

EXECUTIVE SUMMARY

This Executive Summary describes the fiscal year (FY) 2017 Budget for the U.S. Food and Drug Administration (FDA). FDA is the agency within the U.S. Department of Health and Human Services (HHS) responsible for protecting and promoting public health by ensuring the safety, effectiveness, and security of human and animal drugs, biological products, and medical devices; ensuring the safety of food and feed, cosmetics, and radiation-emitting products; and regulating tobacco products.

RECENT ACCOMPLISHMENTS

FDA delivers significant, quantifiable results that help Americans every day and are a sound investment. A selection of recent accomplishments is presented below.

Food Safety

In fall 2015, FDA finalized major new food safety rules to implement the Food Safety Modernization Act (FSMA), the most sweeping overhaul of the country's food safety system since the first federal food safety law was passed in 1906. FSMA has improved FDA's capacity to:

- prevent food safety problems
- detect and respond to food safety problems
- ensure the safety of imported food.

FDA conducted extensive internal planning and external dialogue with other government agencies, industry, and foreign partners to ensure that FSMA rules are implemented in a timely, effective, and collaborative manner. The five foundational FSMA rules issued in 2015 were:

- preventive controls for human food
- preventive controls for animal food
- produce safety
- Foreign Supplier Verification Program (FSVP) for imported foods
- accreditation of third-party certification bodies.

The preventive controls for human food and preventive controls for animal food rule focus on preventing problems in order to improve the safety of food, including food for animals. The human food rule applies to many domestic and foreign firms that manufacture, process, pack, or hold human food. The preventive controls provisions of the animal food rule apply to domestic and imported animal food, including pet food, animal feed, and raw materials and ingredients. Under these rules, firms are required to:

- have written plans that identify hazards
- specify the steps that will be put in place to minimize or prevent those hazards
- identify monitoring procedures and record monitoring results
- specify what actions will be taken to correct problems that arise.

The produce safety rule addresses standards for produce safety by establishing enforceable science- and risk-based processes for the growing, harvesting, packing, and holding of fruits and vegetables on farms. The Foreign Supplier Verification Programs (FSVP) rule will require importers to verify that their suppliers meet the same level of public health protection as required

of domestic producers. Requirements for verification activities are based primarily on the type of food, nature of the hazard identified, and the foreign supplier.

Finally, the accreditation of third-party certification rule will allow bodies to be certified to conduct food safety audits and to certify that foreign food facilities and food produced by such facilities meet applicable FDA food safety requirements. In the coming year, FDA will issue the final two foundational FSMA rules for sanitary transportation and intentional adulteration.

Precision Medicine

FDA is a key participant in the Precision Medicine Initiative, launched by President Obama in January 2015. In addition to supporting national efforts led by the White House, FDA approved several new Precision Medicine-based therapies in the last year, thus bringing the President's vision directly to patients who can immediately benefit from these innovative treatments.

For example, FDA approved a targeted therapy for first-line treatment of patients with metastatic non-small cell lung cancer whose tumors harbor certain gene mutations. Lung cancer is the leading cause of cancer-related death in the U.S., with 158,040 Americans estimated to die from the disease this year.

The identification of patients with these gene mutations is made possible by an FDA-approved companion diagnostic test. The success of Precision Medicine depends on having accurate, reproducible, and clinically useful companion diagnostic tests to identify patients who can benefit from targeted therapies. During the past year, FDA also issued guidance for industry regarding companion diagnostic devices to help spur innovation in the development of these targeted therapies.

To further advance translation of the vision of Precision Medicine into cures for patients with serious illnesses, FDA launched precisionFDA. This initiative supplies a platform where the commercial and academic communities can test, pilot, and validate new approaches to ensure the accuracy of genetic tests. These efforts are critical to advancing the science needed to develop the necessary standards for tests used to detect and interpret differences in an individual's genetic make-up. The understanding of these differences is key to providing useful and actionable information about the state of a person's health and their future risk of disease, in order to inform their treatment choices.

Understanding gender differences is also vital to providing Precision Medicine and improving drug safety assessments. Because side-effects of drugs based on gender differences are not always adequately addressed in preclinical evaluations, better methods are needed. To this end, in FY 2015, FDA scientists found 29 enzymes that acted differently based on gender and that are involved in the metabolism of more than 600 drugs. Also last year, FDA scientists developed a mouse model of gender-related differences in the anticancer drug, doxorubicin (DOX). They observed that male mice reacted more strongly to DOX than female mice.

Combating Antibiotic-Resistant Bacteria

Antibiotics are important in combating infectious diseases in humans and animals. Antibiotic resistance, the ability of bacteria to survive in the presence of antibiotics, is a growing public-health threat. FDA is a critical participant in the Administration's Combating Antibiotic-Resistant Bacteria (CARB) National Action Plan to address the threat of antibiotic-resistant bacteria, which includes efforts to:

- slow the emergence of antibiotic resistant bacteria
- advance the development of diagnostics to detect antimicrobial resistance
- improve antimicrobial stewardship and reduce inappropriate antibiotic use
- accelerate the development of new treatment for antibiotic-resistant bacteria
- develop new strategies to address bacterial infections.

FDA's roles and responsibilities with respect to addressing antimicrobial resistance include:

- appropriate and responsible use of antibiotics in foods and medicines
- surveillance for antimicrobial resistance among foodborne bacteria
- interventions to reduce resistance among foodborne bacteria
- therapeutics, diagnostic tests, and vaccines to manage antimicrobial resistant organisms
- supply chain safety to protect consumers from product adulteration and substandard or counterfeit medical products.

FDA has also been actively implementing the Generating Antibiotics Incentives Now (GAIN) Act, a provision of the Food and Drug Administration Safety and Innovation Act (FDASIA), to promote the development of antibacterial and antifungal drugs. The White House convened a "Forum on Antibiotic Stewardship" to bring together key human and animal health constituencies involved in antibiotic stewardship.

FDA served as a key Federal Animal Health expert during the forum and engaged with stakeholders to gain the commitments sought by the White House. Key human and animal health stakeholders committed to implement changes over the next five years to slow the emergence of resistant bacteria, and prevent the spread of resistant infections.

FDA published the Veterinary Feed Directive (VFD) final rule in June 2015,¹ and in September 2015, FDA issued revised Guidance for Industry #120, "Veterinary Feed Directive (VFD) Regulation Questions and Answers." These publications are an important piece of the overall strategy to promote the judicious use of antimicrobials in food-producing animals and brings the use of these drugs under veterinary supervision so that they are used only when necessary for assuring animal health.

Drug Shortages

FDA continues to make significant progress in reducing the number of drug shortages, from a high of 251 new shortages in 2011 to just 44 new shortages in 2014. Currently, FDA is working to resolve over 70 shortages that began in 2014 and prior years, which is a decrease from the 97 ongoing shortages tracked at the end of 2013. With the passage of Public Law 112-144 Food and Drug Administration Safety and Innovation Act (FDASIA) in 2012, regulations were put in place which allowed FDA to begin to gain control over these staggeringly high numbers and effectively hold industry accountable to require early notification of discontinuances or interruptions in manufacturing of all covered prescription drugs. These requirements have helped FDA to work early on with industry to address problems before shortages occur and have resulted in decreasing numbers of new shortages in recent years.

On March 4, 2015, FDA launched its first mobile application specifically designated to speed public access to valuable information regarding drug shortages. The new mobile application

¹ The veterinary feed directive final rule can be found at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm448446.htm>

offers easy and fast public access to important drug shortage information. Healthcare professionals and pharmacists need real-time information about drug shortages to make treatment decisions, and this application will provide the necessary early notification from manufacturers of a potential disruption in product supply to make these decisions.

Opioids

Identifying solutions to prevent prescription opioid abuse is a top priority for the FDA. In regulating opioid drugs, it is critical to incentivize innovations that are less likely to result in abuse and addiction, and still effective, while also ensuring that patients with debilitating pain have access to effective pain management treatment.

On April 1, 2015, FDA issued final guidance, “Abuse-Deterrent Opioids – Evaluation and Labeling,” to assist industry in developing opioid drug products with potentially abuse-deterrent properties. Prescription opioid products are an important component of modern pain management, but abuse and misuse of these products have created a serious and growing public health problem. One potentially important step towards creating safer opioid analgesics has been the development of opioids that are formulated to deter abuse.

FDA has recently approved additional treatment options for patients who overdose on opioids. In FY 2014, FDA approved a new form of naloxone – a drug that rapidly reverses the effects of an opioid overdose – with an auto-injector to enable a caregiver to administer the drug. This approval offers a new emergency treatment tool to help prevent the tragedy of opioid drug overdose. Additionally, FDA is committed to using its authorities to facilitate the development of overdose reversal drugs. Using expedited approval processes, FDA approved both an auto-injector in FY 2014 and an intranasal formulation in November 2015, both designed for use by lay bystanders, as well as first responders. Both products were approved ahead of their Prescription Drug User Fee Act goal dates—i.e., the date when the Agency was scheduled to complete its review of the applications.

FDA continues to explore alternative methods for making naloxone more available, perhaps without a prescription. Also, in July 2015, FDA held a scientific workshop about the uptake of naloxone in certain medical settings – such as on ambulances and in association with prescriptions for opioids – as well as outside of conventional medical settings to reduce the incidence of opioid overdose fatalities. At the meeting, stakeholders explored legal, regulatory, logistical and clinical aspects related to making naloxone more widely available, and discussed how public health groups can work together to use naloxone to reduce the risk of overdose.

Tobacco Regulation

On May 12, 2015, FDA launched the first phase of its “Fresh Empire” campaign – a youth-focused effort to reduce the number of smokers in our country. The campaign is designed to prevent and reduce tobacco use among at-risk multicultural youth aged 12 to 17 including African American, Hispanic, and Asian American/Pacific Islander youth.

As of December 31, 2015, FDA had contracts to conduct compliance check inspections at tobacco retail establishments with 55 States, territories, and tribal jurisdictions. Compliance check inspections pertain to tobacco marketing, sales, and distribution of tobacco products at retail locations. Since the October 2010 inception of FDA’s Tobacco Retail Compliance Check Inspection Program through December 2015, FDA has:

- completed over 549,300 inspections
- issued over 38,800 warning letters
- levied more than 6,400 civil monetary penalties
- filed 8 No-Tobacco-Sale Order (NTSO) complaints
- commissioned more than 2,300 officers and employees from the States, territories, and their political subdivisions and provides a training program for those that perform inspections.

On November 10, 2015, FDA announced that for the first time it has authorized the marketing of new tobacco products through the premarket tobacco application (PMTA) pathway. The marketing orders are for eight PMTA applications received in March 2015. FDA uses a rigorous scientific review to determine if new tobacco products should come to market under this pathway.

Before making marketing claims that imply modified risk, manufacturers must submit a Modified Risk Tobacco Product (MRTP) application, and receive an FDA order authorizing a claim that the product reduces harm or the risk of tobacco-related disease.

FDA is currently conducting substantive reviews on ten MRTP applications received in June 2014. These MRTP applications were made available to the public in August 2014, and a docket was opened for public comment. FDA continues to review these applications and intends to issue a decision when the substantive scientific review is complete.

OVERVIEW OF THE BUDGET REQUEST

The FY 2017 Budget Request is \$5.1 billion, an overall increase of eight percent or \$358.3 million compared to the FY 2016 Enacted level. The budget includes \$2.7 billion for budget authority – an increase of one-half of one percent or \$14.6 million compared to the FY 2016 Enacted level, \$2.3 billion for user fees² – an increase of twelve percent or \$268.7 million compared to the FY 2016 Enacted level, and \$75.0 million in new mandatory funding to support the Vice President’s Cancer Moonshot.

(Dollars in Thousands)	FY 2016 Enacted			FY 2017 President's Budget			FY 2017 President's Budget +/- FY 2016 Enacted		
	Food Safety	Medical Product Safety and Availability	Total	Food Safety	Medical Product Safety and Availability	Total	Food Safety	Medical Product Safety and Availability	Total
Budget Authority:									
Foods.....	987,328	---	987,328	1,012,603	---	1,012,603	25,275	---	25,275
Human Drugs.....	---	491,503	491,503	---	491,503	491,503	---	---	---
Biologics	---	215,443	215,443	---	215,443	215,443	---	---	---
Animal Drugs and Feeds.....	125,305	33,347	158,652	125,305	36,547	161,852	---	3,200	3,200
Devices and Radiological Health.....	---	323,253	323,253	---	325,764	325,764	---	2,511	2,511
National Center for Toxicological Research.....	10,233	53,098	63,331	7,179	53,098	60,277	-3,054	---	-3,054
FDA Headquarters	77,212	89,375	181,587	77,212	91,075	178,287	---	1,700	-3,300
FDA White Oak Consolidation.....	---	---	48,044	---	---	43,044	---	---	-5,000
Other Rent and Rent Related.....	37,078	36,406	73,484	36,300	35,643	71,943	-778	-763	-1,541
GSA Rental Payments	82,500	94,183	176,683	79,477	90,731	170,208	-3,023	-3,452	-6,475
SUBTOTAL, BA Salaries and Expenses.....	1,319,656	1,336,608	2,719,308	1,338,076	1,339,804	2,730,924	18,420	3,196	11,616
Building and Facilities.....	---	---	8,788	---	---	11,788	---	---	3,000
Total BA.....	1,319,656	1,336,608	2,728,096	1,338,076	1,339,804	2,742,712	18,420	3,196	14,616
Total User Fees.....	16,551	1,393,122	2,017,191	209,767	1,431,079	2,285,908	193,216	37,957	268,717
Total Mandatory Resources - Directed Transfer.....	---	---	---	---	75,000	75,000	---	75,000	75,000
Total Program Level	1,336,207	2,729,730	4,745,287	1,547,843	2,845,883	5,103,620	211,636	116,153	358,333

Budget Structure and Strategic Plan Framework

The Budget is described in terms of budget authority and user fees and is broken down into the following major activities.

- **Food Safety** – ensures the food and feed supply is safe, sanitary, wholesome, and honestly labeled, and cosmetic products are safe and properly labeled.
- **Medical Product Safety and Availability** – ensures that safe and effective human and animal drugs, biological products, devices, and radiological products are available to improve the health of the people in the U.S. and that medical countermeasures – including drugs, vaccines, and diagnostic tests – to counter chemical, biological, radiological, nuclear, and emerging infectious disease threats – are safe, effective, and secure.
- **Tobacco Regulation** – protects Americans from tobacco-related death and disease by regulating the manufacture, distribution, and marketing of tobacco products, and by educating the public about tobacco products and the dangers their use poses.
- **Infrastructure: Facilities and Rent Investments** – ensures FDA staff have functioning offices and labs across the country to execute its food safety and medical product safety mission.

² Includes proposed Food Facility Registration and Inspection, Food Import, International Courier, Cosmetics, and Food Contact Substance Notification fees and proposed increase to the Export Certification fee.

The Budget is structured around FDA’s strategic plan framework,³ which provides strategic direction to help FDA continue to serve and protect the American people. FDA’s Strategic Goals include improving and safeguarding access to – and making better informed decisions about – the products FDA regulates, as well as providing effective oversight of these products. FDA links program-specific actions to support the following priorities within these goals:

- Regulatory Science
- Globalization
- Safety and Quality
- Smart Regulation
- Stewardship.

FOOD SAFETY

The FY 2017 Budget Request is \$1.5 billion for Food Safety, an increase of \$211.6 million above the FY 2016 Enacted Level. The budget includes \$1.3 billion for budget authority – an increase of one percent or \$18.4 million compared to the FY 2016 Enacted level – and \$209.8 million for user fees – an increase of \$193.2 million compared to the FY 2016 Enacted level.

The Budget will improve food and feed safety through the continued implementation of the Food Safety Modernization Act of 2011 (FSMA). This request supports FDA’s strategic goal to Enhance Oversight and strategic priorities in the areas of Regulatory Science, Globalization, Safety and Quality, and Smart Regulation.

BUDGET AUTHORITY

Food Safety: FY 2017 Budget Authority Increase Request

(Dollars in Thousands)	FSMA Implementation						Reductions and Program Changes		Total Request	
	National Integrated Food Safety System		Import Safety		Increase Subtotal					
	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000
Salaries and Expenses Account:										
Foods.....	9	11,262	5	14,013	14	25,275	---	---	14	25,275
Center.....	---	---	---	---	---	---	---	---	---	---
Field	9	11,262	5	14,013	14	25,275	---	---	14	25,275
NCTR.....	---	---	---	---	---	---	---	-3,054	---	-3,054
Other Rent and Rent Related.....	---	---	---	---	---	---	---	-778	---	-778
GSA Rental Payments	---	---	---	---	---	---	---	-3,023	---	-3,023
Subtotal, Salaries and Expenses Account.....	9	11,262	5	14,013	14	25,275	---	-6,855	14	18,420
Total Budget Authority.....	9	11,262	5	14,013	14	25,275	---	-6,855	14	18,420
Non-Field Activities.....	---	---	---	---	---	---	---	-3,054	---	-3,054
Field Activities.....	9	11,262	5	14,013	14	25,275	---	---	14	25,275
Rent Activities.....	---	---	---	---	---	---	---	-3,801	---	-3,801

³FDA Strategic Priorities 2014-2018, September 30, 2014, <http://www.fda.gov/aboutfda/reportsmanualsforms/reports/ucm227527.htm>.

FSMA Implementation

National Integrated Food Safety System: Produce Safety

FDA's FY 2017 budget will build on the FY 2016 investments in enhancing the national integrated food safety system, which is a central element of FSMA's mandate to FDA and crucial to successful implementation of FSMA. The FY 2017 budget will support state capacity to implement the FSMA produce safety rule through funding of state cooperative agreements and grants.

FDA's implementation strategy for the FSMA produce safety rule depends on states being full partners with FDA and the primary frontline interface with growers to foster compliance with the rule. In FY 2017, FDA and state efforts regarding implementation of the produce safety rule will focus on providing educational and technical assistance to industry, especially small and very small farming operations. This effort requires building the capacity and expertise that state agencies will need to deliver timely and effective education and technical assistance so farmers can comply with the new produce safety rule.

FY 2017 resources will be used to conduct non-regulatory pre-assessments to help growers gauge their current compliance and improve as needed to comply with the new rule. This funding will also build state capacity and continue planning for future inspections to verify compliance.

Import Safety

The FY 2017 request will enable FDA to continue progress toward implementing the multifaceted new import safety system mandated by Congress, including the Foreign Supplier Verification Program (FSVP) rule, foreign food facility and produce inspections, and partnerships with foreign governments.

Under the FSVP rule importers must verify that imported food has been produced in a manner consistent with FSMA's new standards for produce safety and preventive controls. This preventive approach to import safety will improve food safety and consumer confidence in imported food but presents an enormous challenge for both FDA and food importers, given that approximately 90,000 consignees received food import shipments in FY 2015.

Building on the FY 2016 investment, FSVP will require additional funding to:

- hire and train staff to perform FSVP inspections
- provide extensive training and technical assistance for importers
- continue outreach to foreign firms and foreign government partners on new FSVP requirements.

To improve import safety, FDA will also expand its overseas presence, as mandated by FSMA. This expansion includes increasing FDA inspections and providing better targeting of foreign food facilities, as well as working with and assisting foreign governments to ensure the safety of food before it is exported to the United States.

FDA will also work with countries that already have capable food safety regulatory systems to enter into "systems recognition" agreements that will enable FDA to rely, where appropriate, on the food safety efforts of countries whose food and feed safety systems provide protections comparable to those in the United States. This investment will strengthen food safety and

efficiency by allowing FDA to leverage resources and focus its efforts on imports from areas of higher risk.

USER FEES

Proposed Food Import User Fee

FDA will use \$105.3 million in new resources provided by the proposed import user fee to facilitate the entry of safe food through enhanced border staffing, improved information systems and other importer support and port of entry streamlining.

Proposed Food Facility Registration and Inspection User Fee

The \$61.3 million proposed fee will provide resources to further modernize the FDA inspection program through the further development and implementation of new inspection models and tools, including training in the new models and information technology to improve targeting and risk-based efficiency of inspection. The fee revenue will also provide essential resources for investment in the state training and capacity needed to fully achieve the vision of a national integrated food safety system that provides high quality, consistent and coordinated food safety oversight nationwide.

Proposed Cosmetics User Fee

FDA will use \$20.2 million in new resources to support FDA cosmetic safety responsibilities. Additional funds will strengthen FDA efforts to develop regulations and guidance, enhance safety evaluations, and improve cosmetics-related communication and outreach to promote greater safety and understanding of cosmetic products.

Proposed Food Contact Substance Notification User Fee (FCN)

FDA will use \$5.2 million in new resources to provide a stable, long-term source of funding to supplement budget authority. FDA has statutory responsibility for the safety of all food contact substances in the United States. The Federal Food Drug and Cosmetic Act specifies that the FCN program can operate only if adequately funded.

MEDICAL PRODUCT SAFETY AND AVAILABILITY

The FY 2017 Budget Request is \$2.8 billion for Medical Product Safety and Availability, an increase of \$116.2 million above the FY 2016 Enacted level. The request includes \$1.3 billion for budget authority – an increase of 0.2 percent or \$3.2 million compared to the FY 2016 Enacted level, \$1.4 billion for user fees – an increase of three percent or \$38.0 million compared to the FY 2016 Enacted level, and \$75.0 million in new mandatory funding for the Vice President’s Cancer Moonshot.

With this request, FDA will improve medical product safety and availability in five key areas:

- supporting animal drug and medical device review
- evaluating Precision Medicine-based diagnostics and treatments
- improving the safety of compounded drugs
- combating antibiotic resistant bacteria
- improving cancer diagnostics and treatments.

The request supports FDA’s strategic goals to Improve and Safeguard Access and Enhance Oversight. Additionally, it supports FDA strategic priorities in the areas of Regulatory Science, Globalization, Safety and Quality, Smart Regulation, and Stewardship.

BUDGET AUTHORITY

Medical Product Safety and Availability: FY 2017 Budget Authority Increase Request

(Dollars in Thousands)	Supporting Animal Drug and Medical Device Review		Precision Medicine		Pharmacy Compounding		Combating Antibiotic Resistant Bacteria		Increase Subtotal		Reductions and Program Changes ¹		Total Request	
	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000
Salaries and Expenses Account:														
Human Drugs.....	---	---	---	---	2	1,000	---	-1,000	2	---	---	---	2	---
Center.....	---	---	---	---	1	560	---	-1,000	1	-440	---	---	1	-440
Field.....	---	---	---	---	1	440	---	---	1	440	---	---	1	440
Animal Drugs and Feeds.....	8	2,200	---	---	---	---	1	1,000	9	3,200	---	---	9	3,200
Center.....	8	2,200	---	---	---	---	1	1,000	9	3,200	---	---	9	3,200
Field.....	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Devices and Radiological Health.....	---	711	3	1,800	---	---	---	---	3	2,511	---	---	3	2,511
Center.....	---	711	3	1,800	---	---	---	---	3	2,511	---	---	3	2,511
Field.....	---	---	---	---	---	---	---	---	---	---	---	---	---	---
FDA Headquarters.....	---	---	---	200	---	---	---	---	---	200	---	1,500	---	1,700
Other Rent and Rent Related.....	---	---	---	---	---	---	---	---	---	---	---	-763	---	-763
GSA Rental Payments.....	---	---	---	---	---	---	---	---	---	---	---	-3,452	---	-3,452
Subtotal, Salaries and Expenses Account.....	8	2,911	3	2,000	2	1,000	1	---	14	5,911	---	-2,715	14	3,196
Total Budget Authority.....	8	2,911	3	2,000	2	1,000	1	---	14	5,911	---	-2,715	14	3,196
Non-Field Activities.....	8	2,911	3	2,000	1	560	1	---	13	5,471	---	1,500	13	6,971
Field Activities.....	---	---	---	---	1	440	---	---	1	440	---	---	1	440
Rent Activities, B&F, and White Oak.....	---	---	---	---	---	---	---	---	---	---	---	-4,215	---	-4,215

¹Includes restoration of \$1.5 million transferred from FDA to HHS OIG in FY 2016.

Precision Medicine

Precision Medicine is a new model in which disease prevention and treatment are based on the biological profile and preferences of each individual. The FY 2017 Budget provides \$4.4 million in budget authority for Precision Medicine, an increase of \$2.0 million above the FY 2016 Enacted level. Advances in technology, such as next generation sequencing (NGS), have dramatically improved the ability to determine which patients are most likely to be susceptible to a specific disease – and thus likely to benefit from preventive measures – and which patients are most likely to respond to, or suffer complications from, a specific treatment. This concept was described by President Obama in his 2015 State of the Union Address as the ability to determine the right treatment for the right patient at the right time.

With the requested increase in FY 2017, FDA will establish the National Medical Device Evaluation System (NES) to identify patients who benefit most or do not benefit from specific types of devices thereby advancing Precision Medicine. The NES will leverage real world data generated as a part of routine clinical practice to spur medical device innovation, faster patient access to safe and effective technologies, and reduce costs to the U.S. healthcare system from new safety problems. FDA will also continue to invest in precisionFDA, which provides a crowd-sourced, cloud-based platform to advance regulatory science around NGS-based analytical tools and datasets.

Compounding

The FY 2017 request will allow FDA to improve oversight of human drug compounding through sustained or increased inspection and enforcement activities, policy development and implementation, and state collaboration and coordination. Increased efforts in these areas will prevent outbreaks that could result in deaths of or injuries to patients who receive poor quality

compounded drugs. FDA has a unique responsibility to protect and promote the public health by working to reduce the risks of compounded human drug products.

Title I of the Drug Quality and Security Act (DQSA), the Compounding Quality Act, provides FDA with additional authorities to strengthen oversight of compounding. FDA's capacity to effectively oversee human drug compounding will be limited without additional resources. Insufficient oversight will increase the likelihood of outbreaks and serious adverse events resulting from poor quality compounded drugs.

During its inspections of compounders, FDA continues to identify serious problems at facilities that are making drugs expected or intended to be sterile. For example, FDA has seen:

- the use of non-sterile drinking water dispensed from a top-loaded bottled water dispenser to make injectable drug products
- dog beds, dog feces, and dog hairs within a compounding facility, including in close proximity to the compounding room
- compounding of sterile drugs by personnel with exposed skin, which sheds particles and bacteria
- use of coffee filters to filter particulates
- toaster ovens used for sterilization
- a kitchen dishwasher and detergent used to clean sterile compounding equipment and utensils
- dead insects in ceilings
- renovations conducted next to sterile compounding operations without taking precautions to prevent contamination of the sterile products.

FDA needs additional resources to continue its inspection efforts and to take regulatory action, as appropriate, to protect the public health. The FY 2017 Budget provides \$18.4 million in budget authority for Compounding, an increase of \$1.0 million above the FY 2016 Enacted level.

In addition to continuing its inspection and enforcement efforts, numerous policy issues must be addressed in implementing the provisions of the FD&C Act applicable to compounding. For example, FDA intends to promulgate specific Current Good Manufacturing Practice (CGMP) requirements for outsourcing facilities and determine regulatory policies for activities conducted by outsourcing facilities that are not covered by section 503B, such as mixing, diluting, and repackaging of biological products and compounding animal drugs.

Outsourcing facilities are also required to report adverse events associated with their products and FDA needs resources to review these reports and investigate the adverse events as appropriate.

Combating Antibiotic Resistant Bacteria

Antibiotics are important in combating infectious diseases in humans and animals. Antibiotic resistance, the ability of bacteria to evade or resist antibiotics, is a growing public health threat. *The National Action Plan for Combating Antibiotic-Resistant Bacteria*, issued by the White House in March 2015, is intended to guide the activities of the U.S. Government as well as guide action by public health, healthcare, and veterinary partners in a common effort to address urgent and serious drug-resistant threats. The FY 2017 Budget provides \$41.6 million for antimicrobial

resistance activities, which includes CARB, the same as the FY 2016 Enacted level. The budget includes \$39.6 million for budget authority and \$2.0 million for user fees.

In FY 2017, the Animal Drugs and Feeds Program will work to address public health safety concerns associated with antimicrobial drug use in animals and to better protect antibiotic effectiveness for both human and animal populations. FDA will work in collaboration with USDA to support efforts to monitor antimicrobial drug use in food-producing animals through the periodic collection of nationally representative on-farm data on antimicrobial-use practices and resistance. FDA will also coordinate with USDA to develop a U.S. Government annual assessment report, including identification of key outcome measures.

Supporting Animal Drug and Medical Device Review

FDA requests \$2.9 million to support ongoing activities within Animal Drug Review Program and Devices Program to achieve enhanced and predictable review performance that meets industry, congressional, and public expectations.

The Animal Drug Review Program for pioneer animal drugs is an important FDA program, supporting both human and animal health. The program strives to meet performance goals for statutory review timeframes, which has allowed pioneer animal drugs to advance to market faster and ensure the availability of animal drug products that are safe and effective for animals as well as for the public with respect to animals intended for food consumption. The increased funding requested will enable FDA to continue to meet premarket animal drug review requirements by having the necessary review staff to carry out these activities...

The Devices Program strives to increase the efficiency of regulatory processes with a goal of reducing the time it takes to bring safe and effective medical devices to the U.S. market. The requested increase supports ongoing review activities in the Devices Program to meet statutory requirements for the review of medical device applications. As a result, the Devices Program can continue to ensure the safety and effectiveness of medical devices that Americans rely on every day, while facilitating scientific innovations that extend and improve lives.

MANDATORY RESOURCES – DIRECTED TRANSFER

Vice President’s Cancer Moonshot

FDA requests \$75 million in mandatory resources as part of the Vice President’s Cancer Moonshot in order to accelerate progress in cancer – to reduce the number of people who develop cancer and to improve the outcome for those who do. Thanks to sustained federal investment in biomedical research, current cancer mortality rates are about 15 percent lower than they were a decade ago. Federal investments in basic, epidemiologic, and clinical research have led to significant advances in the prevention, screening, and treatment of cancer.

In order to support the dramatic increase in the number, complexity, and potency of cancer diagnostics and therapeutics, FDA will establish an Oncology Center of Excellence to streamline collaboration across FDA’s Human Drugs, Biologics, and Devices and Radiological Health, Programs. Though the Center will largely be virtual, involving staff from current programs, FDA requires new resources for a dedicated core staff that will provide leadership direction and project management.

The Center will closely interface with the NIH National Cancer Institute (NCI) to streamline the development and expedite the approval of novel devices, drugs, biologics, and combination

products. The Center will provide NCI intramural and extramural investigators with “one stop shopping” for regulatory and clinical development advice, such as support for the development of:

- new vaccines to prevent cancers caused by viruses
- new and advanced diagnostics for early screening and detection of cancer
- novel single entity and combination medical products.

The Center will also support improved access to new treatments through cancer clinical trials and access programs, and it will enhance sharing of cancer data from clinical trials to promote biological and clinical breakthroughs.

In addition to facilitating a holistic approach to the review of medical products for cancer, the multidisciplinary nature of the Oncology Center of Excellence, combining regulatory scientists and reviewers with expertise in drugs, biologics, and devices will also foster and expedite the development of novel combination products for the treatment of cancer (e.g., nanoparticles coated with a drug or a biologic to deliver therapy locally to a tumor). With the continued development of companion diagnostic tests and the use of combinations of drugs and biologics to treat cancer using methods developed through the science of precision medicine, to most benefit those affected, FDA needs to take an integrated approach in its evaluation of products for the prevention, screening, diagnosis, and treatment of cancer.

INFRASTRUCTURE: FACILITIES AND RENT INVESTMENTS

The FY 2017 Budget Request provides an increase of \$3.6 million over the FY 2016 Enacted level for urgent facility investments that will provide improve the functioning of offices and labs across the country to ensure FDA can execute its Food Safety and Medical Product Safety and Availability mission. This increase includes \$3.0 million in Buildings and Facilities funding to address repairs, improvements and mission support needs at FDA’s owned laboratories and other critical owned facilities across the United States. The request also supports increased rent for FDA’s 291 leased buildings, rent-related funding for operations and maintenance needs, and for White Oak operations.

FDA’s responsibilities continue to escalate as we work to fulfill the mandates of groundbreaking legislation passed in recent years. This expansion of authorities urgently requires that FDA’s critical infrastructure at its owned locations is properly functioning to enable FDA to carry out its mission and respond to food safety and medical product emergencies. This investment will prevent the further deterioration of FDA’s owned facilities.

CURRENT LAW AND PROPOSED USER FEES

FDA requests a \$66.4 million increase in current law user fees for the review of animal drugs and the review and surveillance of human drugs, medical and mammography devices, food and feed, color additives, export certification, and tobacco products. The request includes statutorily mandated increases, infrastructure, and inflation. These increases will fund options for review of medical products used for treating and curing diseases and strategies to reduce the costs of illness and death caused by tobacco products.

Proposed users fees that impact both Food Safety and Medical Product Safety and Availability are displayed below.

Proposed International Courier User Fee

FDA requests \$6.0 million in new user fees to increase surveillance of FDA-regulated commodities at express courier hubs. About 20 percent, or \$1.2 million, of this proposed fee will support imported food safety. Almost 80 percent, or \$4.8 million, of this proposed fee will support imported medical product safety.

Export Certification Fee

FDA is proposing an increase of \$4.3 million for the export certification program by increasing the statutory maximum for the certification fee from \$175 to \$600 per certification and including an inflation adjustment factor for the statutory maximum. 21 U.S.C. § 381(e)(4), originally enacted in 1996, currently limits the maximum export certification fee to \$175 per certification. Because of this cap and increases in the costs of maintaining the export certification program since the program's inception, the certification program expenditures significantly exceed the current revenue of the program. Increasing the maximum fee to an inflation-adjusted \$600 per certification will allow the Agency to fully recover its costs in implementing this program.

OVERVIEW OF PERFORMANCE

The *FDA Strategic Priorities 2014-2018* focus efforts to achieve FDA's public-health mission and to fulfill its role in supporting HHS' larger mission and strategic goals. The FY 2017 Budget is structured around these priorities and goals, as discussed in the Overview of the Budget Request.

Transparency and Accountability

In April 2011, FDA launched FDA-TRACK, which is the Agency-wide performance management system. FDA-TRACK monitors, analyzes, and reports monthly performance on all FDA program offices and on key cross-cutting initiatives. Each quarter, the FDA-TRACK team uses statistical models to analyze monthly performance data collected from each office and initiative. Face-to-face briefings are then conducted with the office directors responsible for each program who present their performance data and results to FDA executive leadership.

These briefings stimulate discussion and facilitate better communication, decision-making, plan of action and ultimately, performance. Briefing summaries and performance results are then posted to the FDA-TRACK website, allowing FDA's stakeholders to monitor progress on more than 600 performance measures and 100 key projects.

The objectives of FDA-TRACK can be explained through its name:

- **Transparency** – provides interested parties an unprecedented look into how FDA performs its work
- **Results** – highlights performance measures and results related to the agency's public-health mission
- **Accountability** – requires senior managers to develop, track, and report performance measures to improve the agency's accountability to the public and holds the program offices accountable for their priorities, plans and results
- **Credibility** – encourages sharing of FDA performance information which is essential for the agency's credibility and provides the opportunity to submit suggestions for continuous improvement efforts

- **Knowledge-sharing** – enables the identification of common issues and interdependencies among program offices to improve FDA’s operational effectiveness, through better collaboration, and the sharing of ideas.

The performance measures in FDA-TRACK represent the foundational activities and outputs produced by FDA employees. Since the inception of FDA-TRACK, FDA has seen significant performance improvement in programs, including:

- the elimination of the backlog of generic new animal drug applications and
- increases in hospital participation in the MedSun Program.

On the operational side, FDA has dramatically improved its advisory committee vacancy rate and progressed to dramatically reduce its Freedom of Information Act backlog.

FDA-TRACK has enabled better performance by providing a medium to track progress, monitor results, discuss concerns, and communicate achievement. Over 49,000 visitors subscribe to the FDA-TRACK monthly updates.

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