ANIMAL DRUGS AND FEEDS

Introduction

FDA's Animal Drugs and Feeds Program summarizes the budget program requirements that justify a $106,332,000 request for FY 2008. The Animal Drugs and Feeds program narrative has four sections:

- summary of FDA's program resources, historical funding and FTE levels
- description of program functions of the Center for Veterinary Medicine and related Field support from the Office of Regulatory Affairs
- effects of the full year FY 2007 continuing resolution on the Animal Drugs and Feeds Program
- description of the program resources changes, base resource activities, program accomplishments, program activity data, and performance plan analysis.

The Animal Drugs and Feeds Program funding table shows a three year span of program level resources, budget authority resources, and proposed user fees enacted in FY 2006, displayed in the FY 2007 President's Budget and FY 2007 Continuing Resolution, and proposed in the FY 2008 President's budget request.

	FY 2006 Actuals	FY 2007 Continuing Resolution	FY 2007 President's Budget	FY 2008 President's Budget	Increase or Decrease
Program Level	**$97,844,000**	**$89,581,000**	**$105,031,000**	**$106,332,000**	**$1,301,000**
Center	*$63,838,000*	*$54,739,000*	*$69,253,000*	*$70,558,000*	*$1,305,000*
FTE	*375*	*298*	*396*	*400*	*4*
Field	*$34,756,000*	*$34,842,000*	*$35,778,000*	*$35,774,000*	*($4,000)*
FTE	*217*	*204*	*219*	*219*	*0*
Total FTE	**592**	**502**	**615**	**619**	**4**
Budget Authority	**$89,580,000**	**$89,581,000**	**$95,494,000**	**$94,809,000**	**($685,000)**
Center	*$54,824,000*	*$54,739,000*	*$59,716,000*	*$59,035,000*	*($681,000)*
Field	*$34,756,000*	*$34,842,000*	*$35,778,000*	*$35,774,000*	*($4,000)*
Pay Increase	--	--	--	*$1,469,000*	*$1,469,000*
Outreach, Coordination and Research Reduction	--	--	--	*($2,154,000)*	*($2,154,000)*
Total FTE	**538**	**502**	**561**	**561**	**0**
User Fees	**$8,264,000**	**$0**	**$9,537,000**	**$11,523,000**	**$1,986,000**
ADUFA - Center	*$8,264,000*	*$0*	*$9,537,000*	*$11,523,000*	*$1,986,000*
Total FTE	**54**	**0**	**54**	**58**	**4**

The historical funding and FTE levels table shows a five year history of program level funding, budget authority funding, user fee funding, and program level FTE.

Historical Funding and FTE Levels

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
2004 Actuals	$84,441,000	$83,358,000	$1,083,000	595
2005 Actuals	$98,022,000	$90,484,000	$7,538,000	610
2006 Actuals	$97,844,000	$89,580,000	$8,264,000	592
2007 Continuing Resolution	$89,581,000	$89,581,000	$0	502
2007 President's Budget	$105,031,000	$95,494,000	$9,537,000	615
2008 President's Budget	$106,332,000	$94,809,000	$11,523,000	619

Statement of Budget Request

The Animal Drugs and Feeds Program requests $106,332,000 in program level resources to accomplish its statutory mission and to protect and promote the public health. The Program is engaged in five primary mission critical activities:

- enforcing applicable provisions of the Federal Food, Drug and Cosmetic Act, and other authorities
- completing the process review of premarket applications as quickly as possible in order to increase the availability and diversity of safe and effective veterinary products ensuring that these products are safe, wholesome, and free of drug residue when they reach the consumer and relieving animal pain and suffering
- monitoring marketed animal drugs and feed products to minimize harm to humans or animals that might arise from the use of these products
- accomplishing postmarket work through science-based review of drug experience reports, nationwide surveillance and monitoring systems, and compliance programs
- engaging in inspections, sample collections, analysis, investigations, and appropriate regulatory actions to control volatile goods and firms with the support of FDA’s field force.

Program Description

The Animal Drugs and Feeds Program is administered by FDA's Center for Veterinary Medicine (CVM) and supported by the Office of Regulatory Affairs (ORA) field force. The authority to regulate animal drugs and medicated feeds is derived from the Food, Drug, and Cosmetic Act, which Congress amended in 1968 to include new authorities relating to animal drugs. These amendments ensure that animal drugs are safe and effective for their intended uses and that the drugs do not result in unsafe residues in foods.

In 2004, Congress enacted the Minor Use and Minor Species Animal Health Act, a statute designed to help make more medications legally available to veterinarians and animal owners to treat both minor animal species and uncommon diseases in major animal species. The Act is designed to help pharmaceutical companies overcome the financial roadblocks they face in providing animal drugs that have limited demand.

The safety of the food supply is a paramount concern for the Program, as the average American consumes nearly 200 pounds of meat and fish, 30 pounds of eggs, and 585 pounds of dairy products each year. While most of these food products are regulated by the USDA, FDA ensures that animal drugs and feeds used in the care of food producing animals do not result in unsafe residues in the food harvested or produced from these animals. In addition, CVM works to protect the health of companion animals through surveillance and compliance monitoring activities designed to prevent marketing of products that are toxic and to support recall of products associated with adverse reactions.

The Program's Scope is Far-Reaching.

CVM's customers consist of:

- 299 million humans in the U.S.
- 130 million dogs and cats
- 5 million horses
- 9 billion chickens
- 266 million turkeys
- 97 million cattle
- 61 million pigs
- 11 million sheep and goats

CVM's core functions are premarket review, consumer and patient safety, and product safety and compliance. Some of CVM's key program areas include the prevention of antibiotic resistance and Bovine Spongiform Encephalopathy (BSE), the safety of food derived from genetically modified animals, and the health of companion animals.

<u>Field Animal Drug and Feeds Activities</u>

ORA's field force supports CVM by conducting preapproval inspections of both domestic and foreign establishments and other premarket-related activities. These activities include bioresearch monitoring of clinical research, pre-approval inspections and laboratory method validations for premarket application decisions, and inspections

of manufacturing facilities to determine if the factory is able to manufacture the product to the specifications stated in their application.

ORA also supports CVM by conducting postmarket inspections of animal drugs and feeds, including BSE and other high risk inspections on an annual basis. ORA also monitors and samples imports to ensure the safety of the food supply. In addition to overseeing regulated products on a surveillance, or "for cause" basis, ORA staff respond to emergencies and investigate incidents of product tampering, terrorist events, or natural disasters that may impact FDA-regulated goods. ORA's counterterrorism program monitors the safety and security of the feed supply.

Effects of Full Year FY 2007 Continuing Resolution

The analysis in this justification assumes funding levels for FY 2007 based on the enactment of the President's FY 2007 budget for the Animal Drugs and Feeds program. For comparison purposes, FDA budget tables also include a column in the FDA budget tables that reflects an FY 2007 Continuing Resolution (CR) level in the event that Congress enacts this level of appropriations for the remainder of FY 2007.

If FDA receives the CR rather than the FY 2007 President's budget request, this 25 percent reduction in workforce and 21 percent reduction in resources will have significant impact on FY 2007 performance for the Animal Drugs and Feeds Program:

- The ADUFA program will terminate, resulting in a reduction in force (RIF) of 54 user fee FTEs and the reversal of performance and management process improvements (see the Animal Drugs and Feeds Performance Appendix for detailed impact regarding loss of the ADUFA program).

- Not receiving the $3.223 million in the President's Budget Request for CVM's Pandemic Influenza Preparedness will have negative public health consequences resulting from the loss of activities, including the inability to develop a method to detect illegal use of antiviral drugs in poultry in order to maintain effectiveness of antiviral drugs needed to treat humans infected with pandemic avian influenza.

- Twenty-three (23) CVM budget authority FTE will be lost in order to pay for increases in pay, rent, and White Oak, and the loss of ADUFA, resulting in a decrease in performance of for-cause actions against firms suspected of violating the ruminant feed ban rule, decrease performance of research activities associated with animal feed safety, and decrease statutory mandated review of periodic drug experience reports and adverse drug events for animal drugs.

Field Animal Drugs and Feeds Activities

If FDA receives the CR rather than the FY 2007 President's budget request, this will have significant impact on FY 2007 performance for the Field Animal Drugs and Feeds Program:

- The animal drugs and feeds establishments performance goal will decline by 106 establishment inspections with FDA not meeting its statutory inspection requirement of biennial inspections for the first time.

- Domestic and Foreign Pre-approval and Bioresearch Monitoring inspections will be reduced by 75 inspections as a result of reduced travel funds, reduced numbers of investigators, and the elimination of the Anima Drug User Fee Act program.

- Maintaining State funding for BSE inspections will severely limit flexibility in operating funds for travel, training, and coordination with States and industry.

- Resources for investigation of suspect products and firms will be limited to those presenting the highest risk.

- Funding under the continuing rate causes a loss of 13 FTE for the Field Animal Drugs and Feeds Program.

If FDA receives the CR rather than the FY 2007 President's budget request, this will have significant impact on FY 2008 performance for the Animal Drugs and Feeds Program:

- Severely injured by the loss of the ADUFA program in FY 2007 and the consequential reputation in the job market, the Program would not be able to hire replacement staff for several years and then only with substantial assurances of longevity.

- Review times for animal drugs will double until new staff is hired and trained to enhance the knowledge base of the review organization.

- The Program will not meet its performance goals.

Field Animal Drugs and Feeds Activities

If FDA receives the CR rather than the FY 2007 President's budget request, this will have significant impact on FY 2008 performance for the Field Animal Drugs and Feeds Program:

- Any new hires are unlikely to exceed 25 percent of typical productivity which means that FY 2008 inspection and laboratory analysis targets may not be met and ORA work will include a higher proportion of entry level tasks than in FY 2006.

- Despite ORA's desire to pursue risk based activities, newly hired employees will require intensive coaching and supervision and may need to assist an experienced ORA specialist for several months before assuming responsibility for complex risk based activities.

- Although ORA should be able to award contracts and grants for the increased sums authorized in the FY 2008 budget, reduced staffing will delay activities funded by the contracts and grants.

Program Resource Changes

Budget Authority

Pay Increase: +$1,469,000
The FDA request for pay inflationary costs is essential for FDA to accomplish its public health mission. Eighty percent of FDA's budget supports the agency workforce. Of this, payroll costs account for almost sixty-percent of the total budget. The increase will allow FDA to maintain staff levels, including a national cadre of specially trained scientific staff. The total estimate for pay increases is $21,773,000. The Animal Drugs and Feeds portion of this increase is $1,469,000. These resources are vitally important for FDA to fulfill its mission to protect the public health by ensuring safe and effective animal drug products reach the market in a timely manner, and by monitoring these products for continued safety after they are used.

Outreach, Coordination, and Research Reduction: -$2,154,000
This proposed reduction reallocates resources from lower priority activities to higher priority activities proposed in the FY 2008 budget. FDA must ensure its resources are used for maximum public health impact. This requires FDA to make funding decisions based on risk-based prioritization of needs. FDA diligently assessed research and outreach activities and proposes a reduction of $3,875,000 in FY 2008. The Animal Drugs and Feeds portion of this reduction is $2,154,000. This reduction contributes to the FDA's ability to fund cost of living pay increases, medical product and food safety initiatives, and rent increases in FY 2008.

CVM will make reductions in four primary areas:

- development of improved Polymerase Chain Reaction (PCR) methodology for the detection of prohibited proteins in animal feed, which support the enforcement of the Agency's BSE Feed Ban

- evaluation of commercially available rapid tests for animal proteins in animal feeds

- development of multi-drug methods for detecting residues in honey

- development and validation of rapid screening methods for detection of pathogens in animal feeds and feed commodities.

User Fees

Current Law User Fees

ADUFA: + $1,986,000 and + 4 FTE
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. ADFUA provides a cost-efficient, high quality animal drug review process that is predictable and performance driven.

The ability to collect ADUFA user fees expires on September 30, 2008. The statute authorizes fee collection to include up to three month of operating costs to carry over into FY 2009 allowing the program to operate if reauthorization is not completed by September 30, 2008. To achieve this carry over reserve and factor in the inflation levels allowed by statute, an increase of $2,092,000 in fee collections is required, for a total of $13,696,000. The Center for Veterinary Medicine's portion of the ADUFA increase is $1,986,000 for a total of $11,523,000.

ADUFA user fees help CVM perform five activities:

- hire additional staff necessary to achieve the review capacity dictated by ADUFA
- advance the work already begun on management initiatives, including quality business systems and new information technology systems and solutions
- develop improved standard operating procedures for review processes and develop scientific policies for review staff
- clarify current FDA thinking by issuing guidance to the industry
- direct and target training and educational opportunities for staff and management to improve the knowledge base of the review organization.

Proposed Fees (Non-Add)

Reinspection User Fee (Mandatory): $2,169,000 and 17 FTE (Non-Add)
The FY 2008 budget includes $23,276,000 in budget authority for reinspection related activities. The Budget also proposes a new mandatory user fee to support reinspection activities. Once legislation is enacted, which authorizes FDA to collect this user fee, the Administration will work with Congress to recategorize these fees as discretionary.

FDA conducts follow-up inspections to verify that a firm implements action to correct violations discovered during an inspection or stemming from a warning letter. This

new user fee will amend the Food, Drug, and Cosmetic Act to permit FDA to collect and retain fees to recover from the inspected firm the full cost of reinspections that FDA performs to ensure that their products and facilities comply with current FDA regulations. FDA currently funds this activity through discretionary appropriations. The total proposed collections for the Agency in FY 2008 are $23,276,000, with $2,169,000 of the collections being allocated to the Field component of the Animal Drugs and Feeds program.

Food and Animal Feed Export Certification User Fee: $67,000 (Non-Add)
The FY 2008 budget includes $3,741,000 in budget authority for export certification related activities. The Budget also proposes a new mandatory user fee to support export certification activities. Once legislation is enacted, which authorizes FDA to collect this user fee, the Administration will work with Congress to recategorize these fees as discretionary.

FDA collects user fees of up to $175 per certificate issued for export certificates for drugs, animal drugs and devices as authorized by Section 801 (e)(4)(B) of the Act. However, there is no similar authority for collecting user fees for export certificates for foods or animal feed. This new user fee will amend the Food, Drug, and Cosmetic Act to permit FDA to collect the cost of food and animal feed export certificate-related activities through user fees. Private sector exporters would bear the cost of the program, but would reap its benefits through the Agency's enhanced ability to facilitate exports of their products. FDA currently funds this activity through discretionary appropriations. The total proposed collections for the Agency in FY 2008 are $3,741,000, with $67,000 of the collections being allocated to the Animal Drugs and Feeds program.

Justification of Base

The Animal Drug and Feeds Program selected five program areas of high importance to speak to in the justification of base. These five areas are increase premarket drug availability, regulate animal biotechnology products, safeguard against Bovine Spongiform Encephalopathy (BSE), ensure food safety, and protect against bio-terrorism. These five program areas capture how CVM spends its base funding.

These program areas support all of FDA's strategic goals to enhance patient and consumer protection and empower them with better information about regulated products, increase access to innovative products and technologies to improve health, and to improve product quality, safety and availability through better manufacturing and product oversight. The table below shows how each program area fits into FDA's strategic goals.

	FDA Strategic Goals		
	Enhance Patient and Consumer Protection and Empower Them With Better Information about Regulated Products	Increase Access to Innovative Products and Technologies to Improve Health	Improve Product Quality, Safety and Availability Through Better Manufacturing and Production Oversight
Program Area			
Increase Premarket Drug Availability		X	X
Regulate Animal Biotechnology Products		X	
Safeguard Against BSE	X		X
Ensure Food Safety	X		X
Protect Against Bio-Terrorism			X

Increase Premarket Drug Availability

FDA increases the number of safe and effective new animal drug products, including generic drugs, by increasing the efficiency, quality, and predictability of the new animal drug review process. The availability of safe and effective animal drugs assures food animal producers and animal owners that the animal drug products are safe and effective for the animals and that the human food derived from treated animals is wholesome and free of harmful drug residues.

Since the inception of the Animal Drug User Fee Act (ADUFA) of 2003, FDA has protected public health by ensuring that an adequate supply of animal drug products are approved as safe and effective, and are readily available for both companion and food

animals. In addition, the generic animal drug review process increases the number of safe and effective new animal drugs available for use by alternative sources beyond the pioneer manufacturer.

The Minor Use and Minor Species Animal Health Act of 2004 (MUMSAHA) helps make more medications legally available to veterinarians and animal owners to treat minor animal species and uncommon diseases in the major animal species. The Minor Use and Minor Species (MUMS) program is the animal equivalent of human orphan products.

With the base resources CVM's activities are focused in six areas:

- CVM furthers implementation of ADUFA and increases the availability of safe and effective animal products, while working with regulated industry to minimize drug development time.
- CVM meets all performance goals defined under ADUFA.
- CVM conducts pre-submission conferences, meetings, and workshops with industry and develops policy and practical guidance documents for industry to clarify current FDA thinking.
- CVM reviews generic new animal drug applications.
- CVM prepares implementing regulations for the MUMSAHA.
- CVM evaluates applications for the Application Integrity Policy to assure the accuracy and conduct of studies to support approval of new animal drugs.

FDA Issues Proposed Regulations for MUMS Indexing

FDA issued proposed regulations to implement Section 572 of the Federal Food, Drug, and Cosmetic Act entitled "Index of Legally Marketed Unapproved New Animal Drugs for Minor Species" or the "the Index." These regulations propose administrative procedures and criteria for index listing a new animal drug for use in a minor species. Such indexing provides a basis for legally marketing an unapproved new animal drug intended for use in a minor species.

The MUMS Animal Health Act of 2004 authorizes the FDA to establish new regulatory procedures intended to make more drugs legally available to veterinarians and animal owners for the treatment of minor animal species and uncommon diseases in major animal species.

Increase Premarket Drug Availability – Field Activities
ORA conducts pre-approval inspections to verify the data submitted in New Animal Drug Applications and to assess the firm's ability to manufacture products in accordance with Current Good Manufacturing Practices.

Regulate Animal Biotechnology Products

The application of biotechnology to the production of animals, and products derived from animals, continues to grow. In order to address potential food and animal safety concerns raised by food products used for human consumption derived from animal biotechnology, FDA needs a through understanding of the scientific and risk issues that animal biotechnology presents. FDA intends to develop an appropriate approach to regulating animal biotechnology that addresses the concerns of the general public and other stakeholders. With the base resources CVM's activities are focused in three areas:

- CVM works with other Federal agencies to clearly define FDA's role in the regulation of animal biotechnology products.
- CVM provides educational information on biotechnology products.
- CVM works with animal biotechnology firms while a policy on transgenic animals is prepared.

Safeguard against Bovine Spongiform Encephalopathy (BSE)

Variant Creutzfeldt-Jakob Disease (vCJD), a fatal brain disease in humans, results from exposure to the agent that causes BSE in cattle. The food supply is a vehicle for exposure to vCJD. To prevent the establishment and spread of BSE through animal feed, FDA finalized a regulation in 1997 entitled, "Animal Proteins Prohibited from use in Animal Feed." This regulation prohibits the use of high risk materials in ruminant cow feed and significantly reduces the risk of transmission of vCJD in humans. With the base resources CVM's activities are focused in three areas:

- CVM evaluates the effects of risk management principles on the spread and the rate of elimination using the Harvard BSE Risk Assessment.
- CVM enforces for-cause actions against firms suspected of violating the ruminant feed ban rule.
- CVM maintains a database and a web-based report that summarizes the most current results of BSE inspections.

Safeguard Against BSE – Field Activities
FDA works closely with USDA and state agricultural and veterinary agencies to implement BSE regulations and control imported products that may put the public at risk. FDA regulates many products that could contain specified risk materials,

including vaccines, foods, dietary supplements, cosmetics, animal drugs, and animal feeds. FDA has established a comprehensive monitoring system to identify products that may pose a health risk and to ensure that they do not enter the U.S. FDA continues to find a very high level of compliance with the 1997 rule that prohibits the inclusion of most animal protein in feeds for cattle and other ruminants. ORA's BSE activities are focused in four areas:

- leveraging with state agencies by funding contract and cooperative agreement inspections of feed mills and renderers, and conducting compliance, follow-up, and audit inspections to state contracts

- collecting and analyzing domestic and import feed and feed component samples for BSE-related contaminants to ensure proper labeling of animal feeds and feed components

- conducting annual BSE inspections of all known renderers and feed mills processing products containing prohibited material; and, any firm found to be in violation of the regulation will be re-inspected in a timely manner

- conducting a sampling program for animal feeds domestically and those detained at U.S. ports of entry that contain ingredients possibly derived from contaminated animals.

Ensure Food Safety

FDA enables consumers to make better, more informed decisions about FDA-regulated products and promotes improved patient and consumer safety by reducing risk from foodborne illness. Millions of people get sick annually from eating contaminated food. Some foodborne illnesses are due to harmful or illegal residues in animal products, while others result from microbiological infection. In order to safely manage animal drug use domestically and internationally, and have safe food from farm to table, CVM must have the knowledge to make proactive and sound, science-based decisions With the base resources CVM's activities are focused in six areas:

- CVM monitors, samples, and investigates reports of pesticide, chemical, and microbiological contamination of animal feed and take enforcement actions as appropriate.

- CVM reviews new applications and previously approved new animal antimicrobial drug

Outbreak of Salmonella in Dog Treats

An outbreak of *Salmonella Infantis* induced salmonellosis associated with dog treats of animal origin occurred in Canada and prompted CVM to investigate similar products sold in the United States. Of 158 dog treats sampled nationwide, 41% (65) were positive for Salmonella, including antimicrobial-resistant variants. The findings prompted CVM to issue a warning to the public on the potential health hazards of dog treats. The rapid response by CVM prevented the outbreak from expanding to the United States.

submissions with respect to antimicrobial resistance and human food safety considerations.

- CVM screens and surveys animal feeds and animal feed components for the presence of bacterial pathogens.

- CVM reviews new animal food additive submissions to improve safety of edible animal products.

- CVM continues comprehensive risk-based Animal Feed Safety System activities.

- CVM maintains early warning systems by collecting information from Drug Experience Reports and Adverse Event Reports.

In the area of tissue residues, use of unapproved drugs or the improper use of approved drugs in domestic food-producing animals can result in unsafe residues in human food. In order to protect public health from illegal drug residues, With the base resources CVM's activities are focused in three areas:

- CVM investigates reports of drug, pesticide, and chemical contaminant residue violations in edible animal tissues and takes enforcement actions as appropriate.

- CVM leverages FDA's Tissue Residue Information Management System with USDA's Residue Violation Information System on residue violators/violations to maintain tissue residue and feed contaminants compliance programs.

- CVM provides technical support on residue findings of fluoroquinolones in imported seafood.

In the area of animal drug compounding, there is a potential for causing harm to public health and to animals when drug products are compounded, distributed, and used in the absence of adequate and well-controlled safety and effectiveness studies. In the effort to regulate animal drug compounding and the marketing of unapproved drugs CVM develops and implements intervention measures to address the shipment, receipt, and use of bulk active pharmaceutical ingredients in compounding animal drugs.

<u>Ensure Food Safety – Field Activities</u>
In order to ensure the safety of the food supply, ORA focuses it's efforts in three areas:

- conducting inspections to determine the cause of illegal drug residues in food and takes enforcement actions against repeat violators to protect consumers from potentially harmful drug residues in food

- investigating farm practices of management and animal drug use for program decision support, identification of educational needs, and policy development

- inspecting animal feed establishments to assure that the feed produced is properly labeled; does not contain unsafe additives or contaminates; and if drugs are present, they are safe and effective for their intended use.

Protect Against Bio-Terrorism

FDA's mission includes protecting the health and safety of all food producing, companion, and other non-food animals, and assuring that food products from animals are safe for human consumption. FDA must work to develop profiles of possible or probable food threats and points of attack. FDA must have the capacity to quickly and accurately identify outbreaks at any point in the food chain, and to take prompt action to mitigate their effects. To protect against bioterrorism, CVM is developing ways to protect FDA-regulated products, including foods and animal feed, from contamination, tampering, and harmful uses. With the base resources CVM's activities are focused in five areas:

- CVM performs risk analysis of the vulnerability of livestock and poultry feed.

- CVM strengthens relationships with state partners and expand contracting efforts with state labs in order to provide surveillance and surge capacity related to counterterrorism activities.

- CVM works with Iowa State University on a database that assists first responders by quickly identifying labs that have the capability to analyze feed and/or animal tissues for the presence of a chemical or biological agent.

- CVM maintains a comprehensive inventory of registered animal drug establishments and listed animal drug products to assess the availability or anticipated shortage of animal drug products that would be needed to deal with terrorist attacks.

- CVM works with CDC on a bioterrorism surveillance system for companion animals that can be used as an early detection mechanism for antibiotic resistant microbes and bioterrorist agents.

Research, Development, and Evaluation

FDA is responsible for the post-approval monitoring of retail meats for drug resistant foodborne pathogens under the NARMS program, and for molecular typing of those pathogens as part of the national PulseNet program. The multi-faceted NARMS program strives to provide for the safe use of antimicrobials in food animals, while ensuring that significant human antimicrobial therapies are not compromised or lost. FDA conducts research to understand the microbiology of animal feeds and the dissemination of resistant organisms via livestock feeds. With the base resources CVM's activities are focused in three areas:

- CVM monitors for the prevalence of enteric bacteria in retail meats, and for the changes in their susceptibilities to a panel of antimicrobial agents that are important in human and animal medicine.

- FDA coordinates NARMS, which regulates the use of antimicrobials and other drugs in animals and humans, and responds with appropriate action if public health is threatened

- FDA identifies potential animal and public health problems by tracking the changes in susceptibility among bacterial isolates from all three arms of NARMS.

FDA Releases 2004 NARMS Retail Meat Annual Report

The National Antimicrobial Resistance Monitoring System (NARMS) – Enteric Bacteria Retail Meat Annual Report for 2004 has been published. Its primary purpose is to monitor the prevalence of antimicrobial resistance (AR) among foodborne pathogenic and commensal organisms, in particular, *Salmonella*, *Campylobacter*, *Enterococcus,* and *E. coli*. The results generated by the NARMS Retail Meat program establish a reference point for analyzing trends of antimicrobial resistance among these foodborne bacteria.

The NARMS retail meat surveillance program is an ongoing collaboration between FDA, the Centers for Disease Control and Prevention (CDC), and 10 participating FoodNet laboratories in the United States.

FDA supports the drug review function by conducting studies in animal drug safety and efficacy, antimicrobial resistance mechanisms, metabolism, standardization of test methods, and pharmcokinetics and pharmacodynamics. The goal of these efforts is to provide a scientific basis for guideline development. With the base resources CVM's activities are focused in four areas:

- CVM conducts method validation for new drug approvals for food producing animals.

- CVM resolves new and emerging scientific issues that impact FDA's ability to make approval decisions.

- CVM develops and validates multi-residue drug screening methods and methods to detect the presence of prohibited toxic and microbiological substances that could be introduced into U.S. animal feed supplies.

- CVM identifies food animal species that may be associated with transmission of antimicrobial resistance to human bacterial pathogens.

FDA supports compliance programs by developing analytical methods and evaluating screening tests that detect drug residues in domestic and imported food products and that detect material prohibited by the BSE feed regulation. The research supports

CVM's regulatory decision-making. With the base resources CVM's activities are focused in seven areas:

- CVM supports research projects, with a focus on analytical methods for detecting illegal use of certain drugs and other compounds.

- CVM completes the validation of a real-time PCR method that is capable of detecting cattle, swine, sheep, goats, horses, or deer material along with poultry, goose, and turkey to further enhance FDA's ability to detect potentially violative animal feeds.

- CVM evaluates commercially available rapid tests for animal proteins in animal feeds.

- CVM develops and validates multi-residue drug screening methods.

- CVM develops an analytical method to detect illegal use of antiviral drugs in poultry in order to maintain effectiveness of antiviral drugs needed to treat humans infected with pandemic avian influenza.

- CVM sets up a national reference laboratory to test poultry products for the presence of antiviral drug.

- CVM enforces the CVM prohibition of the use of antiviral drugs in poultry.

Selected FY 2006 Accomplishments

Increase Premarket Drug Availability

The following FY 2006 accomplishments support FDA's strategic goals to (1) increase access to innovative products and technologies to improve health; and (2) improve product quality, safety and availability through better manufacturing and production oversight. CVM demonstrates the following results that ensure new animal drug products are safe and effective for both animals and the public with respect to both companion animals and animals intended for food consumption. In addition, four results demonstrate how CVM ensures faster review time so that more drugs are readily available to the public:

- FDA met or exceeded all the ADUFA performance goals for FY 2005 on the applications that were submitted and acted on in FY 2005.

- As of September 30, 2006, FDA has met or exceeded all of the performance goals defined under ADUFA for FY 2006 for applications that were submitted and acted on. Additional applications received in FY 2006 remain pending review and action, but are still within ADUFA timeframes.

- FDA met its goal of having 50 percent of additional FDA review staff recruited and on-board by the first quarter of FY 2006.

- FDA published three policy and procedure documents that were adopted in FY 2006 to improve the efficiency, quality, and predictability of the new animal drug review process.

FDA approved the following noteworthy animal medicines in FY 2006.

DRUG	PURPOSE
EQUIOXX (Firocoxib)	Oral Paste for Horses - an NSAID administered for up to 14 days for the control of pain and inflammation associated with osteoarthritis
ZILMAX (zilpaterol hydrochloride)	For increased rate of weight gain, improved feed efficiency and increased carcass leanness in cattle feed in confinement for slaughter during the last 20-40 days on feed.
CYDECTIN (moxidectin)	Oral Drench for Sheep - for the treatment and control of various internal parasites in sheep. This was a minor species approval
AQUAFLOR (florfenicol)	Type A medicated article – for the control of mortality due to enteric septicemia of catfish.

In the area of generic animal drugs, CVM met with the generic animal drug sponsors Animal Drug Alliance to explore the possibility of establishing user fees to support the review of abbreviated new animal drug applications.

In the area of antimicrobial resistance, CVM conducted a Veterinary Medicine Advisory Committee meeting on the microbial food safety of a one of its kind drug for bovine respiratory disease in cattle. The meeting was part of the overall pre-approval risk management strategy to lessen or control antimicrobial resistance to this new drug.

CVM demonstrates results in two areas of the Office of Minor Use and Minor Species Animal Drug Development (OMUMS):

- By the end of FY 2006, OMUMS initiated the review process on more than 50 requests for designation of drugs intended for minor use or minor species and granted 38 of those requests.

- On August 22, 2006, CVM published the proposed indexing regulations which establish formal procedures to implement a major portion of the MUMS act; this is the second of three sets of implementing regulations required to be published by the MUMS legislation.

Regulate Animal Biotechnology Products

In FY 2006 CVM supported FDA's strategic goal to increase access to innovative products and technologies to improve health by understanding scientific and risk issues in order to develop an appropriate approach to regulating animal biotechnology. With the base resources CVM is able to demonstrate results in five areas:

- CVM continued development of a transgenic animal policy by participating in on-going deliberations with USDA Biotechnology Regulatory Services and with other parts of FDA to evaluate the role of genetically engineered animals in the Coordinated Framework for the Regulation of Biotechnology.

- Approximately a dozen one-on-one sessions were conducted with prospective and current sponsors of Investigational New Animal Drug Applications and Import Tolerances for animal biotechnology products relating to requirements necessary to receive marketing approval.

- CVM completed an update of the draft Risk Assessment on Animal Clones and their Progeny, Proposed Risk Management Plan, and a draft GFI on the use of cloning technology in animal breeding and release of clones and their progeny into the food supply.

- CVM completed a peer review of the draft risk assessment, a communications package and a detailed "rollout" plan for the public release of the entire package.

- CVM began distributing the draft risk assessment, proposed risk management plan, and draft GFI to other USG agencies for comment and information and conducted detailed briefing sessions on the cloning package to develop a seamless release strategy.

Safeguard against Bovine Spongiform Encephalopathy (BSE)

In FY 2006 CVM supported FDA's strategic goal to enhance patient and consumer protection and empower them with better information about regulated products by safeguarding human and animal health in the U.S. from BSE. With the base resources CVM is able to demonstrate results in nine areas:

- On October 6, 2005, FDA published a Proposed Rule that would ban the use of certain high risk cattle materials in all animal feeds and pet food receiving more than 800 comments including comments relating to the agency's analysis of the potential economic and environmental impacts of the proposed measures; the measures proposed by this rule add an additional firewall to the protections already provided by the current BSE feed rule.

- FDA worked with Federal and State agencies and industry to discuss alternative disposal of bovine-origin material that will be diverted from animal feed use by the new rule.

- CVM completed the development of a real-time Polymerase Chain Reaction (PCR) based method capable of detecting cattle, swine, sheep, goats, horses, or deer material along with poultry, goose, and turkey for use in analyzing samples of animal feeds and feed ingredients in support of the animal protein prohibition.

- CVM completed the evaluation of a fourth commercially available diagnostic test kit marketed for the detection of ruminant proteins in animal feed.

- CVM initiated training and installation of the Harvard BSE Risk Assessment simulations that enables testing of proposed risk management proposals in terms of the effects on the spread, and rate of elimination of BSE.

- FDA and CVM conducted training sessions for Federal and State investigators on the BSE compliance program 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 worked with USDA to show that U.S. BSE controls measures meet international BSE-related standards for trade of cattle and bovine origin materials.

- CVM provided personnel and expertise on BSE and animal feed issues to the U.S. Department of Agriculture in support of its efforts to reopen foreign markets for U.S. beef.

- CVM worked with ORA to evaluate applications from over 30 state feed regulatory agencies for BSE cooperative agreement funding to strengthen the BSE component of their feed programs.

Safeguard against Bovine Spongiform Encephalopathy (BSE) – Field Activities

BSE Cooperative Agreements: Currently, there are 8 BSE Cooperative Agreements in place with state agencies in support of the FDA Ruminant Feed Ban. Specifically, ORA provides the necessary support to: train state personnel dedicated to conduct BSE testing and inspections, provide supplies and laboratory equipment for analysis of feed samples using FDA validated methods, and increase the number of inspections of renderers, protein blenders and feed mills conducted by state personnel.

BSE Finding in Cow in Alabama: FDA and USDA conducted a joint investigation in response to a positive BSE finding in a cow in Alabama in March 2006. The investigation determined that the animal was born prior to FDA's 1997 feed ban. Therefore, FDA conducted investigations at local feed mills and found that all of those handling prohibited materials were in compliance with the FDA's feed ban. This compliance demonstrates that FDA's BSE feed ban is providing a reliable firewall against further transmission of BSE.

Ensure Food Safety

In FY 2006 CVM supported FDA's strategic goals to enhance patient and consumer protection and empower them with better information about regulated products and improve product quality, safety, and availability through better manufacturing and production oversight by keeping animals intended for food consumption safe for human consumption.

In the area of pandemic influenza, CVM is able to demonstrate results in two areas:

- CVM drafted guidance banning the use of high risk avian influenza materials from being used in animal feed.

- CVM established a CVM Avian Pandemic Influenza Work Group that develops policies and approaches to feed and animal drug hazards that are consistent with other FDA components and other federal agency actions.

FDA Prohibits Use of Human Anti-Viral Drugs in Poultry

The FDA has issued an order that prohibits the extralabel use in poultry of two classes of approved human anti-influenza drugs to help preserve the effectiveness of these drugs for treating or preventing influenza infections in humans.

The order prohibits the extralabel use of anti-influenza adamantine and neuraminidase inhibitor drugs in chickens, turkeys, and ducks. Extralabel use refers to the use of a human or animal drug that is beyond the scope of the approved labeling.

The extralabel use of these human antiviral drugs in poultry could lead to the emergence of resistant strains of type A influenza. Avian influenza, including the H5N1 subtype, is identified in other countries as a type A influenza. Extralabel use of human antivirals in poultry could become a concern if highly pathogenic avian influenza emerged in the United States. The Order of Prohibition was issued as a final rule and took effect June 20, 2006.

With the use of the Animal Feed Safety System, CVM is able to demonstrate results in two areas:

- CVM prepared and made available for public review draft documents that provide (1) the health consequence scoring for chemical, biological, and physical contaminants in animal feed, and (2) those contaminants in animal feed FDA will be considering at this time as part of the risk-ranking model.

- CVM drafted a standard operating procedure describing the internal procedure for ensuring the development of appropriate analytical feed methods as a component of the regulatory limit-establishing process for animal feed contaminants.

In order to provide safe use of antimicrobials in food animals while ensuring that significant human antimicrobial therapies are not compromised or lost, CVM demonstrates results in five areas related to antimicrobial resistance:

- CVM completed development of standardized in vitro susceptibility testing methods for different types of bacteria.

- CVM completed and published studies comparing different molecular fingerprinting techniques from animals and retail meat and poultry.

- CVM funded a cooperative research agreement to the University of Maryland to study antibiotic resistance bacteria in food animals, abattoir workers, and human referent groups.

- The review of the penicillin approvals was completed and CVM is considering what further action may be needed.

- FDA developed a regulatory strategy for managing the potential risks associated with the use of antimicrobial drugs in food-producing animals and held several public meetings.

In the area of the National Antimicrobial Resistance Monitoring System (NARMS), CVM demonstrates results in four areas:

- CVM released the third annual NARMS retail meat report on September 21, 2006 providing 2004 data on the prevalence of antimicrobial resistant foodborne pathogens and commensal bacterial among retail meat and poultry samples, comprising results from nearly 4800 samples.

- CVM improved NARMS testing methods and sampling strategies which in turn are being incorporated into public health surveillance systems in Canada, Europe, and Central and South America, and are now being used by WHO laboratories worldwide.

- CVM worked with USDA and CDC to develop complementary databases, as well as address harmonization of testing methods and data reporting in order to enhanced the transparency of the program to stakeholders

- CVM strengthened NARMS by establishing a DNA fingerprinting database of Salmonella and Campylobacter isolated from NARMS retail meats.

In the area of tissue residue CVM demonstrates results in four areas:

- CVM successfully converted the Residue Violation Information System (RVIS), which contains information on all tissue residue violations and violators identified since 1988, to a web-based application that uses an Oracle Relational Database.

- CVM finalized a document regarding Tissue Residue and Milk Program Coordination and obtained Field Committee agreement to incorporate these principles into the compliance program.

- CVM scientists developed a method to detect residues of nitrofurans, a class of banned animal drugs, in milk.

- CVM provided guidance and support to both CFSAN and the States for the cooperative, Grade “A” milk program in order to ensure that both the milk industry and the States have confidence in the drug residue testing mandated by the Pasteurized Milk Ordinance.

In the area of aquaculture CVM demonstrates results in four areas:

- CVM researchers made significant progress in developing methods for drug residues in aquacultured products with the validation of a multiresidue method for multiple fish species being completed.

- CVM researchers identified a new metabolite which will allow for the development of a method for detection of ivermectin in fish products.

- CVM published online a freely accessible database of literature for researchers and regulators and designated the PhishPharm Database, detailing drug metabolism, residues, and pharmacokinetics in multiple fish species.

- CVM provided data to support the development of two international antimicrobial susceptibility testing standards published in July 2006 that have been accepted as an Official Method by the Clinical Laboratory Standards Institute, providing the first internationally recognized standards for AST of aquatic bacteria.

Ensure Food Safety – Field Activities

Counterfeit Veterinary Drugs: In July 2006, seven individuals and two businesses were indicted in the Eastern District of Washington on 175 charges related to a conspiracy to sell and distribute counterfeit, adulterated and misbranded animal drugs. These counterfeit animal drugs, which originated in Mexico, were intended to be used in the treatment of infectious diseases in cattle, swine and poultry. The charges included trafficking in counterfeit drugs, and money laundering. Asset forfeiture in the amount of $1.4 million is being sought.

Protect Against Bio-Terrorism

In FY 2006 CVM supported FDA's strategic goal to improve product quality, safety, and availability through better manufacturing and production oversight by protecting the public from bio-terrorism. With the base resources CVM is able to demonstrate results in five areas:

- CVM scientists developed methods to detect the presence of toxins, drugs, pesticides, and other substances that could be introduced into the U.S. animal feed supplies by bioterrorists.

- As part of the Strategic Partnership Program Agroterrorism initiative, CVM performed vulnerability risk analysis on export grain elevator operations in New Orleans with USDA, FBI, and industry during an immediate post-Katrina situation to harden soft targets against terrorist attacks and tampering.

- CVM traveled to Nebraska and conducted vulnerability assessment of major cattle feedlot operations with USDA, FBI, and the State that produced a document for the industry that assists industry in protection from deliberate attacks, exotic animal diseases, and harmful chemicals that may have devastating economic consequences

- CVM correlated information on a secret level for the National Veterinary Stockpile and drugs within the Strategic National Stockpile to leverage capabilities and avert shortages.

- In December 2005, the CVM Veterinarian published an article entitled “Federal Agencies Partner with Private Industry for Bioterrorism Vulnerability Assessment,” which outlines our strategy and offers a mechanism to volunteer to participate in this effort.

Animal Drugs and Feeds
Program Activity Data (PAD)

PROGRAM WORKLOAD & OUTPUTS	FY 2006 Actuals	FY 2007 Continuing Resolution*	FY 2007 President's Budget	FY 2008 President's Budget**
New Animal Drug Applications (NADAs):[1]				
Received	16	16	16	15
Completed	13	7	16	16
Approved	6	3	7	7
Pending[2]	8	17	8	7
New Animal Drug Application Supplements:[1, 3]				
Received	598	598	598	598
Completed	561	345	608	616
Approved	430	264	436	480
Pending[2]	195	448	185	167
Abbreviated New Animal Drug Applications (ANADAs):[1]				
Received	45	46	46	47
Completed	43	26	43	41
Approved	17	7	15	13
Pending[2]	52	72	55	61
Abbreviated New Animal Drug Application Supplements:[1, 3]				
Received	127	128	128	129
Completed	120	50	116	114
Approved	80	35	77	75
Pending[2]	104	182	116	131
Investigational New Animal Drug (INAD) Files:[4]				
Received	2,193	2,193	2,193	2,193
Completed	2,231	899	2,237	2,243
Pending[2]	351	1,645	307	257

***** Under the FY 07 Continuing Resolution funding scenario, the Agency *does not* trigger collection of user fees and the ADUFA program terminates.

**This column reflects performance estimates using the FY 07 PB funding request level as the baseline. *Anticipate substantially lower performance in FY 08* if the Agency executes the FY 07 Continuing Resolution funding level (full year continuing resolution).

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[1] 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.

[2] Reflects submissions (received during the fiscal year) which still require review.

[3] 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.

[4] An INAD or JINAD file is established at the request of the sponsor to archive all sponsor submissions for a phased drug review including: 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)

PROGRAM WORKLOAD & OUTPUTS [2]	FY 2006 Actuals	FY 2007 Continuing Resolution*	FY 2007 President's Budget	FY 2008 President's Budget**
Generic Investigational New Animal Drug (JINAD):[4]				
Received	191	191	191	191
Completed	321	42	191	191
Pending[2]	42	191	42	42
Food (Animal) Additive Petitions[5]	13	13	13	13
Investigational Food Additive Petitions	36	36	36	36
Adverse Experience Reports (AERs)				
Received----------→	32,000	32,000	32,000	32,000
Reviewed----------→	18,000	15,000	18,000	17,000

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

ANIMAL DRUGS & FEEDS FIELD

PROGRAM OUTPUTS- DOMESTIC INSPECTIONS	FY 2006 Actuals	FY2007 Continuing Resolution	FY2007 President's Budget	FY2008 President's Budget
Pre-Approval /BIMO Inspections	64	65	125	125
Drug Process and New ADF Program Inspections	209	168	194	194
BSE Inspections	2,510	2,594	2,594	2,844
Feed Contaminant Inspections	19	10	10	10
Illegal Tissue Residue Program Inspections	218	180	233	233
Feed Manufacturing Program Inspections	333	170	220	220
State Contract/Coop Agreement Inspections: BSE	5,410	4,527	4,844	4,844
State Contract Inspections: Feed Manufacturers	383	314	336	336
State Contract Inspections: Illegal Tissue Residue	276	285	706	635
State Partnership Inspections: BSE and Other	1,036	900	900	900
Total Above FDA and State Contract Inspections	**10,458**	**9,213**	**10,162**	**10,341**
State Contract Animal Drugs/Feeds Funding	$1,785,384	$1,785,384	$1,910,361	$2,044,086
BSE Cooperative Agreement Funding	$3,000,000	$3,000,000	$3,000,000	$3,000,000
State Contract Tissue Residue Funding	$281,031	$281,031	$697,500	$320,375
Total State Funding	**$5,066,415**	**$5,066,415**	**$5,607,861**	**$5,364,461**
Domestic Laboratory Samples Analyzed	2,053	1,725	1,725	1,880
PROGRAM OUTPUTS- IMPORT/FOREIGN INSPECTIONS				
Foreign Pre-Approval/Bioresearch Monitoring Program Inspections	31	30	45	45
Foreign Drug Processing and New ADF Program Inspections	11	10	10	10
Total Above Foreign FDA Inspections	**42**	**40**	**55**	**55**
Import Field Exams/Tests	4,063	4,500	4,500	4,500
Import Laboratory Samples Analyzed	510	1,075	1,075	1075
Import Physical Exam Subtotal	4,573	5,575	5,575	5,575
Import Line Decisions	225,959	240,549	240,549	256,081
Percent of Import Lines Physically Examined	2.02%	2.32%	2.32%	2.18%

Performance Analysis

Based on the final performance update for FY 2005, the Animal Drugs and Feeds Program exceeded all ADUFA performance goal(s). Final performance numbers for FY 2006 will not be available until January 2008. However, as of September 30, 2006, the preliminary performance assessment for FY 2006 indicates FDA has exceeded the ADUFA goal(s). The program also met the field performance targets for FY 2006. Additional information about the Animal Drug and Feeds program goals and results are provided in the Performance Detail section.

With the passage of the Animal Drug User Fee Act (ADUFA) of 2003 and the resulting availability of user fees, the Program changed its new animal drug review performance goals to reflect the more ambitious performance target plans under ADUFA. The ADUFA performance goal targets are dependent upon a sustained level of base and user fee resources. See the Performance Appendix for detailed discussion of the performance goal.