ANIMAL DRUGS AND FEEDS

The FY 2009 program level budget request for the FDA Animal Drugs and Feeds Program is $119,320,000.

The following table shows a three-year funding history for the Animal Drugs and Feeds Program.

FDA Program Resources Table

	FY 2007 Actual	FY 2008 Enacted	FY 2009 Estimate	FY 2009 +/- FY 2008
Program Level	**$105,718,000**	**$108,560,000**	**$119,320,000**	**$10,760,000**
Center	*$69,331,000*	*$71,261,000*	*$80,357,000*	*$9,096,000*
FTE	*369*	*376*	406	30
Field	*$36,387,000*	*$37,299,000*	*$38,963,000*	*$1,664,000*
FTE	*219*	*219*	225	6
Program Level FTE	**588**	**595**	**631**	**36**
Budget Authority	**$94,749,000**	**$97,037,000**	**$103,534,000**	**$6,497,000**
Center	*$58,362,000*	*$59,738,000*	*$64,714,000*	*$4,976,000*
Field	*$36,387,000*	*$37,299,000*	*$38,820,000*	*$1,521,000*
Food Protection (non-add)	*$74,833,000*	*$76,653,000*	*$82,271,000*	*$5,618,000*
Med. Prod. Safety & Devel. (non-add)	*$19,916,000*	*$20,384,000*	*$21,384,000*	*$1,000,000*
Admin. Savings & Man. Efficiencies (non-add)			*-$121,000*	*-$121,000*
Budget Authority FTE	**537**	**537**	**552**	**15**
User Fees	**$10,969,000**	**$11,523,000**	**$11,525,000**	**$2,000**
Center ADUFA	*$10,969,000*	*$11,523,000*	*$11,525,000*	*$2,000*
Proposed User Fee				
Center Animal Generic Drug			*$4,118,000*	*$4,118,000*
Field Animal Generic Drug			*$143,000*	*$143,000*
User Fee FTE	**51**	**58**	**79**	**21**
Mandatory User Fees			***$2,236,000***	***$2,236,000***
Field Reinspection (non-add)			*$2,169,000*	*$2,169,000*
Center Export Certification (non-add)			*$67,000*	*$67,000*
Mandatory User Fees FTE			**23**	**23**

Animal Drugs and Feeds Program Statutory Authority

Legal Authorities: The FDA Animal Drugs and Feeds Program operates 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*

Allocation Method: Direct Federal/intramural

Program Description and Accomplishments

The FDA 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. In addition, the Center for Veterinary Medicine (CVM) works to protect the health of companion animals. CVM accomplishes these through premarket review, surveillance and compliance monitoring activities designed to prevent marketing of products that are toxic and to support recall of products associated with adverse events.

The authority to regulate animal drugs and medicated feeds derives from the Food, Drug, and Cosmetic Act which was amended by Congress in 1968 to include new authorities relating to animal drugs. The Animal Drugs and Feeds Program is funded through appropriations and user fees. The user fee program, known as the Animal Drug User Fee Act (ADUFA), was enacted in FY 2003 and recommended to be reauthorized for FY 2009.

The Center for Veterinary Medicine (CVM) conducts the activities of the Animal Drugs and Feeds program, with assistance from the Office of Regulatory Affairs (ORA). ORA provides FDA leadership on enforcement, import, inspection, and laboratory policies. Through its Field offices nationwide, ORA supports the Animal Drugs and Feeds Program by conducting pre- and post-market inspections of both domestic and foreign establishments to determine the safety and effectiveness of manufactured products. ORA also monitors and samples imports to ensure the safety of the animal drug and feeds supply. In instances of criminal activity, ORA's Office of Criminal Investigations (OCI) complements the regular Field force. The Field Animal Drugs and Feeds Program is funded by appropriated dollars that allow the Field to perform inspections and fund inspections through State contracts.

The Animal Drugs and Feeds Program executes its regulatory responsibilities in three areas: Premarket and Medical Product Safety, Food and Feed Protection, and Other Postmarket Safety and Effectiveness Activities.

<u>Premarket and Medical Product Safety – Center Activities</u>

* 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.

Under Premarket and Medical Product Safety, the Animal Drugs and Feeds Program is responsible for bringing to market, innovative, high quality, and safe medical products for consumers and animals. Premarket and Medical Product Safety supports the President's vision for transforming healthcare for the 21st century and the Department of Health and Human Services (HHS) priority to transform health through improved regulatory processes that safely make new drugs, procedures, and technology available in less time.

During the premarket review, the program reviews premarket applications of pioneer and generic animal drugs for safety and effectiveness. In addition, under the Minor Use and Minor Species (MUMS) Animal Health Act of 2004, FDA reviews drug conditional approval requests, indexing requests, and new requests for designation to increase the number of safe and effective new animal drug products for minor animal species and uncommon diseases in major animal species. FDA must ensure that the human food derived from treated animals is wholesome and free of harmful drug residues.

Passage of the Animal Drug User Fee Act (ADUFA) of 2003 made user fees available to enhance review performance. ADUFA permits collection of application, product, establishment, and sponsor fees to enhance the animal drug review process. Under ADUFA, FDA agreed to pursue a comprehensive set of six review performance goals. FDA's overall performance to date for the FY 2004 through FY 2007 receipt of cohorts indicates FDA is meeting or exceeding those ADUFA performance goals. Review and action time on 90% of original new animal drug applications and reactivations decreased from 295 days in FY 2004 to 200 days in FY 2007.

During FY 2007, CVM approved 17 original new animal drug applications, 7 significant supplemental applications and 20 significant generic animal drug applications. Examples include Slentrol, the first drug approved for the management of obesity in dogs in the United States, Vetmedin, a new drug for managing the signs of mild, moderate, or severe congestive heart failure in dogs due to certain conditions, and *CERENIA*™, first of a new class of drugs approved in two formulations for prevention and treatment of vomiting in dogs.

In the area of generic animal drugs, CVM has a Generic Animal Drug Team dedicated to the review of generic animal drug applications and submissions that are maintained and reviewed independently under a separate review queue than applications under ADUFA. To ensure that review time for generic animal drugs applications and submissions do not increase due to activities under ADUFA, a baseline of sentinel submission review times averaged over several fiscal years (2001 through 2003) was established. FDA staff continually monitors current year completed review times for these submissions. In addition, CVM has held productive negotiations for a user fee program with the Generic Animal Drug Industry.

Under MUMS, CVM reviews minor species drug conditional approval requests and new requests for designation. In April FY 2007, FDA announced their first conditionally approved new animal drug which was for columnaris disease in catfish. In July 2007, FDA published the final rule on designation of new animal drugs for minor use and species. And in August 2007, the first minor use designations were published for Triolostane VETORYL™, treatment of hyper-adrenocorticism due to adrenocortical tumor in dogs, and Ondansetron 028, prevention of

cisplatin-induced emesis in dogs. Seven new designations were granted in 2007 bringing the total number of designations granted since passage of the MUMS Act in 2004 to 50.

Another growing area is the application of genetically engineered animals. Producing animals through genetic engineering raises potential food and animal safety issues, and CVM needs to act based on a thorough understanding of the scientific and risk issue that are involved. In FY 2007, CVM continued to work with developers of genetically engineered animals to help develop data to ensure that research animals did not enter the food supply and to lead to potential approval for commercialization. In addition, CVM worked on developing a coordinated, science-based approach strategy to regulate genetically engineered animals and their products in CVM and across FDA.

CVM reviews new applications and previously approved new animal antimicrobial drug submissions with respect to antimicrobial resistance and human safety. CVM provides Guidance For Industry #152 as a possible process for evaluating the potential effects of antimicrobial new animal drugs on non-target bacteria as part of the new animal drug application process. In FY 2007, microbial food safety information for 16 different antimicrobial new animal drugs from 14 different sponsors for uses in food-producing animals were reviewed with a number of them successfully meeting CVM's microbial food safety criteria.

CVM conducts regulatory research to support Premarket and Medical Product Safety. Regulatory research activities allow CVM to validate the safety and efficacy of animal derived food and animal health products to ensure approved products are safe to eat for humans and animals. In FY 2007, through a pharmacoknestics/pharmacodynamics program to assess the effects of drugs in diseased animals, CVM scientists are studying the antibiotic tilmicosin in 16 beef steers.

Pre-Market and Medical Product Safety –Field Activities

ORA's Field force conducts preapproval inspections to support CVM's review of New Animal Drug Applications (NADA). The Field inspects manufacturing establishments to determine their ability to manufacture the product to the specifications stated in their application. ORA also 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 people participating in studies are protected.

Food and Feed Protection – Center Activities

The Animal Drugs and Feed Program ensures animal drugs and feed products currently on the market remain safe and effective for consumers by monitoring animal drug and feed products, manufacturers, and adverse events. Seventy-percent of CVM's work is devoted to the safety of the food supply. A key to food safety is reducing the risk of foodborne illnesses that sicken millions of people each year. Some foodborne illnesses are due to harmful or illegal residues in animal products, while others result from microbiological infection. Food and Feed Protection supports the HHS priority to transform health by proactively communicating with providers and patients, and sustains the HHS goal of protecting the public from infectious, occupational, environmental, and terrorist threats and prevents the spread of infectious disease.

During FY 2007, CVM met the challenge of pet food contaminations; melamine and salmonella contaminated pet food**.** CVM dedicated significant staff time on a priority basis to help determine the cause of these contaminations and to resolve these problems. For example, CVM was involved in finding the cause and source of the problems and the reason for its use in pet food. CVM then helped with locating the melamine-containing products and administering the recalls and inspections to ensure compliance with the recalls. All the while, CVM communicated with consumers and industry stakeholders.

Reducing the risk of Bovine Spongiform Encephalopathy (BSE) in the food supply is also a goal of CVM's. In FY 2007, CVM completed work on a final rule, proposed in October 2005, that would amend the 1997 BSE feed rule regulation to remove the highest risk tissues from all animal feed, including pet food, to prevent the spread of BSE. In addition, the revisions would augment the current animal feed regulation by further reducing the risks of BSE associated with cross-contamination and on-farm mis-feeding.

In FY 2007, CVM staff conducted nine BSE regulation training sessions for FDA field staff and state regulators in order to enhance uniformity and quality of domestic inspections, to provide clear detailed instructions for inspections and enforcement follow-up and to provide updates on the science of BSE and animal protein detection methods. CVM, working with ORA, updated the inspection checklist and database to incorporate additional information regarding feed transportation. CVM also added a new inspectional emphasis on targeting BSE inspections of the animal feed transportation industry. CVM issued assignments directing the field to collect information on feed salvagers and transporters to improve our establishment inventory for those types of firms.

Related to regulatory research in the area of BSE, CVM began studies to produce antibodies capable of detecting bovine meat and bone meal. The approach being used would generate antibodies capable of detecting just bovine meat and bone meal, a protein source prohibited from being fed to ruminants, from other bovine proteins exempted under the 1997 Feed Ban. This new test could be used as an adjunct test to the two methods currently used by FDA (Polymerase Chain Reaction (PCR) and feed microscopy) or as a stand-alone test for laboratories that do not have the resources to perform those methods.

Another highly publicized issue in FY 2007 was producing animals through cloning. In FY 2007, CVM released for public comment Animal Cloning: A Draft Risk Assessment, Proposed Management Plan, and a draft Guidance for Industry on the use of cloning technology in animal breeding and the release of animal clones and their progeny into the food supply. Based on more current data and information, including public comments, CVM has updated the Draft cloning document and is moving it through the approval process.

CVM also monitors antimicrobial drugs used in food-producing animals to determine the development of resistance. CVM serves as leader for the National Antimicrobial Resistance Monitoring System (NARMS) program, which monitors trends in the antimicrobial drug susceptibilities of selected enteric bacterial organisms in humans, animals, and retail meats to a panel of antimicrobial drugs important in human and animal medicine. During FY 2007,

extensive review of the NARMS program by the FDA Science Board was completed focusing on 4 major areas: sampling strategies, data reporting and harmonization, coordinated research, and international surveillance activities. CVM has responded to the Board's recommendations, and is prioritizing recommendations for improving the program. The first NARMS Executive report was released in January 2007summarizing data from all three components of the program in an integrated format.

CVM plays a vital role in Pandemic Influenza Preparedness because of uncontrolled use of antiviral drugs in agriculture. In FY 2007, CVM scientists initiated and made significant progress on a multiyear study to develop a method to detect four antiviral drugs in chicken and turkey tissue. Research efforts in FY 2007 focused on developing a liquid chromatography/mass spectrometry based analysis capable of detecting all four antiviral drugs in a single analysis. In addition, CVM continued enforcement against extra label use of antiviral drugs in poultry.

Protecting the food supply from bioterrorism is also part of FDA's mission. CVM works with other Federal agencies to help the country prepare for a biological emergency, natural disaster, or terrorist attack by making sure there is a safe animal feed supply system. In July 2007, CVM and FDA's Center for Food Safety and Applied Nutrition (CFSAN) participated in the conduct of a CARVER + Shock vulnerability analysis of an animal feed manufacturer in a feed producing region in the central part of the United States.

CVM also conducts regulatory research to support bioterrorism. In 2007, CVM scientists developed methods to detect the presence of pesticides and industrial contaminants, such as melamine, that could be introduced into the United States animal feed supplies by bioterrorists. The research is part of a multiyear effort by CVM researchers to develop screening methods intentionally added deleterious substances in animal feeds

<u>Food and Feed Protection – Field Activities</u>
ORA works to ensure that animal drugs and feed products currently on the market remain safe and effective for consumers by monitoring animal drug and feed products and manufacturers. The Field conducts BSE inspections and follow-up investigations and inspections of findings of illegal drug residues in meat and poultry. ORA works to identify the source of adulteration and supports CVM in taking corrective actions against repeat violators to prevent the problem from re-occurring.

ORA inspected 671 registered domestic animal drugs and feed establishments to ensure the safety of marketed animal drugs and animal feeds in FY 2007. By conducting appropriate and effective pre- and post- approval monitoring and surveillance activities the Field seeks to mitigate the effects of harmful products entering into the supply chain.

In 2007, ORA played a lead role in responding to the pet food contamination event. The field coordinated a widespread investigation and massive recall of over 5,300 pet food products by several major companies that resulted following the reports of illnesses and death of both cats and dogs. ORA took aggressive action to protect animal health by assuring prompt removal of contaminated products from the marketplace, thoroughly investigating the situation, establishing import controls to prevent entry of contaminated ingredients, and communicating with the

public. Melamine, a substance typically used as a fertilizer and in the production of plastics but in this case used to boost protein levels in substandard ingredients, was identified in wheat gluten and rice protein concentrate at concentrations as high as 20%. ORA also shares information gathered in trace back investigations with CVM and works with the Center to identify ways to make products safer and prevent future outbreaks from occurring.

ORA works with State counterparts on safety activities. ORA funds grants and cooperative agreements to perform State inspections, in areas such as BSE and Tissue Residue. State inspection staffs also attend ORA-sponsored training courses, which allow these partners to more effectively contribute to FDA's mission.

Other Postmarket Safety and Effectiveness Activities – Center Activities

The Animal Drugs and Feeds Program is responsible for monitoring adverse events and addressing zoonotic diseases. Other Postmarket Safety and Effectiveness Activities support the HHS priority to transform health by proactively communicating with providers and patients, and sustains the HHS goal of protecting the public from infectious, occupational, and environmental threats and prevents the spread of infectious disease.

CVM maintains an early warning system by collecting and reviewing information from Drug Experience Reports (DER). In FY 2007, CVM received approximately 38,000 adverse experience reports, also known as adverse drug events, and was able to review 23,000 of these complaints. As of August 2007, CVM received approximately 5,168 drug experience reports containing promotional labeling and advertising pieces. During the year, CVM reviewed more than 8,700 promotional labeling and advertising pieces submitted by drug sponsors. As a result, the Center in FY 2007 issued five warning letters and four untitled letters requesting discontinuation of violative labeling and advertising materials. The issues ranged from unsubstantiated claims for prevention of zoonotic disease, to omission of pertinent information, and to inappropriate minimization of risk.

During FY 2007, CVM has continued to work on the PV-Works project, which will facilitate the electronic submission of adverse drug experience reports enhancing CVM's ability to process the reports. CVM also facilitated DER reviews by implementing a process that converts paper submissions of DER components, such as promotion and advertising documents and labels, to electronic form. This improvement enables electronic review of an entire DER submission, increasing the efficiency of the review process.

CVM has the responsibility to control the spread of zoonotic diseases, disease that can be transmitted from animals to humans, by pets and exotic animals under the Public Health Service Act provisions, such as monkeypox through exposure to certain African rodents and prairie dogs, and control of salmonellosis through exposure to pet turtles. In FY 2007, CVM developed a brochure for disseminating information on the hazards of handling turtles. CVM continues to work with the turtle growers, states and CDC to address public health concerns.

Other Post-Market Safety and Effectiveness Activities— Field Activities

ORA supports the Center's evaluation of adverse event reports. The Field conducts 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 compliant files during inspections for compliance with FDA reporting regulations.

In the event of a public health incident concerning a disease from animal (i.e. salmonella from pet turtles) ORA will assist CVM by conducting any appropriate investigations.

Five Year Funding Table with FTE Totals

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
2005 Actual	$98,022,000	$90,484,000	$7,538,000	610
2006 Actual	$97,844,000	$89,580,000	$8,264,000	592
2007 Actual	$105,718,000	$94,749,000	$10,969,000	588
2008 Enacted	$108,560,000	$97,037,000	$11,523,000	595
2009 Estimate	$119,320,000	$103,534,000	$15,786,000	631

Budget Request

The FY 2009 President's Budget requests $119,320,000 in program level funding for the Animal Drugs and Feeds Program, including the support of 631 FTE. The Field portion of the request is $38,963,000, supporting 225 FTE. The request represents an increase of $10,760,000 (or 10 percent) over the FY 2008 enacted level in budget authority and user fee amounts. This total funding level meets the required trigger for the Animal Drugs and Feeds Program, enabling FDA to collect the ADUFA user fees that supplement the appropriated portion of the new animal drugs review program. The Program will be able to retain more than 54 user fee supported FTE to continue its efforts to improve the quality and timeliness of the new animal drug review process. The overall increase provides additional budget authority to cover a targeted increase to improve food and feed protection activities, implementation of a grant program provided by the Minor Use Minor Species (MUMS) Animal Health Act, and a cost of living pay increase for the entire Animal Drugs and Feed Program.

<u>Protecting America's Food Supply Initiative</u>
The FY 2009 budget request for the Protecting America's Food Supply Initiative is $82,271,000, an increase of $5,618,000 over the FY 2008 enacted level. Base funding for the Protecting America's Food Supply Initiative encompasses all of the Animal Drugs and Feeds program and its goals for ensuring the safety of animal feeds and the safety of foods that are derived from animals that are used for human food.

The FY 2009 budget requests $5,618,000 for the Protecting America's Food Supply Initiative. Of the total increased amount, $3,913,000 is the Animal Drugs and Feeds program's portion of the initiative that will fund activities addressing risk assessment, emergency response, and risk communication. In addition, $1,705,000 of the amount is for the cost of living pay increase. The CVM portion of the cost of living pay increase is $1,043,000 and the field portion is $662,000.

The cost of living pay raise will contribute to maintaining the Results Act performance targets and program activity estimates at the FY 2008 levels.

The Protect America's Food Supply initiative will allow FDA to accomplish its mission of ensuring the safety of domestic and imported food by implementing priority components of the Food Protection Plan. CVM will undertake efforts to protect America's food supply in three areas: risk assessment, emergency response and risk communications. Under the risk assessment area, CVM will develop mechanisms to protect animal feeds from becoming contaminated with harmful ingredients. CVM will also improve its risk-based safety framework, establish processing and ingredient standards, develop definitions for animal feeds, and update feed labeling standards. CVM plans to improve its emergency response areas by hiring additional scientific staff, reviewing and updating its emergency response plans, and developing better methods for efficiently handling incident information. CVM will develop a risk communication program for disseminating timely and accurate information through a variety of methods to the public and stakeholders.

Under the Protect America's Food Supply Initiative, the ORA's Field Animal Drugs and Feeds Program will also support the Administration's Import Safety Action Plan by targeting inspection resources on areas of feed contaminant and illegal tissue residues that impact on the safety of food products that are consumed by the American public. These resources will allow ORA to perform an additional 20 drug process and new Animal Drugs and Feeds program inspections, 10 feed contaminant inspections, and 20 illegal tissue residue inspections. Additionally, ORA will use these added resources to conduct and additional 35 domestic and 35 import laboratory sample analyses in FY 2009. Through these highly targeted inspections, the ability of ORA to ensure that only safe and effective animal drugs and feeds are available to American consumers will be strengthened.

Modernizing Medical Product Safety and Development Initiative

The FY 2009 budget request for the Medical Product Safety and Development Initiative is $21,384,000, an increase of $1,000,000 over the FY 2008 enacted level. Base funding for modernizing medical product safety and development encompasses all of the Animal Drugs and Feeds program and its goals for ensuring the safety of animal drugs and medicate feeds. The increase will permit CVM to implement a grant program provided under the Minor Use Minor Species (MUMS) Animal Health Act. The grant program will provide incentives for developing designated new animal drugs to treat minor species and uncommon diseases in major animal species (minor use) providing additional public health protection from animal diseases that can be transferred to humans and from illegal drug residues in food derived from treated animals.

Administrative and Management Efficiencies

The Animal Drugs and Feeds program will absorb $121,000 in administrative savings and management efficiencies by seeking internal leveraging opportunities and capturing efficiencies to benefit programs and stakeholders. Specifically, agency-wide administrative and management efficiencies include business process improvement projects, improvements achieved through Business Review Boards, Bioinformatics and Science Board reviews, and efficiencies achieved through Strategic Action Plan initiatives and other crosscutting workgroups.

User Fees Inflationary Increase

The ability to collect ADUFA user fees expires on September 30, 2008. The ADUFA user fee collection estimate is $13,698,000 and 62 FTE for FY 2009, with the Animal Drugs and Feeds program portion totaling $11,525,000 and 58 FTE, an increase of $2,000 over the FY 2008 President's Budget. FDA may need to amend its budget request when Congress reauthorizes ADUFA II and establishes new performance goals and fee levels.

Enacted in November 2003, ADUFA helps the FDA, through a strengthened animal drug pre-market review program, to provide greater public health protection by ensuring that animal drug products that receive FDA approval are safe and effective, and are readily available for both companion animals and animals intended for food consumption. ADUFA provides a cost-efficient, high quality animal drug review process that is predictable and performance driven.

Proposed User Fee Increase

The Animal Drugs and Feeds program proposes receiving user fee resources for new Animal Generic Drug User Fees (AGDUFA) generating resources that will allow FDA to improve product review performance and reduce review time. FDA is requesting an increase for AGDUFA user fee collection authority that will provide an additional $4,831,000 and 22 FTE of which $4,261,000 and 21 FTE will go to the Animal Drugs and Feeds Program.

The process for the review of generic animal drug applications is not as predictable or speedy as both FDA and industry would like despite management initiatives to increase efficiency. Increasing review staff through user fee revenues will shorten the time to approval, thereby making lower cost medications available to the food animal production industry, veterinary practitioners, companion animal owners, and the general public sooner.

Animal Drugs and Feeds Program Outputs / Outcomes Table

#	Key Outcomes/Outputs	FY 2004 Actual	FY 2005 Actual	FY 2006 Target	FY 2006 Actual	FY 2007 Target	FY 2007 Actual	FY 2008 Target	FY 2009 Target
Long-Term Objective 3.1: Increase the number of safe and effective new medical products available to patients.									
1	Complete review and action on original NADAs & reactivations of such applications received during FY 2009. (243201) (output)	100%	100%	90% w/in 230 days	100%	90% w/in 200 days	01/09	90% w/in 180 days	90% w/in 180 days
Long-Term Objective 4.2: Detect safety problems earlier and better target interventions to prevent harm to consumers.									
2	Number of domestic and foreign high risk animal drug and feed inspections. (244202) (output)	NA	NA	NA	NA	NA	NA	233[1]	233
3	Number of targeted prohibited material BSE inspections (244203) (output)	647	588	516	516	490	523	490	490

1. Promote safe and effective animal drug availability ensuring public and animal health by meeting ADUFA performance goals. (243201)

Context: The FY 2008 goal and target reflects one of the ADUFA user fee goals and the Center's move toward completion of 90% of specified new animal drug submission reviews within statutorily mandated time frames over a five-year period under the initial implementation of ADUFA in FY 2004. The FY 2009 goal assumes reauthorization of ADUFA and continued achievement of statutory review timeframe(s).

Performance: Based on the final performance update for FY 2006, FDA exceeded all ADUFA performance goal(s). FDA reviewed and acted on all seven (7) original NADAs and reactivations of such applications received during FY 2006 within 230 days. Final performance numbers for FY 2007 will not be available until January 2009. However, as of September 30, 2007, the preliminary performance assessment for FY 2007 data indicates FDA has exceeded the ADUFA goal(s). Additional information is forthcoming in the FY 2007 ADUFA Performance Report.

2. Number of domestic and foreign high risk animal drug and feed inspections. (244202)

Context: Important features of the risk-based strategy for this revised goal will be to reduce the occurrence of illness and death by focusing resources on manufacturing establishments and other industry components that have the greatest potential for risk. This will result in different inspection frequencies as establishment processes come under control and present lower risk, or as new risks are identified. In FY 2008, this revised goal will focus on pre-market approval

[1] This new FY 2008 goal is the result of a concerted effort to develop a better high risk measure for Animal Drugs and Feeds. This new goal guarantees that the riskiest establishments are inspected, thus better protecting the public health.

inspections and implementing risk-based cGMP inspection plans for animal drug and feed manufacturing facilities that will utilize risk modeling to identify the highest risk firms to be inspected. The FY 2008 target is being maintained into FY 2009 because this is a new, risk-based goal for which we have no historical experience, and are unsure how the new site-selection methodology will evolve.

Performance: In FY 2007, FDA exceeded the previous registered animal drugs and feed establishments' statutory inspection goal of 620 by inspecting 671 registered establishments. The FY 2008 target reflects the new high-risk prioritized goal for which accomplishment data will not be available until the end of FY 2008.

3. Number of targeted prohibited material BSE inspections. (244203)

Context: FDA developed a comprehensive public protection strategy of education, inspection and enforcement action to ensure compliance with the Bovine Spongiform Encephalopathy (BSE) feed regulations. Using an inventory of all known renderers and feed mills processing products containing prohibited material, FDA will continue to conduct annual inspections to determine compliance with the BSE feed rule. Inventories of these firms may vary from year to year based on changes at the firm such as consolidations, business closures, relocations, etc. The FY 2008 target is being maintained into FY 2009 because this goal is a 100% accomplishment goal; therefore, the target is set to the number of known manufacturers at the beginning of the fiscal year.

Performance: In FY 2007, FDA completed the inspection of all 523 firms known to be processing with prohibited materials as part of a concentrated effort to prevent an outbreak of BSE in the U.S.

Animal Drugs and Feeds Program Activity Data (PAD)

Animal Drugs & Feeds Workload and Outputs	FY 2007 Actual	FY 2008 Estimate	FY 2009 Estimate
New Animal Drug Applications (NADAs)[2]			
Received	21	20	20
Completed	22	22	23
Approved	18	19	19
Pending [3]	7	5	2
New Animal Drug Application Supplements [1, 4]			
Received	605	605	605
Completed	610	618	627
Approved	496	540	540
Pending [2]	187	174	152
Abbreviated New Animal Drug Applications (ANADAs) [1]			
Received	23	24	27
Completed	37	35	32
Approved	20	18	18
Pending [2]	38	27	22
Abbreviated New Animal Drug Application Supplements [1, 3]			
Received	142	143	149
Completed	88	86	82
Approved	71	69	69
Pending [2]	157	214	281
Investigational New Animal Drug (INAD) Files [5]			
Received	2457	2457	2464
Completed	2491	2491	2491
Pending [2]	320	286	259

[2] Includes originals and reactivations. If the application is not approvable, the sponsor may submit additional information until the Agency is able to approve the application.
[3] Reflects submissions (received during the fiscal year) which still require review.
[4] A supplemental application is a sponsor request to change the conditions of the existing approval. They can be significant (a new species or indication), or routine (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.
[5] An INAD or JINAD file is established at the request of the sponsor to archive all sponsor submissions for a phased drug review including: request for interstate shipment of an unapproved drug for study, protocols, technical sections, data sets, meeting requests, memos of conference and other information.

Animal Drugs and Feeds Program Activity Data (PAD)

Animal Drugs & Feeds Workload and Outputs	FY 2007 Actual	FY 2008 Estimate	FY 2009 Estimate
Generic Investigational New Animal Drug (JINAD) Files 4			
Received	145	160	160
Completed	149	140	140
Pending 2	38	58	78
Food (Animal) Additive Petitions [6]	30	30	30
Investigational Food Additive Petitions	64	64	64
Adverse Experience Reports (AERs)			
Received	38,000	40,000	43,000
Reviewed	23,000	25,000	27,000

[6] Non-drug substances added to animal feed are considered Food Additive Petitions and require review and approval.

Field Animal Drugs and Feeds Program Activity Data (PAD)

Field Animal Drugs & Feeds Workload and Outputs	FY 2007 Actual	FY 2008 Estimate	FY 2009 Estimate
DOMESTIC INSPECTIONS			
Pre-Approval/Bioresearch Monitoring Program Inspections	36	79	79
Drug Process and New ADF Program Inspections	190	171	191
BSE Inspections	1765	2594	2594
Feed Contaminant Inspections	29	20	30
Illegal Tissue Residue Program Inspections	176	240	260
Feed Manufacturing Program Inspections	326	141	141
State Contract/Coop Agreement Inspections: BSE	5979	4684	4700
State Contract Inspections: Feed Manufacturers	418	354	336
State Contract Inspections: Illegal Tissue Residue	310	310	350
State Partnership Inspections: BSE and Other	346	600	600
Total Above FDA and State Contract Inspections	**9575**	**9193**	**9281**
State Contract Animal Drugs/Feeds Funding	$2,030,000	$2,233,300	$2,550,000
BSE Cooperative Agreement Funding	$3,000,000	$3,000,000	$3,000,000
State Contract Tissue Residue Funding	$452,000	$323,000	$342,801
Total State Funding	**$5,482,000**	**$5,556,300**	**$5,892,801**
Domestic Laboratory Samples Analyzed	3182	1775	1810
IMPORT/FOREIGN INSPECTIONS			
Foreign Bioresearch Monitoring Inspections	25	22	24
Foreign Drug Processing & New ADF Program Inspections	14	10	15
Total Above Foreign FDA Inspections	**39**	**32**	**39**
Import Field Exams/Tests	3656	4500	4500
Import Laboratory Samples Analyzed	717	655	690
Import Physical Exam Subtotal	4373	5155	5190
Import Line Decisions	235,571	245,592	256,039
Percent of Import Lines Physically Examined	1.86%	2.10%	2.03%