Requirements for establishing and implementing a supply-chain program for its suppliers. Published in June 2018.

- Draft GFI #245, *"Hazard Analysis and Risk-Based Preventive Controls for Food for Animals"* to help owners, operators, or agents in charge of a facility to develop a food safety plan that complies with PCAF requirements. Published in January 2018.
- Draft GFI, *"Foreign Supplier Verification Programs for Importers of Food for Humans and Animals"* to provide questions and answers to facilitate importers' understanding of the FSVP requirements. Published in January 2018.
- GFI, *"Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs."* Published in January 2018.

In FY 2018 the FDA continued to proactively engage with industry and regulatory partners on FSMA to foster a greater understanding and to educate stakeholders on how to comply with FSMA-related regulations and guidance documents. This was accomplished by conducting listening sessions, webinars, and meetings on FSMA-related regulations and guidance documents, as well as active participation in the FSMA Technical Assistance Network (TAN), a central source for information and questions related to FSMA rules, programs, and implementation strategies.

Preventing and Responding to Animal Food Emergencies

The Animal Drugs and Feeds Program provides funds to support the activities of the Veterinary Laboratory Investigation and Response Network (Vet-LIRN), a network of 44 state and university veterinary diagnostic laboratories. The collaboration of veterinary diagnostic laboratories with FDA has helped the Agency prevent and respond to animal food emergencies by carefully investigating the clinical aspects of the reported illness. Such partnerships expand FDA's ability to protect animal and human health.

In FY 2018, FDA and the Vet-LIRN increased its capacity for conducting state-of-the-art susceptibility testing and genetic analysis. Vet-LIRN laboratories conducted dozens of investigations into consumer complaints of illness or death potentially due to animal food. They leveraged use of Whole Genome Sequencing (WGS) technology to contribute to the recall of several pet food products in 2018. Those products were contaminated with Salmonella, Listeria or E. coli all of which can cause disease in people as well as their animals. During 2018 Vet-LIRN also investigated multiple cases of hyperthyroidism in pets and found that the illness was caused by foods containing thyroid tissue, which should have been excluded.

WGS is a critical tool that helps FDA provide scientific research solutions that ensure the safety of human and animal health. The high capacity and low costs of rapid DNA sequencing technology and advances in analytical software have made it possible to routinely determine and interpret the complete DNA sequence obtained from microorganisms, enabling the Agency to more rapidly identify emerging patterns of resistance.

Veterinary diagnostic laboratories often have opportunities for early detection of emerging diseases and are poised to play an increased role in biosurveillance for antibiotic-resistant bacteria that could affect humans. In 2018 Vet-LIRN continued implementation of a pilot project to monitor antimicrobial susceptibility and to sequence selected veterinary pathogens. Twenty Vet-LIRN laboratories are gathering data on antibiotic susceptibility for various Salmonella

species, E. coli and Staphylococcus pseudointermedius, and they are providing the isolates to four Vet-LIRN laboratories that have sequencing capabilities. Integrated monitoring by these veterinary diagnostic laboratories could inform risk-based intervention strategies for FDA.

Leveraging Real-World Adverse Event Data

The Animal Drugs and Feeds Program has the largest animal drug adverse event database in the world, containing real-world safety and effectiveness data from more than 840,000 cases, a case may include more than one animal, especially cases involving food producing animals which are often treated and managed as a group. The majority of cases reported, approximately 80 percent, involve companion animals. The data includes adverse events reported in more than 89,000,000 food animals, and approximately 800,000 companion animals. The Program uses a comprehensive adverse event reporting system to monitor the continued animal safety of animal food and drugs, human user safety, and the effectiveness of approved animal drugs.

In FY 2018, FDA received more than 100,000 adverse event reports. Onecase can include both initial and follow up reports. Some reports triggered drug safety communications. One example was an FDA warning alerting pet owners and veterinary professionals about the potential for neurological adverse events associated with certain flea and tick products. In FY 2017, drug safety reports triggered a warning about eye injury and irritation in both people and dogs following application of two canine ear medications.

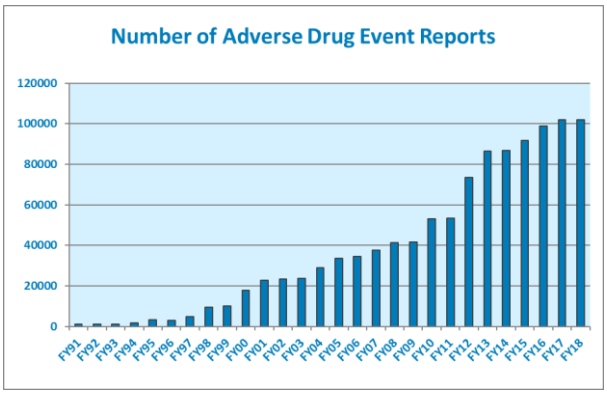

Figure 10 Adverse Drug Event Reports

The number of adverse event reports received each year continues to grow. The long-term trend of increased reporting may be attributed to both increases in the number of approved animal drug products and increased awareness of reporting.

Efforts continue to increase the functionality, utilization, and analysis of this pharmacovigilance database to improve animal drug safety. Adverse event signal detection and management strategies are under development to help identify potential safety and effectiveness issues and enable the program to monitor, detect and respond to products that could potentially put humans and animals at risk. The Program is continuing efforts to harmonize pharmacovigilance internationally to enhance animal drug safety globally.

Animal Drug Inspections

FDA's Office of Regulatory Affairs (ORA) conducts preapproval inspections to support application reviews for pioneer and generic new animal drugs. To help ensure the integrity of scientific testing and the reliability of clinical and non-clinical submission data, FDA also conducts bioresearch monitoring (BIMO) inspections of study facilities, clinical investigators, institutional review boards, and contract research organizations that submit data to FDA.

Accurate test results are essential to the review and approval of new animal drugs and help to ensure that the rights and welfare of animals are protected. Post-approval, ORA inspects manufacturing establishments of marketed products to determine their ability to manufacture

products to the specifications stated in their applications and to ensure compliance with current good manufacturing practice requirements (CGMPs). FDA also inspects non-clinical laboratories that conduct testing to determine whether Good Laboratory Practices have been followed.

FUNDING HISTORY[53]

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2016 Actual	$188,042,000	$158,629,000	$29,413,000
FY 2017 Actual	$190,879,000	$162,852,000	$28,027,000
FY 2018 Actual	$210,732,000	$174,430,000	$36,302,000
FY 2019 Annualized CR	$220,030,000	$174,434,000	$45,596,000
FY 2020 President's Budget	$239,515,000	$192,314,000	$47,201,000

BUDGET REQUEST

The FY 2020 Budget Request for the Animal Drugs and Feeds Program is $239,515,000, of which $192,314,000 is budget authority and $47,201,000 is user fees. Budget authority increases by $17,880,000 compared to the FY 2019 Annualized Continuing Resolution level and user fees increase by $1,605,000. The Center for Veterinary Medicine (CVM) amount in this request is $166,904,000. The Office of Regulatory Affairs amount is $72,611,000.

The Animal Drugs and Feeds Program is responsible for ensuring animal drugs and food products are safe and effective, quality manufactured and properly labeled. This supports the health of food-producing and pet (companion) animals, including minor species, and enhances the availability and diversity of CVM approved products. CVM's responsibilities include all stages of the total product lifecycle, such as ensuring safety and effectiveness of an animal drug before approval, conducting preapproval inspections, reviewing food additives for safety and utility, and ensuring food for animals is safe, made under sanitary conditions, and properly labeled. In addition, the Animal Drugs and Feeds Program fosters a flexible, risk-based review framework for innovative technologies by engaging sponsors early in their drug development process.

In addition, as part of the product lifecycle, the Animal Drugs and Feeds Program bolsters critical post-market efforts by rapidly responding to product safety concerns and public health emergencies. The Program examines the safety and effectiveness of animal drugs on the market, reviews Adverse Drug Experience reports, monitors the safety of animal devices, investigates livestock and pet illnesses, provides outreach and education, and conducts compliance and enforcement actions when appropriate. Ongoing risk-based efforts to reduce the marketing and distribution of high-risk unapproved animal drugs will continue. FDA's efforts are ongoing to limit compounding to legitimate veterinary medical needs to treat animal health issues where there are no alternatives and the compounded drug does not compete against approved products. Unapproved animal drugs, including compounded products, pose a public health risk because they have not been evaluated for safety and effectiveness and may not be properly manufactured or labeled.

[53] Numbers reflect comparability adjustments for FY 2018, FY 2019, and FY 2020 consistent with budget figures.

The Animal Drugs and Feeds Program will continue prevention-focused efforts under the FDA Food Safety Modernization Act (FSMA) by working to build a modern, science- and risk-based animal food safety system through the establishment of and compliance with preventive control standards to protect human and animal health. The Program continues to develop guidance documents and conduct training, education and outreach, in conjunction with our state regulatory and public health partners. The Animal Drugs and Feeds Program works extensively with state partners to continue building an integrated food safety system that supports animal food standards, response efforts, and enhanced surveillance and communication systems.

The Animal Drugs and Feeds Program will continue implementation of the five-year antimicrobial resistance action plan to advance antimicrobial steawardship in veterinary settings, reduce overuse of antimicrobial drugs, and combat the rising threat of resistance. The Program will also continue monitoring and surveillance efforts on antimicrobial resistance among enteric (intestinal) pathogenic bacteria via the National Antimicrobial Resistance Monitoring System (NARMS). Outbreak and response efforts will also continue to be strengthened by using state and academia veterinary diagnostic laboratory capability and capacity via the Veterinary Laboratory Investigation and Response Network (Vet-LIRN) to assist FDA with responding to public health emergencies and by investigating potential problems with animal food, including pet food, and animal drugs.

The Animal Drugs and Feeds Program will also conduct field inspections, investigations, and enforcement activities to ensure the adherence to regulatory requirements that protect human and animal health. These activities in the FY 2020 Budget Request support mission critical activities, and Presidential, HHS, and FDA human and animal health priorities.

Budget Authority

Food Safety (+$13.9 million / 23 FTE)

Advancing FSMA: (+$5.9 million / 1 FTE)

Center: +$0.3 million / 1 FTE

FDA provides state regulatory programs with contract and cooperative agreement funding to conduct domestic animal food facility inspections required by FSMA. The FY 2020 Budget request will enhance compliance with the preventive control rules by funding cooperative agreements with state animal food regulatory programs enabling states to increase their capability to conduct FSMA related domestic inspections. In addition, CVM will be able to hire additional FTEs to provide technical expertise to support both FDA and state partners in the administration of the cooperative agreements and development of preventive controls programs within the state agencies.

Field Animal Drugs & Feeds: +$5.6 million/ 0 FTE

FDA provides state regulatory programs with contract and cooperative agreement funding to conduct domestic food and feed facility inspections required by FSMA. FDA expects that states will continue to gradually increase the number of inspections they conduct as FDA transitions to prevention-oriented inspections. The National Association of State Departments of Agriculture (NASDA) and Association of American Feed Control Officials (AAFCO) requested funds for FDA to provide states to complete Preventive Control (PC) inspections by updating and building new state programs. The cooperative agreements will support work for states to implement the

recommendations of the NASDA PC Animal Food Framework that include evaluating and building infrastructure, updating inspection and enforcement programs, developing outreach and training programs, and shifting laboratory resources to focus on hazard analysis.

Strengthening Response Capabilities for Foodborne Outbreaks: (+$3.0 million / 10 FTE)

Center: +$3.0 million / 10 FTE

With this funding increase, the Animal Drugs and Feeds Program will increase surveillance and expand collaboration to more rapidly identify and respond to the growing number of outbreaks and other public health threats associated with animal food, including pet food contamination, and residues in the edible tissue of food producing animals. There has been an increase in the number of recalls for two reasons:

- industry has identified new hazards when complying with the FSMA preventive controls
- the increasing application of whole genome sequencing enhanced the sensitivity of our surveillance systems to identify foodborne outbreaks that previously would have gone undetected.

The Program will also increase its capacity to coordinate and communicate with other federal, state and local food safety partners to help ensure that unsafe products are removed from the marketplace as quickly as possible to limit exposure.

Promoting Innovation and Emerging Technologies While Maintaining Product Safety: (+$5 million / 12 FTE)

Center: + $5.0 million / 12 FTE

The Animal Drugs and Feeds Program will use this funding increase to strengthen its capacity to review biotechnology plants. The Program also will use this funding to enhance the pre-market animal food program to meet 80 percent of established timeframes for Food Additive Petitions (FAPs) and Generally Recognized as Safe (GRAS) notices, while working to eliminate the backlog of review requests for these products. With industry submissions of FAPs increasing by 150 percent in the last four years and submissions of GRAS notices increasing by 200 percent in FY 2017, this funding is critical for ensuring that new and innovative animal food ingredients that demonstrate safety and utility reach the market.

The Program will publish two guidance documents on ingredient pre-submission interactions and evaluation of genome edited plants to improve efficiency and effectiveness for industry before and during the submission process. The Program also will continue to conduct scientific reviews of animal food ingredients to ensure they are safe for the target animals and for the humans eating the edible tissue from these animals.

Medical Product Safety (+ $4 million / 4 FTE)

New Medical Data Enterprise: (+ $4.0 million / 4 FTE)

Center: + $4.0 million / 4 FTE

With this funding increase, the Animal Drugs and Feeds Program would enhance its capacity to utilize real world evidence from adverse experience reports to promptly detect, monitor, and learn from problems experienced with FDA-regulated animal health products. The data generated by this effort could be used to facilitate product expansion into new indications, to ensure that unsafe or ineffective products do not reach U.S. consumers, and to more rapidly identify and respond to

public health threats. The Program would also support the judicious use of antimicrobial drugs in veterinary settings by enhancing collaboration with stakeholders and other Federal agencies to optimize the use of existing antimicrobial drugs and to foster innovation and the development of alternative animal health products. The Program would act on recommendations from the FDA's Science Board, including expanding the scope of the National Antimicrobial Resistance Monitoring System (NARMS) to test farm-raised seafood products at retail, test other pathogenic foodborne bacteria and enhance data collection capabilities to provide a framework for improvements that will strengthen the scientific basis for regulatory decision making and public health interventions to address this important medical challenge.

USER FEES

Current Law User Fees: +$1.6 million

Center: +$1.682 million / Field: -$0.077 million

The Animal Drugs and Feeds Program request includes an increase of $1,605,000 for user fees, which will allow FDA to fulfill its mission of promoting and protecting the public health by ensuring safety and efficacy of animal drug products.

PERFORMANCE

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

Measure	Year and Most Recent Result / Target for Recent Result(Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020+/- FY 2019
243201: Complete review and action on original New Animal Drug Applications (NADAs) and reactivations of such applications received during the fiscal year. *(Output)*	FY 2017: 100% w/in 180 days Target: 90% w/in 180 days (Target Exceeded)	90% w/in 180 days	90% w/in 180 days	Maintain
243202: Complete review and action on Non-administrative original Abbreviated New Animal Drug Applications (ANADAs) and reactivations of such	FY 2017: 100% w/in 270 day Target: 90% w/in 270 days (Target Exceeded)	90% w/in 240 days	90% w/in 240 days	Maintain

Measure	Year and Most Recent Result / Target for Recent Result(Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020+/- FY 2019
applications received during the fiscal year. *(Output)*				
244204: Complete review and action on warning letters received to better safeguard our food supply by alerting firms to identified deviations in order to become compliant. *(Output)*	FY 2018: 63% w/in 25 working days Target: 50% w/in 25 working days (Target Exceeded)	50% w/in 25 working days	50% w/in 25 working days	Maintain
244302: Respond to consumer complaints related to animal food safety issues by initiating in-depth Vet-LIRN investigations within 30 days of receipt. *(Output)*	FY 2018: 100% Target: 90% (Target Exceeded)	90%	90%	Maintain
214221: Percentage of Human and Animal[54] Food significant inspection violations which receive appropriate follow-up after regulatory action was taken. *(Output)*	Baseline: 90% (New Measure)	80%	80%	Maintain
224221: Percentage of Human and Animal[55] Drug significant inspection violations which receive	Baseline: 86% (New Measure)	80%	80%	Maintain

[54] Due to Program Realignment, ORA's Workplan now combines Human and Animal food inspection activities together, so this combination performance goal is repeated in both the Foods and Animal Drugs and Feed program narratives.

[55] Due to Program Realignment, ORA's Workplan now combines Human and Animal drug inspection activities together, so this combination performance goal is repeated in both the Human DrugsFoods and Animal Drugs and Feed program narratives.

Measure	Year and Most Recent Result / Target for Recent Result(Summary of Result)	FY 2019 Target	FY 2020 Target	FY 2020+/- FY 2019
appropriate follow-up after regulatory action was taken. *(Output)*				
214222: Percentage of Human and Animal[56] Food follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. *(Outcome)*	Baseline: 78% (New Measure)	65%	65%	Maintain
224222: Percentage of Human and Animal[57] Drug follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. *(Outcome)*	Baseline: 67% (New Measure)	55%	55%	Maintain

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

Reauthorization of ADUFA and AGDUFA

ADUFA IV and AGDUFA III have been reauthorized for FY 2019 through FY 2023. ADUFA IV includes two new performance goals: commencing tissue residue method demonstrations within 120 days, and conducting pre-submission conferences within 60 days. ADUFA IV also reduces review times on two performance goals from 180 days to 60 days for categorical exclusions and Animal Drug Availability Act (ADAA) Combinations. Additionally, CVM committed to working on implementation of the U.S. - EU GMP Inspection Mutual Recognition Agreement. AGDUFA III includes a significant reduction in performance goal review times

[56] Due to Program Realignment, ORA's Workplan now combines Human and Animal food inspection activities together, so this combination performance goal is repeated in both the Foods and Animal Drugs and Feed program narratives.

[57] Due to Program Realignment, ORA's Workplan now combines Human and Animal drug inspection activities together, so this combination performance goal is repeated in both the Human DrugsFoods and Animal Drugs and Feed program narratives.

across all submission types. Both ADUFA IV and AGDUFA III require electronic submission to improve efficiency, and require all approved drugs to include the NADA or ANADA number on the labeling to allow veterinarians and consumers to know it is an FDA approved product.

New Vet-LIRN Performance Measure

The Veterinary Laboratory Investigation and Response Network (Vet-LIRN) rapidly responds to consumer complaints related to animal food safety issues. The Network's 44 state and university veterinary diagnostic laboratories contributed to the initiation of nearly 300 case investigations in FY 2018 where there was compelling indication of harm caused by a regulated product and where animal diagnostic samples were available for testing. These laboratories provided pivotal data that led to either manufacturer recalls of contaminated products, or data that helped FDA avoid major expenses for regulatory actions because the investigation results demonstrated that certain products were unlikely to have caused the illnesses.

New ORA Field Performance Measures

ORA is embarking on an initiative to move from output focused performance goals such as inspection counts to public health outcome-based performance goals. This initiative seeks to provide more meaningful performance goals for internal and external stakeholders, and to showcase more direct public health impacts for ORA. The new performance goals introduced for FY 2019 measure topics such as our commitment to follow-up on firms receiving significant inspection violations, as well as measurements related to ORA regulatory impact on violators, and are tracked on a 3-year rolling basis. Due to the nature of regulatory actions and subsequent follow-up conducted by FDA, the duration of these events can vary considerably. After regulatory action, FDA also works to schedule follow-up after a reasonable time has passed to allow the firm to correct for the original violations. A 3-year rolling timeline also ensures tracking of all significant violations that require attention, and allows for a more robust analysis.

PROGRAM ACTIVITY DATA

Animal Drugs and Feeds Program Activity Data (PAD)

Animal Drugs & Feeds Program Activity Data (PAD)			
CVM Workload and Outputs	**FY 2018 Actual**	**FY 2019 Estimate**	**FY 2020 Estimate**
New Animal Drug Applications (NADAs) [1]			
Received	19	23	23
Completed	23	20	21
Approved	14	16	17
Pending [2]	14	17	19
New Animal Drug Application Supplements [1, 3]			
Received	591	575	600
Completed	536	560	590
Approved	438	475	500
Pending [2]	157	172	182
Abbreviated New Animal Drug Applications (ANADAs) [1]			
Received	23	23	26
Completed	19	21	22
Approved	6	16	18
Pending [2]	15	17	21
Abbreviated New Animal Drug Application Supplements [1, 3]			
Received	315	325	335
Completed	298	300	305
Approved	208	200	215
Pending [2]	151	176	206
Investigational New Animal Drug (INAD) Files [4]			
Received	2,885	3,400	3,600
Completed	2,840	3,400	3,500
Pending [2]	354	354	454
Generic Investigational New Animal Drug (JINAD) Files [4]			
Received	669	635	645
Completed	551	615	640
Pending [2]	223	243	248
Food (Animal) Additive Petitions Completed	104	100	100
Investigational Food Additive Petitions Completed	107	110	110
Adverse Drug Event (ADE) [5]			
ADE Reports Received	102,100	105,000	107,000
Post-Approval ADE Data Reviews	161	190	210

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

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

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

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

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

Field Animal Drugs and Feeds Program Activity Data (PAD)

Field Animal Drugs & Feeds Program Activity Data (PAD)									
Field Animal Drugs and Feeds Program Workload and Outputs	**FY 2018 Actuals**			**FY 2019 Estimate**			**FY 2020 Estimate**		
	Total	**Animal Drugs**	**Feeds**	**Total**	**Animal Drugs**	**Feeds**	**Total**	**Animal Drugs**	**Feeds**
FDA WORK									
DOMESTIC INSPECTIONS									
UNIQUE COUNT OF FDA DOMESTIC ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***1,436***	***160***	***1,276***	***1,664***	***298***	***1,398***	***1,664***	***298***	***1,398***
Pre-Approval /BIMO Inspections	33	33	0	79	79	0	79	79	0
Drug Process and New ADF Program Inspections	120	120	0	175	175	0	175	175	0
BSE Inspections	746	0	746	1,205	0	1,205	1,205	0	1,205
Feed Contaminant Inspections	5	0	5	25	0	25	25	0	25
Illegal Residue Program Inspections	322	0	322	450	0	450	450	0	450
Feed Manufacturing Program Inspections	179	0	179	200	0	200	200	0	200
Domestic Laboratory Samples Analyzed	1,223	13	1,210	1,560	20	1,540	1,560	20	1,540
FOREIGN INSPECTIONS									
UNIQUE COUNT OF FDA FOREIGN ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS [1]	***74***	***70***	***4***	***74***	***69***	***5***	***74***	***69***	***5***
Foreign Pre-Approval/Bioresearch Monitoring Program Inspections	20	20	0	40	40	0	40	40	0
Foreign Drug Processing and New ADF Program Inspections	51	51	0	33	33	0	33	33	0
Foreign Feed Inspections	2	0	2	5	0	5	5	0	5
BSE Inspections	1	0	1	0	0	0	0	0	0
TOTAL UNIQUE COUNT OF FDA ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***1,510***	***230***	***1,280***	***1,738***	***367***	***1,403***	***1,738***	***367***	***1,403***
IMPORTS									
Import Field Exams/Tests	3,557	868	2,689	3,795	495	3,300	3,795	495	3,300
Import Laboratory Samples Analyzed	963	0	963	867	2	865	867	2	865
Import Physical Exam Subtotal	**4,520**	**868**	**3,652**	**4,662**	**497**	**4,165**	**4,662**	**497**	**4,165**
Import Line Decisions	456,684	65,887	390,797	479,518	69,181	410,337	503,494	72,640	430,854
Percent of Import Lines Physically Examined	0.99%	1.32%	0.93%	0.97%	0.72%	1.02%	0.93%	0.68%	0.97%
STATE WORK									
UNIQUE COUNT OF STATE CONTRACT ANIMAL FEEDS ESTABLISHMENT INSPECTIONS	***3,050***	***0***	***3,050***	***3,396***	***0***	***3,396***	***3,396***	***0***	***3,396***
State Contract Inspections: BSE	2,713	0	2,713	3,500	0	3,500	3,500	0	3,500
State Contract Inspections: Feed Manufacturers	549	0	549	620	0	620	620	0	620
State Contract Inspections: Illegal Tissue Residue	85	0	85	0	0	0	0	0	0
State Contract Animal Drugs/Feeds Funding	$3,369,732	0	$3,369,732	$3,470,824	0	$3,470,824	$3,574,949	0	$3,574,949
State Contract Tissue Residue Funding	$0	0	$0	$0	0	$0	$0	0	$0
Total State Funding	**$3,369,732**	**$0**	**$3,369,732**	**$3,470,824**	**$0**	**$3,470,824**	**$3,574,949**	**$0**	**$3,574,949**
GRAND TOTAL ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***4,563***	***230***	***4,333***	***5,134***	***367***	***4,799***	***5,134***	***367***	***4,799***

[1] The FY 2018 actual unique count of foreign inspections includes 5 OIP inspections (4 for China and 1 for India).

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

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

4 Tissue residue funding has ended in FY18 and state contract illegal tissue residue inspections are no longer being conducted.