2007 through FY 2011.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2007 Actual	\$105,718,000	\$94,749,000	\$10,969,000	588
FY 2008 Actual	\$109,625,000	\$97,365,000	\$12,260,000	589
FY 2009 Actual	\$135,359,000	\$121,519,000	\$13,840,000	680
FY 2010 Actual	\$153,919,000	\$134,360,000	\$19,559,000	767
FY 2011 Continuing Resolution	\$154,863,000	\$134,798,000	\$20,065,000	767

Summary of the Budget Request

The FY 2012 budget request for the Animal Drugs and Feeds Program is \$176,458,000. This amount is an increase of \$21,595,000 above the FY 2010 Enacted Budget. The Center for Veterinary Medicine amount in this request is \$117,009,000 supporting 487 FTE. The Field amount is \$59,449,000, supporting 307 FTE.

The base funding for the Animal Drugs and Feeds Program is \$154,863,000, which includes \$101,652,000 for the Center activities and \$53,211,000 for the Field activities.

The Animal Drugs and Feeds Program is committed to meeting its mission of protecting human and animal health. With the base funding, CVM will achieve its responsibilities for the evaluation, approval and surveillance of

- animal drugs,
- food additives,
- feed ingredients
- animal devices.

CVM mission activities increase the availability and diversity of safe and effective products that relieve animal pain and suffering, sustain their health, improve food-producing animal productivity and do not compromise public health.

Base funding also allows the Animal Drugs and Feeds Program to meet the trigger requirements for user fee collections under ADUFA and AGDUFA. These user fees supplement the appropriated portion of the new animal drug review program while enabling the Program to retain user fee supported FTE. With these user fees, the Program will continue to improve the quality and timeliness of the new animal drug and animal generic drug review process.

Prioritizing Prevention

Center Activities (Base Amount: \$35,503,000)

FY 2012 increase for current law user fees: +\$2,775,000 (+\$2,383,000 ADUFA, +\$310,000 AGDUFA and +\$82,000 Food Export Certification)

Initiatives

Transforming Food Safety and Nutrition Initiative: Preventive Controls for Food and Feed Processing (+\$3,000,000; 10 FTE)

CVM will implement a preventive, risk-based system to fully address all aspects associated with the manufacturing, packing, and storage of animal feed. Currently, only medicated feeds are required to be made under GMP regulations in 21 CFR 225. CVM will develop regulations to help the animal feed industry design a systems approach to preventing, eliminating, or reducing to acceptable levels potential risks to human and

animal health. This system will ensure that hazards are properly identified and controls are in place and will help to:

- eliminate or control risks from feed hazards
- establish regulatory limits for feed hazards
- develop guidance documents
- provide training and outreach to regulatory partners and industry.

FDA Regulatory Science and Facilities Initiative: Building Expertise to Regulate New Animal Biotechnology Products (+\$1,850,000; 10 FTE)

CVM faces a revolution at the intersection of agriculture, biomedical sciences, and other cross-disciplinary public health initiatives that challenge our current veterinary, biomedical and food safety capacities. The revolution centers around biotechnology, genetically engineered animals that produce new or improved products. Genetically engineered animals provide the potential for new or improved versions of human and animal drugs that treat human and animal diseases (with biopharm products).

FDA will increase its ability to regulate this complex new technology by hiring and training staff with core scientific capacities to improve the knowledge base and expertise in facilitating the review and potential approval of animal biotechnology products. This initiative is necessary for FDA to fulfill its mission to the public by supporting the creation of a world-class science workforce that will bring much-needed core scientific capacities in animal biotechnology to FDA. Funding this initiative will increase the accuracy and efficiency of FDA review process and reduce adverse health events and the time-to-market period for new animal biotechnology products. In addition, this investment will create a regulatory pathway for animal biotechnology, provide a stimulus to innovations key to public health, increase our stakeholders' understanding of animal biotechnology, and increase public confidence in FDA's ability to regulate this new technology.

FDA Regulatory Science and Facilities Initiative: Nanotechnology (+\$210,000; 0 FTE)

Animal Drugs and Feeds will conduct activities that support the following FDA-wide nanotechnology priorities: (1) laboratory and product testing capacity, (2) scientific staff development and training and (3) collaborative and interdisciplinary research to address product characterization and safety. Together, these priorities will better enable FDA to bring benefits of nanotechnology to bear while reducing its risks.

Field Activities (Base Amount: \$12,372,000)

Initiatives

Transforming Food Safety and Nutrition: Preventive Controls for Food and Feed Processing - FSMA Section 110 (+\$674,000; 0 FTE)

Investments will allow FDA to implement preventive controls in feed processing facilities. ORA will conduct the following activities with the resources in this subprogram

- administer training on preventive controls to both FDA and State investigators. These resources will fund approximately 270 people – ORA investigators and State, Tribal, and Territorial inspectors – to attend a one-week training course utilizing a combination of face-to-face and distance learning mediums.

Transforming Food Safety and Nutrition: Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 (+\$467,000; 2 FTE)

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the animal food and feed supply, and sustainable multi-year infrastructure investments to provide more uniform coverage and safety oversight of the animal food and feed supply. ORA will conduct the following activities with the resources in this subprogram:

- fund 1 FTE to develop and validate certification testing instruments
- fund 1 FTE for program oversight thru ORA audits of regulatory and public health partners to measure performance against FDA program standards

Strengthening Surveillance and Enforcement - A. Strengthening Surveillance

Center Activities (Base Amount: \$13,286,000)

Initiatives

Transforming Food Safety and Nutrition Initiative: Integrated Food Safety System (+\$1,274,000; 5 FTE)

CVM will work with our partners, federal and state, to:

- develop standard lab methods to detect animal feed contamination
- develop and conduct training for food safety officials related to animal feed safety standards
- integrate the scientific and inspection capabilities of both federal and state regulatory agencies.

This standardization will assure all regulatory partners are applying the same requirements in analyzing the safety of the feed supply. This will improve oversight and accountability of our animal feed programs. In addition, CVM will work with our partners to develop a network to share data enabling the regulatory partners to close gaps in our oversight of the feed industry. In particular, the development and enhancement of surveillance networks aimed at coordinating infrastructure - facilities, equipment, and professional expertise of state and federal laboratories. It is critical for FDA to prevent and respond to high priority microbial and chemical contamination events and form the

science basis for feed safety standards, including the development of guidances and regulations.

Transforming Food Safety and Nutrition Initiative: Import Oversight (+\$2,621,000; 8 FTE)

With the increasing amount of animal feed products being imported into the country, FDA will establish new systems to prevent the importation of unsafe feeds rather than rely on detention of a product at the border. This will include assessments of feed safety systems in exporting countries for comparability to the US feed safety systems and establishing an accreditation system for third party certifiers that will review and assess the feed safety systems in other countries. FDA will conduct outreach with international public health agencies to help establish international cooperation and ensure a safe feed supply.

Transforming Food Safety and Nutrition Initiative: NARMS (+\$1,100,000; 1 FTE)

With this increase, FDA will expand the current National Antimicrobial Resistance Monitoring System (NARMS) surveillance and monitoring infrastructure to expand the number of retail meat testing sites, and to test additional high-priority commodities such as seafood and animal feeds. This expansion of NARMS will allow FDA to make more informed science based decisions related to the use of safe and effective antimicrobial drugs for animals, while promoting prudent and judicious use of antimicrobial drugs in animal and human medicine. NARMS is the only National Surveillance program for monitoring changes in antimicrobial resistance in foodborne pathogens.

Field Activities (Base Amount: \$13,843,000)

Initiatives

Transforming Food Safety and Nutrition: Import Oversight – FSMA Sections 201, 301, 302, 305, 306 and 307 (+\$233,000; 1 FTE)

This investment supports a comprehensive prevention-focused import feed and pet food safety program that will rely on the food supply chain such as:

- feed and animal food manufacturers
- processors
- packers
- distributors
- importers.

This program provides assurances that the feed and pet food imported to the United States are safe and meet regulatory requirements. ORA will conduct the following activities with the resources in this subprogram:

- hire 1 FTE to assist in the development, implementation and conduct of Voluntary Qualified Importer Program (VQIP) inspections

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 (\$700,000; 3 FTE)

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide more uniform coverage and safety oversight of the food supply. ORA will conduct the following activities with the resources in this subprogram:

- hire 1 FTE to serve as a National Work Plan Analyst. This FTE will assist ORA with its movements towards an integrated national workplan
- hire 1 FTE to serve as an Official Establishment Inventory (OEI) Coordinator for the field
- hire 1 FTE to serve as a Scientific Coordinator. This resource will support the states as FDA moves to national standards for laboratories

Strengthening Surveillance and Enforcement - B. Strengthening Enforcement

Center Activities (Base Amount: \$8,858,000)

FY 2012 increase for current law user fees: +\$521,000; 2 FTE (Recall)

Field Activities (Base Amount: \$12,087,000)

FY 2012 increase for current law user fees: +\$3,189,000; 20 FTE (+\$2,550,000; 18 FTE Food Reinspection and +\$639,000; 2 FTE Recall)

Initiatives

Transforming Food Safety and Nutrition: Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 (+\$685,000; 3 FTE)

This initiative incorporates CFSAN, CVM, ORA, and Headquarters and Office of the Commissioner (HQ/OC) activities to achieve an integrated food safety system. Budget authority funds for this initiative will enable FDA to support an increase of 33 tissue residue inspections.

Transforming Food Safety and Nutrition: Import Oversight – FSMA Sections 201, 301, 302, 305, 306 and 307 (+\$234,000; 1 FTE)

This investment supports a comprehensive prevention-focused import food and feed safety program that will rely more heavily on those in the food supply chain – food and feed manufacturers, processors, packers, distributors, and importers – to provide assurances that the food and feed imported to the United States are safe and meet regulatory requirements. ORA will conduct the following activities with the resources in this subprogram

- hire 1 FTE to expand existing foreign inspection program

Improving Response and Recovery

Center Activities (Base Amount: \$2,235,000)

Initiatives

Transforming Food Safety and Nutrition Initiative: Integrated Food Safety System (+\$226,000; 1 FTE)

CVM will work with our partners to develop a network of share data. Share data will enable regulatory partners to close gaps in our oversight of the feed industry. In particular, the development and enhancement of surveillance networks aimed at coordinating infrastructure - facilities, equipment and professional expertise of state and federal laboratories. It is critical for FDA to prevent and respond to high priority microbial and chemical contamination events and form the science basis for feed safety standards, including the development of guidances and regulations.

Field Activities (Base Amount: \$9,832,000)

Animal Drug Review

Center Activities (Base Amount: \$24,310,000)

FY 2012 increase for current law user fees: +\$1,794,000 (+\$1,588,000 ADUFA and +\$206,000 AGDUFA)

Initiatives

FDA Regulatory Science and Facilities Initiative: Nanotechnology (+\$90,000; 0 FTE)

Animal Drugs and Feeds will conduct activities that support the following FDA-wide nanotechnology priorities: (1) laboratory and product testing capacity, (2) scientific staff development and training and (3) collaborative and interdisciplinary research to address product characterization and safety. Together, these priorities will better enable FDA to bring benefits of nanotechnology to bear while reducing its risks.

Field Activities (Base Amount: \$2,544,000)

FY 2012 increase for current law user fees: +\$82,000 (+\$65,000 ADUFA and +\$17,000 AGDUFA)

Post-market Safety and Compliance

Center Activities (Base Amount: \$17,460,000)

Initiatives

Protecting Patients: Improving Postmarketing Safety in Animal Drugs (+\$500,000; 3 FTE)

FDA relies on information from adverse event reporting (ADE) to ensure safety of drugs throughout the drug life cycle. With this funding, FDA will acquire scientific and technological resources and expertise necessary to analyze data to improve the safety of animal drugs through a more comprehensive, proactive, and efficient analysis of reported ADE data. Early identification of unsafe and ineffective drugs through a more robust surveillance system will help foster public assurance that FDA is working for their benefit by promoting confidence in the nation's foods and drugs.

Real time surveillance is necessary to prevent injuries and death assuring public confidence that ineffective drugs are detected early on and that public health are not at risk due to a lag in review time. These resources will help provide a real time active surveillance system in detecting animal safety, human use hazards, and product ineffectiveness issues proactively before a crisis arises.

Field Activities (Base Amount: \$2,533,000)

Proposed Medical Products Reinspection User Fee: (+\$134,000; 1 FTE)

Initiatives

Protecting Patients: Increasing Medical Product Inspections (+\$184,000; 1 FTE)

FDA will expand inspections to ensure greater technical assistance and compliance. The increase in inspections will not be fully realized until the end of fiscal year 2014 due to the time it takes to hire and fully train investigators to conduct these complex inspections, especially in the foreign arena.

This component will permit FDA to rise to the challenge of protecting patients in the 21st century. It supports critical international efforts, important internal upgrades to scientific capacity, and essential partnerships with the private sector. With the proposed resources, the component will lead to:

- additional inspection capacity
- improved data collection and risk analysis for medical products
- enhanced postmarket safety assessment.

By September 30, 2012, ORA will complete its hiring of additional employees and will have begun training these employees. By September 30, 2014, once the new employees are fully trained, ORA will conduct an additional 17 domestic Animal Drug Manufacturing /Type A Medicated Articles Inspections.

BA Increase for Pay Costs: +\$309,000 (Center: \$191,000; Field: \$118,000)

Contract and Administrative Savings (Total Program: -\$1,257,000)

The request for \$147,899,000 in total budget authority for the Animal Drugs and Feeds Program also reflects a contract savings reduction of -\$1,257,000. The Center's portion of the savings reduction is -\$795,000 and the Field's portion is -\$462,000.

Center Activities

Contract and Administrative Savings (-\$795,000; 0 FTE)

The Center for Veterinary Medicine (CVM) will achieve contract savings by:

- reducing costs by using existing FDA and center contracts and by identifying other measures to award contracts that can reduce costs
- determining where services can be accomplished in-house rather than by procuring services from outside sources
- using in-house expertise to teach training courses instead of paying contractor services
- streamlining activity time reporting processes to improve efficiency and productivity, which will reduce the need for contract support for this system
- using telework to increase productivity, improve efficiency, and reduce overhead costs for rental space.

Field Activities

Contract and Administrative Savings (-\$462,000; -3 FTE)

The Office of Regulatory Affairs (ORA) will achieve contract savings by:

- reducing administrative support FTE, both in Headquarters and in the ORA field offices
- consolidating tasks and eliminating redundancies to improve productivity and efficiency gains throughout ORA.

Animal Drugs & Feeds Program Activity Data (PAD)			
Animal Drugs & Feeds Workload and Outputs	FY 2010 Actuals	FY 2011 Estimate	FY 2012 Estimate
New Animal Drug Applications (NADAs) ¹			
Received	12	12	13
Completed	13	13	14
Approved	11	11	11
Pending ²	3	2	1
New Animal Drug Application Supplements ^{1,3}			
Received	552	552	552
Completed	493	523	552
Approved	344	344	344
Pending ²	212	241	241
Abbreviated New Animal Drug Applications (ANADAs) ¹			
Received	21	21	21
Completed	32	32	32
Approved	10	10	12
Pending ²	25	14	3
Abbreviated New Animal Drug Application Supplements ^{1,3}			
Received	187	187	187
Completed	196	196	196
Approved	112	112	112
Pending ²	166	157	148
Investigational New Animal Drug (INAD) Files ⁴			
Received	3,377	3,377	3,377
Completed	3,088	3,377	3,379
Pending ²	702	702	700
Generic Investigational New Animal Drug (JINAD) Files ⁴			
Received	271	271	271
Completed	269	271	271
Pending ²	67	67	67
Food (Animal) Additive Petitions	39	39	39
Investigational Food Additive Petitions	89	89	89
Adverse Experience Reports (AERs) ⁵			
Received	52,926	55,000	58,000
Reviewed	11,562	12,100	31,900

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

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

³A 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.

⁴An 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, protocols, technical sections, data sets, meeting requests, memos of conference, and other information.

⁵Received and reviewed in the current fiscal year.

**Combined Field Activities – ORA
Program Activity Data**

Field Animal Drugs & Feeds Program Activity Data (PAD)

Field Animal Drugs and Feeds Program Workload and Outputs	2010 Actual	FY 2011 Estimate	FY 2012 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	2,181	1,938	1,750
Pre-Approval /BIMO Inspections	53	79	79
Drug Process and New ADF Program Inspections	229	205	205 ¹
BSE Inspections	1,721	1,486	1,205
Feed Contaminant Inspections	42	25	25
Illegal Residue Program Inspections	362	400	454 ²
Feed Manufacturing Program Inspections	222	141	141
Domestic Laboratory Samples Analyzed	2,250	2,458	2,458
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	52	66	66
Foreign Pre-Approval/Bioresearch Monitoring Program Inspections	29	45	45
Foreign Drug Processing and New ADF Program Inspections	37	33	33
Foreign Feed Inspections	3	10	10 ³
TOTAL UNIQUE COUNT OF FDA ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	2,233	2,004	1,816
IMPORTS			
Import Field Exams/Tests	5,202	3,600	4,550
Import Laboratory Samples Analyzed	755	740	740
Import Physical Exam Subtotal	5,957	4,340	5,290
Import Line Decisions	237,039	237,162	237,285
Percent of Import Lines Physically Examined	2.51%	1.83%	2.23%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	5,401	6,054	5,670
UNIQUE COUNT OF STATE PARTNERSHIPS ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	124	300	300
State Contract/Coop Agreement Inspections: BSE	5,385	5,800	5,200
State Contract Inspections: Feed Manufacturers	416	350	425
State Contract Inspections: Illegal Tissue Residue	176	550	650
State Partnership Inspections: BSE and Other	124	300	300
State Contract Animal Drugs/Feeds Funding	\$2,532,300	\$2,950,000	\$2,937,853
BSE Cooperative Agreement Funding	\$2,893,500	\$3,000,000	\$3,000,000
State Contract Tissue Residue Funding	\$408,700	\$401,000	\$429,395
Total State Funding	\$5,834,500	\$6,351,000	\$6,367,248
GRAND TOTAL ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	7,758	8,358	7,786

¹ For ORA investigators hired with FY 2012 increases, the full performance year is FY 2014. During the full performance year (FY 2014), the FY 2012 funding increase for inspections will allow ORA to conduct an additional 17 animal drug inspections.

² For ORA investigators hired with FY 2012 increases, the full performance year is FY 2014. During the full performance year (FY 2014), the FY 2012 funding increase for inspections will allow ORA to conduct an additional 33 tissue residue inspections.

³ For ORA investigators hired with FY 2012 increases, the full performance year is FY 2015. During the full performance year (FY 2015), the FY 2012 funding increase for inspections will allow ORA to conduct an additional 12 foreign animal feed inspections.