

EXECUTIVE SUMMARY

This Executive Summary describes the fiscal year (FY) 2019 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.

New Steps to Confront the Opioid Crisis

FDA is addressing the opioid crisis facing the nation, including through the establishment of the Opioids Policy Steering Committee in 2017.

FDA took immediate action where needed, which included the agency's first-of-its-kind request to remove a currently marketed opioid pain medication from sale due to the public health consequences associated with the product's abuse and misuse. FDA identified the following ways to decrease exposure to opioids, prevent new addiction, and support the treatment of those with opioid use disorder:

- development of new Risk Evaluation and Mitigation Strategy requirements for makers of immediate-release opioids
- labeling changes with clarifying information on the use of medication-assisted treatments for patients suffering from opioid use disorder
- creative approaches to packaging, storage, and disposal of opioid medications.

Record Medical Product Approvals

Calendar year 2017 saw groundbreaking medical products brought to market, a record number of generic drug approvals to promote competition, and advancing policies to promote innovation and improve people's lives. For example, FDA coordinated the approval of a novel diagnostic device that can detect hundreds of genetic mutations in a single test to coincide with the Centers for Medicare & Medicaid Services' proposed coverage of the device, thereby facilitating earlier access to the innovative medical technology for Medicare beneficiaries.

In August 2017, FDA also saw a whole new way to treat disease with the approval of the first gene therapy in the United States – with two more approved since then. Innovations like these are creating a turning point in the treatment of serious illnesses with more potential to cure intractable and inherited diseases

FDA approved a record number of novel drugs and biologics in 2017, including 46 new molecular entities; and more than two-thirds were approved using one or more of our expedited review programs. FDA also had a record number of drugs with orphan indications approved and eliminated the entire backlog of pending orphan drug designation requests.

FDA broke records with the highest number of generic drugs approved in a single month, multiple times in 2017 and recorded the highest annual total of generic drug approvals in the agency's history with 1,027 approvals.

In calendar year 2017, the agency approved a record number of new devices, 95 – more than four times the number of novel devices that received market approval in 2009.

Regulatory Efficiency

FDA faces the challenge of regulating new areas of science like gene therapy, targeted medicine, and digital health where traditional approaches to product regulation may not be well suited. To meet these challenges, FDA is taking a fresh look at how to adapt our approaches to make sure that we are enabling beneficial new technology to develop, while maintaining FDA's gold standard for product review and consumer protection. Accomplishments in 2017 included:

- a novel pathway for review of precision-medicine based diagnostic tests by accredited third-parties to reduce the burden on test developers and streamline regulatory assessment
- a pilot program exploring a new way of regulating digital health devices
- a suite of guidances to clarify how FDA will regulate digital health technologies to encourage innovation.

FDA also helped manufacturers of low- to moderate-risk medical devices by reducing unnecessary submissions to the FDA for changes that could not significantly affect device safety or effectiveness, so patients can benefit from upgraded products more quickly.

Other accomplishments in 2017 included:

- developing comprehensive policy framework on regenerative medicine to spur safe and effective innovation
- issuing draft guidance for manufacturers of 3D printed medical devices
- launching a new searchable database to better inform patients and health care professionals of adverse events reported with drug and biologic products
- facilitating faster patient access to needed compounded medicines, while protecting the public from poorly compounded drugs.

FDA continues to promote and encourage work that will enable us to utilize real world data in our regulatory decision making.

FDA took the following actions in 2017 to alert the public and raise awareness of potential safety concerns and violations:

- took action against stem cell clinics marketing products without FDA approval, putting patients at risk
- warned companies making false claims that their unapproved products can treat or cure life-threatening diseases
- advanced a new framework for regulating homeopathic products based on consumer risk
- alerted the public to the dangers of unproven and untested products.

Drug Competition

FDA plays a pivotal role in fostering drug competition through the approval of safe, effective, and lower-cost generic drugs.

FDA is finding innovative ways to help foster competition and provide patients with more access to affordable medications. In May 2017, FDA announced various actions as part of the agency's Drug Competition Action Plan to increase competition in the market for prescription drugs and facilitate entry of lower-cost alternatives.¹

To encourage generic drug development, FDA has:

- prioritized review of generic drug applications
- issued guidance to enhance regulatory certainty for generic drug development and review
- made significant progress on the massive generic drug review backlog to facilitate enhanced generic drug choices.

FDA also approved a record number of generic drugs in 2017 with 1,027 approvals.

Emergency Response, Recovery, and Medical Countermeasures

FDA has wide-ranging responsibilities to protect the public when the nation is faced with public health threats, whether naturally-occurring, or man-made. The devastation caused by Hurricanes Harvey, Maria, and Irma brought to light the critical work the agency does in overseeing the safety of the food and medical supply in this country. FDA worked around the clock to ensure farmers in Texas and Florida could safely handle their crops affected by flooding. FDA remains committed to the recovery in Puerto Rico and that island's long-term success, and worked closely with drug and medical device manufacturers in Puerto Rico to take steps to address potential and apparent shortages of medical products that resulted from the devastation left by Hurricane Maria. FDA's work and commitment to hurricane victims and patients in need of critical medical products will continue into 2018.

In addition, over the past two years, FDA mobilized more than 500 staff members to respond to the Zika virus outbreak, including deployments to Zika-affected Puerto Rico. As part of the U.S. Government response efforts, FDA has worked to:

- protect the nation's blood and tissue supply
- facilitate the development and availability of diagnostics, including authorizing 20 diagnostics for emergency use
- support development of vaccines and therapies.

Zika response efforts are part of the FDA's Medical Countermeasures program, which is critical to ensuring that the United States is able to protect against chemical, biological, radiological, nuclear, and emerging infectious disease threats, such as pandemic influenza, Ebola virus, and Zika virus.

Food Safety

Efforts to improve food safety require partnerships to achieve our public health goals. In FY 2017, FDA awarded approximately \$31 million to 43 state government organizations to help implement the produce safety rule through training and compliance activities, following up on nearly \$22 million in funds made available to states in FY 2016.

In August 2017, in order to help businesses meet the requirements of the FDA's Final Rule for Preventive Controls for Human Food, FDA released a new software tool to help owners and

¹ Association for Accessible Medicines, 2017 Generic Drug Access and Saving Report in the U.S. (2017). Available at <https://accessiblemeds.org/resources/blog/2017-generic-drug-access-and-savings-us-report>

operators of food facilities create a food safety plan specific to their facilities. The Food Safety Plan Builder is a free software application that businesses can download from the FDA's website to guide them, step-by-step, through the creation of a food safety plan. The development of a food safety plan is one requirement of the new law. While the software tool was primarily developed with small businesses in mind, it can be used by manufacturers of any size.

In May 2017, FDA extended the compliance date for menu labeling by a year, and in November 2017, FDA announced additional draft guidance on the menu labeling requirements. Menu labeling regulations require the disclosure of certain nutritional information for standard menu items in chain restaurants and similar retail food establishments. The draft guidance addresses concerns that were raised about challenges establishments faced in understanding how to meet their obligations under the new regulations. These new policy steps should allow covered establishments to implement the requirements by the May 2018 compliance date.

Tobacco Regulation

On July 28, 2017, FDA announced a new comprehensive plan for tobacco and nicotine regulation that will serve as a multi-year roadmap to better protect kids and significantly reduce tobacco-related disease and death. The approach places nicotine, and the issue of addiction, at the center of the agency's tobacco regulation efforts. The goal is to ensure that the FDA has the proper scientific and regulatory foundation to efficiently and effectively implement the Family Smoking Prevention and Tobacco Control Act.

FDA has begun a public dialogue about lowering nicotine levels in combustible cigarettes to minimally or non-addictive levels through achievable product standards. On March 16, 2018, FDA published an Advance Notice of Proposed Rulemaking (ANPRM) to seek input on the potential public health benefits and any possible adverse effects of limiting nicotine in cigarettes to minimally or non-addictive levels.

Further, FDA indicated that it is seeking public input on several other issues to help ensure that the Agency has the proper science-based policies in place to meaningfully reduce the harms caused by tobacco use. On March 21, 2018, FDA published an ANPRM to seek public comment on the role that flavors in tobacco products—including menthol—play in attracting youth, as well as the role some flavors may play in helping some smokers switch to potentially less harmful forms of nicotine delivery. FDA also announced on March 23, 2018 an ANPRM to solicit additional comments and scientific data related to the patterns of use and resulting public health impacts from premium cigars.

To encourage innovations that have the potential to make a notable public health difference and to put foundational rules in place to provide increased clarity and efficiency for industry, the Agency extended the premarket application deadlines described in the May 2016 final rule for certain products. Specifically, the FDA is deferring enforcement of deadlines to submit tobacco product review applications for newly regulated tobacco products that were on the market as of August 8, 2016. Under these revised timelines, applications for newly regulated combustible products, such as cigars, pipe tobacco, and hookah tobacco, would be submitted by August 8, 2021, and applications for non-combustible products such as electronic nicotine delivery systems (ENDS) would be submitted by August 8, 2022.

On November 29, 2017, FDA announced the formation of a new Nicotine Steering Committee, which will be a forum for developing and implementing nicotine policy to address the public

health effects of tobacco usage in this country. The primary focus will be on nicotine replacement therapy (NRT) products for combustible tobacco product cessation. The formation of this group reflects the need to critically examine the evolving science behind the FDA's evaluation of the safety and efficacy of NRT products.

OVERVIEW OF THE BUDGET REQUEST

The FY 2019 Budget Request is \$5.8 billion – an overall increase of 11 percent or \$662.9 million compared to the FY 2018 Annualized CR level.² The request includes \$3.2 billion for budget authority – an increase of 14 percent or \$432.9 million compared to the FY 2018 Annualized Continuing Resolution (CR) level. The request includes \$2.5 billion for user fees – an increase of 7 percent or \$189.9 million compared to the FY 2018 Annualized Continuing Resolution level. FDA will also begin implementation of a working capital fund in FY 2019, consistent with the authority requested in the President's Budget.

(Dollars in Thousands)	FY 2018 Annualized CR			FY 2019 President's Budget			FY 2019 President's Budget +/- FY 2018 Annualized CR		
	Food Safety	Medical Safety and Availability	Total	Food Safety	Medical Safety and Availability	Total	Food Safety	Medical Safety and Availability	Total
	\$000	\$000	\$000	\$000	\$000	\$000	\$000	\$000	\$000
Programs									
Budget Authority:									
Foods.....	1,022,211	---	1,022,211	1,029,863	---	1,029,863	7,652	---	7,652
Human Drugs.....	---	488,264	488,264	---	686,364	686,364	---	198,100	198,100
Biologics	---	213,854	213,854	---	251,854	251,854	---	38,000	38,000
Animal Drugs and Feeds.....	124,951	36,779	161,729	125,806	54,479	180,284	855	17,700	18,555
Devices and Radiological Health.....	---	327,442	327,442	---	455,442	455,442	---	128,000	128,000
National Center for Toxicological Research.....	10,164	52,737	62,901	10,233	54,967	65,200	69	2,230	2,299
FDA Headquarters	73,016	89,352	180,980	73,540	115,352	198,565	524	26,000	17,585
FDA White Oak Consolidation.....	---	---	42,752	---	---	49,430	---	---	6,678
Other Rent and Rent Related	36,053	35,401	71,454	36,300	50,197	86,497	247	14,796	15,043
GSA Rental Payments	78,937	90,115	169,052	79,477	88,944	168,421	540	-1,171	-631
SUBTOTAL, BA Salaries and Expenses.....	1,345,331	1,333,944	2,740,639	1,355,218	1,757,599	3,171,920	9,887	423,655	431,281
21st Century Cures.....	---	19,864	19,864	---	70,000	70,000	---	50,136	50,136
MCMi.....	---	9,932	9,932	---	---	---	---	-9,932	-9,932
Building and Facilities.....	---	---	11,708	---	---	11,788	---	---	80
Total BA.....	1,345,331	1,363,740	2,782,143	1,355,218	1,827,599	3,253,708	9,887	463,859	471,565
Total User Fees.....	15,863	1,698,281	2,354,957	15,863	1,806,922	2,544,847	---	108,641	189,890
Total Program Level, Pre-Transfer	1,361,194	3,062,021	5,137,100	1,371,081	3,634,521	5,798,555	9,887	572,500	661,455
Additional Opioids Allocation (non-add)	0	0	0	0	10,000	10,000	0	10,000	10,000

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 accurately labeled, and that 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., including medical countermeasures - the drugs, vaccines, and diagnostic tests to counter chemical, biological, radiological, nuclear, and emerging infectious disease threats.
- **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.

² Includes reductions to Foreign High Risk Inspections and HHSOIG Transfer. See FDA HQ narrative for details.

- **Infrastructure: Facilities and Rent Investments** – ensures FDA staff have optimally functioning offices and labs across the country to execute the agency's food safety and medical product safety mission.

The Budget is structured around four core mission goals: enhancing oversight of FDA-regulated products, improving and safeguarding access to FDA-regulated products to benefit health, promoting better informed decisions about the use of FDA-regulated products, and strengthening organizational excellence and accountability. FDA has also published *Healthy Innovation, Safer Families: FDA's 2018 Strategic Policy Roadmap*, which provides an overview of some of the key priorities the Agency is pursuing to advance FDA's public health mission.³

FOOD SAFETY

The FY 2019 Budget provides \$1.4 billion for food safety, an increase of \$9.9 million compared to the FY 2018 Annualized CR. The request includes \$1.3 billion for budget authority – an increase of \$9.9 million compared to the FY 2018 Annualized CR, and \$15.9 million for user fees – flat with the FY 2018 Annualized CR. This request aligns to FDA's Strategic Policy Roadmap priorities to strengthen food safety and empower consumers to make better and more informed decisions about their diets and health.

Food Safety (+\$10 million)

The FY 2019 funding level restores the FY 2018 Annualized CR rescission to the food safety program and maintains current FY 2017 activities. In FY 2019, FDA will continue its statutory mission of promoting and protecting public health by ensuring that the food supply is safe, sanitary, wholesome, and properly labeled. The FY 2019 level will also allow FDA to continue its critical FDA Food Safety Modernization Act (FSMA) implementation activities.

MEDICAL PRODUCT SAFETY AND AVAILABILITY

The FY 2019 Budget Request for medical product safety and availability is \$3.6 billion, an increase of \$572.5 million above the FY 2018 Annualized CR. The request includes \$1.8 billion for budget authority – an increase of \$463.9 million compared to the FY 2018 Annualized CR – and \$1.8 billion for user fees – an increase of \$108.6 million compared to the FY 2018 Annualized CR. As part of this user fee funding level, the FY 2019 Budget proposes to reauthorize the expiring Animal Drug and Animal Generic Drug User Fee programs, as well as reforms to the Over-the-Counter Monograph program supported by new fees. The proposed legislation authorizes the collection and spending of these fees subject to appropriations.

The FY 2019 Budget level for medical product safety aligns to FDA's Strategic Policy Roadmap priorities to reduce the burden of the addiction crises that are threatening American families and leverage innovation and competition to improve healthcare, broaden access, and advance public health goals.

Innovation Initiatives (+\$400M)

New scientific opportunities, as well as advances in manufacturing and commerce, give FDA new ways to advance our mission to protect and promote public health. Leveraging these opportunities requires us to make investments in regulatory science that can reduce uncertainty

³ <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm591993.htm>

for innovators, spur investment in new industries and provide principles for the safe and effective development of new technologies. These same advances also give us new ways to support greater availability and use of generic drugs as a way to promote price competition and patient access. The FY 2019 Budget includes \$400 million for initiatives aimed at supporting new and ongoing efforts to foster more investment and innovation in the development of therapeutics and diagnostics that target unmet medical needs; advance drug and device competition; stand up new domestic industries – such as pharmacy outsourcing facilities; and create more modern, domestically-based manufacturing, including continuous manufacturing of drugs and biological products, including vaccines. These manufacturing platforms can bring more businesses back to the U.S., help lower drug and device development costs and reduce the risk of shortages. Investing in these initiatives will help the FDA advance goals that we all share: improved treatment and diagnostic options for patients; lower healthcare costs; the development of new industries that will lead to U.S.-based jobs; and manufacturing advances that are more reliable, lower cost and high quality.

Promote Domestic Manufacturing: Advancing Modern Drug and Biological Product Manufacturing Technologies, Through the Development of Efficient Regulatory Pathways (+\$58M)

The FY 2019 Budget Request for FDA includes \$58.2M to promote domestic manufacturing. These technologies have great potential to accelerate new, more targeted therapies, enhance product quality and bolster stability in the U.S. drug supply to meet domestic and global needs. These new manufacturing platforms may be especially important in the development of personalized medicines and innovations in cell- and gene-based therapies and vaccines. With these resources, FDA will help reduce the cost and uncertainty of adopting new manufacturing technologies by developing a science-based framework that includes the regulatory tools and guidance for how products will be evaluated, and by funding research, development and testing of these technologies.

Advance a New Domestic Drug Industry and Promote Access by Establishing the Outsourcing Facility Sector as a Robust and Reliable Source of Compounded Products (+\$25M)

The FY 2019 Budget includes \$25 million to create a “Center of Excellence on Compounding for Outsourcing Facilities.” With these resources, FDA will expand engagement with outsourcing facilities and states to help the pharmacy outsourcing industry grow to meet its intended function and adhere to higher quality standards to protect patient health. The Center of Excellence will identify and propose solutions to market barriers to lower the cost for pharmacies to become outsourcing facilities. The Center will provide much-needed education and training to improve product quality, safety, and purchaser confidence, and help the FDA adjust its regulatory oversight to better match the scope of production of an individual compounding pharmacy. FDA will work with industry to improve manufacturing practices, create new programs relating to requested review of method design and stability study protocols, and work with state partners to reduce challenges associated with state regulatory diversity and support state-based oversight of pharmacies.

Bring MedTech Manufacturing Home: Advance Medical Device Manufacturing and Quality (+\$12M)

The FY 2019 Budget includes \$12 million to establish a voluntary program for device manufacturers to receive certification for meeting objective manufacturing and product quality criteria. As medical devices become more complex – and given the frequent modifications made to devices – spurring advanced manufacturing and creating a competitive marketplace for device quality is critical for both driving technological innovations and assuring patient safety. FDA is already working collaboratively with industry, patients, providers, and payers through the Medical Device Innovation Consortium to develop the parameters of the program. As part of this approach, the FDA will recognize third-party certifiers and offer regulatory incentives for those manufacturers who receive certification demonstrating their quality capability. These actions will increase manufacturing innovation, accelerate availability of high-quality devices to patients and foster a competitive marketplace around device quality similar to other industries, such as automotive and aerospace, that will advance device innovations, reduce manufacturing costs, and improve the quality and safety of medical devices.

Create a New Medical Data Enterprise: Advance the Use of Real-World Evidence to Improve Human and Animal Health and Support Pre-Market Evaluation and Post-Market Safety (+\$100M)

The FY 2019 Budget includes \$100 million to advance the use of real-world experience to better inform patient care and provide more efficient, robust, and potentially lower-cost ways to develop clinical data that can inform product review and promote innovation. The effort will cover a broad range of medical products, including drugs, biologics, and medical devices. FDA will establish a new capability, including the development of data and analytical tools, to conduct near-real-time evidence evaluation down to the level of individual electronic health records for at least 10 million individuals in a broad range of U.S. healthcare settings. In the case of transcatheter heart valves, leveraging real-world evidence has already resulted in a greater than 400 percent cost savings for industry, improved post-market surveillance and moved the United States from 42nd to, in some cases, first-in-the-world approvals for life-saving technologies. Expanding FDA's capacity to utilize real-world evidence to evaluate the pre- and post-market safety and effectiveness of medical products will generate processes that could improve the efficiency of the regulatory process, better inform patients and providers about pre- and post-market safety, reduce some of the burdens that drive up the time and cost required to bring beneficial innovations to the market and address barriers that can make certain important safety and effectiveness information around the real-world use of products hard to collect and evaluate.

Facilitate Growth and Spur Transformation of the Digital Health Technology Industry by Shifting Regulation to an Efficient and Novel Framework for Reliable Post-Market Oversight (+\$70M)

The FY 2019 Budget includes \$70 million for FDA to work collaboratively with industry, patients, and providers to establish a new paradigm for digital health technologies. This paradigm will allow companies to market lower-risk products without FDA premarket review and market higher-risk products following a streamlined FDA premarket review. FDA will further reduce the time and cost of market entry of digital health technologies while assuring appropriate patient safeguards by relying on post-market collection of real-world data to support

new and evolving product functions. FDA will also create a Center of Excellence on Digital Health to establish the regulatory paradigm, build new capacity to evaluate and recognize third-party certifiers, and support a cybersecurity unit to complement the advances in software-based devices. Implementing these regulatory innovations and information technology improvements are essential for advancing software-based technologies to improve the health and quality of life of patients while assuring critical safeguards as the current regulatory framework is not well-suited for driving the development of safer, more effective software-based devices, including the use of machine learning and artificial intelligence.

Create a New Platform for How the Agency More Efficiently Develops and Validates Modern Science-Based Principles for New Drug Development (+\$78M)

The FY 2019 Budget Request for FDA includes \$77.5 million for investments in CDER and FDA HQ to keep pace with rapidly advancing science in drug development.

Applying Cutting Edge Science to Advance Drug Development and Review: Drug Innovation Platform

The FY 2019 budget includes \$57.5 million to build a knowledge management system and portal to existing and developing information on drug development and previous regulatory decisions. Rapidly advancing science in drug development requires FDA to have up-to-date scientific standards and assessment tools, as well as evolving technologies, methods, and approaches. Without these tools, the Agency's ability to support innovation and review applications will lag behind the latest science and inhibit innovation. Currently, FDA has a number of drug development guidances where updates to assure new scientific information and new approaches to drug development are incorporated. In addition, guidances are needed in a number of disease areas where there is no existing guidance and therefore no articulated pathway to market for new treatments.

FY 2019 funding for a content management platform will enable the FDA to build on evolving information and decisions and identify gaps in regulatory policies and pathways. FDA's decision-making rests on the regulatory and statutory framework, and on the scientific expertise of its staff, but would be supported and facilitated by a comprehensive knowledge management system that provides access to and analysis of prior regulatory decisions and previously submitted clinical trials information and other relevant datasets. This investment will enable rapid, consistent responses to regulatory questions and prevent delays in response to innovations in drug development.

Oncology Center of Excellence

As part of this initiative to support new drug development, the FY 2019 Budget includes \$20 million for the Oncology Center of Excellence (OCE) to stand up a new model for team-based product review that fosters collaboration across FDA's medical product centers, improves review efficiency, and expedites the development of novel science that can improve the lives of patients with cancer. Section 3073 of the 21st Century Cures Act required FDA to establish one or more intercenter institute(s) to help develop and implement processes for coordination of activities in major disease areas between the drug, biologics, and device centers. FDA has established the OCE to create a unified policy approach and clinical review for all drugs, biologics, and devices used in medical oncology.

With these resources, the FDA OCE will leverage the combined talents and skills of all FDA regulatory scientists and reviewers who work in medical oncology product review. OCE will also serve as a single point of contact for external stakeholders for FDA's work in cancer, including professional societies and patient advocacy groups. FDA medical and professional staff will coordinate review of oncology product applications across the medical product centers, policy development, and collaboration with external stakeholders. This Center of Excellence will help expedite the development of oncology and hematology medical products and support an integrated approach in the clinical evaluation of drugs, biologics, and devices for the treatment of cancer.

Stimulate Investment In, and Innovation of, Medical Products Targeted to Rare Diseases (+\$20M)

The FY 2019 Budget Request for FDA includes \$20 million⁴ to foster investment and innovation in, and medical product development for, rare diseases. FDA will develop clinical trial networks to create an understanding of the natural history (such as individual patient experiences and progression of symptoms) and clinical outcomes of rare diseases. FDA will leverage this novel framework when promising medical products have been identified for patients. The initial focus will be on rare and ultra-rare diseases, where product development can be challenging because of the difficulty of recruiting clinical trials. FDA will stimulate medical product development for rare diseases by expanding and enhancing the understanding of rare diseases and the research and drug development processes in this space.

Modernize Generic Drug Development and Review to Enable Increased Competition, Promote Generic Drug Substitution, and Provide Affordable Options for American Patients (+\$38M)

The FY 2019 Budget Request includes \$37.6 million to create a new review platform that will significantly modernize generic drug review from a text-based to a data-based assessment with structured submissions and FDA assessments. This more automated system will improve clarity for generic sponsors, making initial reviews more efficient and decreasing the risk of refuse-to-file letters, increasing the rate of first-cycle approvals, and greatly increasing overall efficiency. This investment also will support efforts to update generic drug labeling, with an initial focus on oncology products, as part of the agency's efforts to ensure that patients and their providers have access to up-to-date information to inform clinical decisions. If more generic drugs had up-to-date product labels reflecting the latest treatment information, it would encourage wider adoption of generic medicines.

Animal Drug Review (+\$10 million)

The FY 2019 Budget includes \$9.7 million to support FDA's animal drug review activities. This increase enables the Animal Drugs and Feeds Program to review pioneer and generic new animal drugs within agreed-upon performance targets, meeting statutory timeframes, despite the continually increasing workload, and ensures the long-term stability of both programs moving forward. Additionally, with this funding increase, the Program will meet the statutory conditions required by the FD&C Act to collect and spend user fees. User fees are increased on a yearly basis to cover their portion of any additional workload, but FDA's direct budget authority has not correspondingly increase to keep up with the additional workload. These programs have

⁴ \$10 million will support activities in CDER and \$10 million will support policy related activities in FDA HQ.

had a significant impact on human and animal health, reducing review timeframes, promoting the development of safe and effective drugs to reach the market sooner.

21st Century Cures - FDA Innovation Account (+\$50 million)

The 21st Century Cures Act (Cures Act) enacted into law on December 13, 2016, established an “FDA Innovation Account” for FY 2017 – FY 2025 and authorizes funding, subject to the annual appropriation process, to carry out designated provisions of Title III, which focus on medical product development activities regulated by FDA.⁵ For FY 2019, the Cures Act authorized \$70 million for the FDA Innovation Account. If these funds are appropriated and available, they would help FDA implement provisions to accelerate medical product innovation while reducing regulatory burden, to increase efforts for critical scientific and methodological research, and to increase the involvement of patients and their perspectives in research and the medical product development process, among others. The law also includes provisions aimed at reducing administrative burdens for researchers supported by the federal government, improving the provision of mental health services, and providing direct financial support for states addressing opioid abuse.

Over-the-Counter Drug Monograph Reform (+\$22 million)

The FY 2019 Budget includes \$22 million in proposed user fees for oversight of Over-the-Counter Drug Monograph products. FDA strongly supports implementing meaningful reforms to the regulation of over the-counter (OTC) monograph drug products to promote innovation and to reduce regulatory burden supported by an OTC monograph user fee program. On June 7, 2017, Secretary Price transmitted the User Fee Goals document and FDA’s technical assistance to OTC monograph reform and user fee legislation to Congress. This user fee program is essential for supporting the modernization of OTC monograph activities, as these resources will support improving the timeliness of review activities, facilitating innovation on behalf of consumers, and enabling the agency to better respond to urgent safety issues. The recommendations submitted by the Administration are based on public input as well as negotiations with industry, and for the first 5 years, 100 percent of user fee revenue is targeted to come from facility fees. The goals of the OTC Monograph User Fee program are to:

- Build basic infrastructure to meet the goals of monograph reform (hiring, training and information technology)
- Enable industry-initiated innovation (innovation order requests, confidential development meetings, timelines, and performance goals)
- Enable streamlining of industry and FDA safety efforts
- Enable efficient completion of Category III final GRASE (Generally Recognized as Safe and Effective) determinations requested by industry or initiated by the FDA
- Develop measures to track success and agency accountability.

Opioids (+\$10 million)

As part of the FY 2019 Budget, the Administration is also requesting mandatory resources to address the opioid addiction crisis, including \$10 million for FDA activities.⁶ These resources

⁵ In other Cures Act titles not focused on FDA, the Agency is required to provide consultation and serve on working groups, headed by other HHS agencies. These include, among others, consultation with the National Institutes of Health (NIH) on research on pregnant and lactating women, tick-borne diseases, animal care and research, and certain activities related to the NIH ClinicalTrials.gov data bank.

⁶ These funds are presented as a non-add in FDA’s budget tables.

would support, among other things, investment in FDA regulatory science in development of tools to stem the misuse and abuses of opioids and for FDA to provide technical assistance related to clinical study design related to MATs (medication-assisted treatments). FDA proposes applying funds to develop algorithm-driven diagnostics to support the opioid use disorder treatment workforce. The goal is to enable evidence-based treatment to allow clinicians to more optimally prescribe MATs. Additionally, to accelerate the development of generic versions of opioid drug products with abuse deterrent formulations (ADF), FDA will use the resources to fund studies to identify additional tools and methodologies that can be used to evaluate whether differences in formulations impact abuse deterrence. FDA anticipates that identification of such tools and methodologies will help generic drug applicants streamline the testing necessary to support approval, resulting in increased competition. FDA welcomes the opportunity to make a meaningful impact on this crisis through these scientific projects that will promote the development of opioids that are harder to manipulate and abuse and concurrently increase access to MATs.

Export Certification (+\$4 million)

The FY 2019 Budget includes 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.

Generics Spur Access and Competition (Legislative Proposal)

The Federal Food, Drug, and Cosmetic Act provides an incentive to generic drug applicants by granting a 180-day period of exclusivity to the applicant that is first to file a substantially complete application to FDA. Increasing the availability of generic drugs helps to create competition in the marketplace, which then helps to make treatment more affordable and increases access to health care for more patients.

Some "first filers" can block subsequent generic competitors from receiving approval under this exclusivity provision. Similarly, first filers that receive tentative approval but then intentionally delay seeking final approval can block subsequent competitors. As a result, first filers can "park" their exclusivity, and consumers are denied access to generic products and must keep paying brand price.

The FY 2019 Budget includes a legislative proposal to address this problem. The proposal makes the tentative approval of a subsequent generic drug applicant that is blocked solely by a first applicant's 180-day exclusivity, where the first applicant has not yet received final approval, a trigger of the first applicant's 180-day exclusivity. This means the period of exclusivity would immediately begin for the first filer. This proposal will enhance competition and facilitate more timely access to generic drugs. This proposal is estimated to create \$1.8 billion in Medicare savings over 10 years.

INFRASTRUCTURE: FACILITIES AND RENT INVESTMENTS

The FY 2019 Budget provides an increase of \$28 million over the FY 2018 Annualized CR level to ensure that FDA's offices and labs across the country and its fully integrated headquarters Campus are optimally functioning to enable FDA to carry out its mission and respond to food safety and medical product emergencies. This level supports increased FTE levels associated with medical product user fees, increased facility costs related to real estate taxes, rental rates, maintenance, and utilities, and White Oak campus utility infrastructure capacity and reliability improvements, security infrastructure, and the campus safety program.

The FY 2019 Budget also attempts to sustain the current condition of FDA's owned buildings at its six mission-critical sites, as FDA's owned buildings continue to age and equipment and systems failures occur, leading to more demands for repairs and non-standard maintenance requests.