

EXECUTIVE SUMMARY

This Executive Summary describes the fiscal year (FY) 2018 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.

Medical Product Approvals

In calendar year 2016, FDA approved 22 novel drugs, 11 original applications for biological products, and 91 medical devices. These approvals included:

- the first treatment for spinal muscular atrophy and Duchenne muscular dystrophy
- new drugs for Parkinson's disease, primary biliary cirrhosis, and hepatitis C
- cancer drugs to treat ovarian cancer, bladder cancer, soft tissue sarcoma, and chronic lymphocytic leukemia
- two new diagnostic agents for detecting certain forms of cancer.

Eighty-six percent of the new drug approvals were approved first in the U.S., which remains faster than other regulators. Seventy-three percent of the new drugs used at least one expedited review pathway, including breakthrough designation.

In addition, 2016 marked the highest number of generic drug approvals and tentative approvals in the history of the FDA's generic drug program – more than 800. Many of these approvals were for first-time generic drugs, with the introduction of a generic counterpart for a brand-name product for which there was previously no generic.

Emergency Response and Medical Countermeasures

Since November 2015, 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 15 diagnostics that are currently authorized for emergency use
- support development of vaccines and therapies
- review proposals for innovative products to suppress mosquito populations.

These efforts are part of the agency'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 and Nutrition

Efforts to improve food safety through implementation of the Food Safety Modernization Act (FSMA) require partnerships to achieve our public health goals. In FY 2016, FDA awarded nearly \$22 million in funds to states to help implement the produce safety rule through training and compliance activities. Also in the past year, FDA signed two international systems recognition agreements – one with Canada and one with Australia – that recognize that their food safety protection systems levels are similar to FDA’s. Work is occurring on more systems recognition agreements. These agreements will allow better risk-based deployment of FDA resources.

In May 2016, FDA finalized the first major update for the Nutrition Facts label in more than 20 years. This new label gives consumers better nutrition information based on the latest nutrition science. The new label lists added sugars in the foods and gives more realistic serving sizes to help consumers make informed choices about what, and how much, they eat.

In June 2016, FDA also issued a draft guidance that provides practical, short- and long-term voluntary sodium reduction targets for the food industry. The draft targets are intended to help consumers to gradually reduce sodium intake with limited effect on flavor and taste. FDA is still reviewing thousands of public comments to this draft guidance.

In May 2017, FDA extended the compliance date for menu labeling by a year. This regulation requires the disclosure of certain nutritional information for standard menu items in chain restaurants and similar retail food establishments. The additional time allows FDA to consider ways to reduce the cost and improve the flexibility of these requirements.

Program Alignment

In May 2017, as part of the broader agency Program Alignment initiative, FDA’s Office of Regulatory Affairs (ORA) began implementation of a program-based management structure that aligns staff by FDA-regulated product. This organizational approach replaces a management structure based on geographic regions. Program alignment benefits all FDA regulated industries and public health, as it allows for better vertical integration within field offices and labs by commodity category, such as food and feed, drugs, and devices. Program alignment also offers better horizontal integration between the field and headquarters programs. Program alignment improves agency efficiency, streamlines operations, and allows better cost accounting and personnel management.

Tobacco Regulation

FDA works to protect 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. FDA actions in FY 2016 included:

- issuing 17 new or revised guidances, four final rules and one proposed rule
- conducting more than 165,000 retailer inspections
- issuing more than 13,900 warning letters
- taking more than 3,600 civil money penalty actions
- issuing 31 No-Tobacco-Sale-Orders (NTSO) for violations of certain restrictions such as sales to minors

- making the first-ever marketing decision for a Modified Risk Tobacco Product (MRTP) application.

In 2016, FDA launched two new public education campaigns aimed at preventing and reducing tobacco use among youth and young adults.

On May 10, 2016, FDA finalized a rule – Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act – which extends FDA’s authority to all tobacco products, including electronic nicotine delivery systems (such as e-cigarettes and vape pens), cigars, hookah (waterpipe) tobacco, pipe tobacco and nicotine gels, among others. This final rule went into effect on August 8, 2016.

OVERVIEW OF THE BUDGET REQUEST

The FY 2018 Budget Request is \$5.1 billion, an overall increase of ten percent or \$456.1 million compared to the FY 2017 Annualized Continuing Resolution (CR) level. The budget includes \$1.9 billion for budget authority – a decrease of 31 percent or \$854.4 million compared to the FY 2017 Annualized CR level – and \$3.2 billion for user fees – an increase of 68 percent or \$1.3 billion compared to the FY 2017 Annualized CR level. The Budget supports a program level of \$3.2 billion for medical product safety and availability – an increase of 19 percent or \$504.8 million compared to the FY 2017 Annualized CR level – and \$1.3 billion for food safety – a decrease of six percent or \$82.8 million compared to the FY 2017 Annualized CR level.

Budget Structure and Strategic Plan Framework

The Executive Summary provides an overview of the FY 2018 Budget Request in terms of program and policy proposals. The Budget is also 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.

The Budget is structured around FDA’s strategic plan framework,¹ 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

¹FDA Strategic Priorities 2014-2018, September 30, 2014, <http://www.fda.gov/aboutfda/reportsmanualsforms/reports/ucm227527.htm>.

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.

REGULATORY EFFICIENCIES AND USER FEE RECALIBRATION

FDA is committed to fostering an environment that enables industry to advance innovative, safe, and effective treatments and cures to the patients who need them as quickly as possible. To achieve this goal in FY 2018, FDA will implement programs and process improvements to achieve greater regulatory efficiency and speed the availability of innovative, safe, and effective medical products in the market. These improvements are described in the PDUFA VI, MDUFA IV, GDUFA II, and BSUFA II commitment letters submitted to Congress in January 2017.

Outcomes of these efforts will include:

- Streamlining clinical trials to reduce time and costs, consistent with the evidentiary standards in statute, by taking actions such as fostering the development and implementation of the science and technology of real-world evidence generation and utilization
- Increasing patient input and promoting patient-centered outcomes to integrate patient voice throughout the regulatory process, thereby better enabling patient perspectives to shape product development, review, and approval
- Increasing engagement with manufacturers, including providing standardized and predictable pathways for early interactions to help reduce uncertainty in medical product development
- Reducing review times by streamlining processes and gaining efficiencies to the greatest extent possible
- Reducing regulatory burden and leveraging FDA’s statutory mandates, including recent enhancements through the 21st Century Cures Act
- Promoting greater preparedness for novel and emerging public health threats, including emerging infectious diseases.

In addition, the Budget includes a package of administrative actions that will promote regulatory efficiency and speed the development of safe and effective medical products including:

- Simplifying administrative requirements to reduce drug and device manufacturers' reporting burden
- Clarifying treatment of value-based purchasing arrangements
- Improving predictability for payers and enhance dissemination of evidence by fostering the exchange of scientifically sound information between manufacturers and payers pre-approval to reduce uncertainty and improve payer ability to more accurately set premiums.

In support of these efficiencies, the FY 2018 President’s Budget recalibrates FDA medical product user fees to over \$2.5 billion in 2018, an increase of \$1.2 billion over the 2017

annualized CR level. The Budget supports through 100 percent user fee funding medical product review and approval activities associated with the prescription and generic drugs, biosimilar, medical device, and animal drugs programs, including operational and support costs associated with White Oak campus operations, rent payments to the General Services Administration, other commercial rent and rent-related charges, as well as anticipated FY 2018 inflation for rent costs. Legislative revisions will be needed for all of these programs to ensure continuity of review and approval activities.

21ST CENTURY CURES ACT – FDA INNOVATION ACCOUNT

The 21st Century Cures Act (Cures Act) was enacted into law on December 13, 2016. The Cures Act 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.² For FY 2018, the Cures Act authorized \$60 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.

EXPORT CERTIFICATION

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 better recover its costs in implementing this program.

BUDGET AUTHORITY REDUCTIONS

The FY 2018 Budget Request includes reductions totaling \$127.2 million in budget authority, targeted to certain areas where better tools and policies will allow FDA to do more with less, while preserving core mission activities. These reductions will be coupled with policy efforts to improve the efficiency of the programs that see reductions, to improve effectiveness and take a risk-based approach to FDA’s consumer protection mission.

² 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.

Food Safety

In FY 2018, FDA will preserve its most critical public health and safety activities, including outbreak response, implementation of FSMA regulations, and ensuring that foods are safe and properly labeled.

To reduce expenditures, FDA will reduce staff across the food safety program through attrition. Not backfilling critical vacancies may lead to a loss of some specialized expertise. FDA will also make targeted reductions to lower public health impact areas. This will include reduced funding for imported food safety through decreased international capacity building. FDA will reduce funding for cosmetics safety work, which will limit FDA's ability to monitor and take action against unsafe cosmetics. FDA will decrease funding for its research program, which supports work related to food safety technology, outbreak response, and FSMA implementation. FDA plans to reduce funding to programs that support state and local health organizations.

Medical Product Safety

In FY 2018, FDA will continue to uphold its public health mission to ensure the safety and efficacy of human and animal drugs, biological products, devices, and radiological products.

As a result of budget authority reductions, FDA will reduce staff across medical product safety programs through attrition. FDA will reduce support to scientific research activities, including contracts that promote drug safety and research studies, critical investments in innovation and research, and essential training and development opportunities for personnel.

At proposed budget levels FDA will support at lower funding levels regulated product field exams, import entry review, investigations, sample analysis, and inspections for surveillance, compliance, and follow up activities, both domestically and abroad. Risk assessments will be impacted along with sharing information with regulatory partners. FDA will reduce investment in lab equipment, maintenance, and operating expenses will limit capacity to analyze samples for surveillance and compliance purposes as well as detecting emerging threats or potential outbreaks from product contamination or adulteration.

WORKING CAPITAL FUND AUTHORITY

As part of the FY 2018 President's Budget, FDA is also requesting authority to establish a Working Capital Fund (WCF). A WCF will allow the FDA to operate in a more efficient business environment by relying on the collection of funds for administrative services directly from its customers. More specifically, the fund will help FDA achieve the following:

- create a customer-focused and service-oriented mechanism through improving customer investment and management accountability
- recapitalize resources to support IT infrastructure and other administrative service capital needs
- enhance transparency, accountability, and efficiency.

The Working Capital Fund will provide the environment for centralized offices to operate in a more efficient business environment by collecting funds from internal customers to finance operations and allow for infrastructure investments across fiscal years – particularly as it relates to capital investments in the IT area. Upon receiving authority to establish a Working Capital

Fund, FDA will work toward implementation that aligns services and costs, based on consumption, to its program lines.

INFRASTRUCTURE: FACILITIES AND RENT INVESTMENTS

The FY 2018 Budget Request provides an increase of \$36.4 million over the FY 2017 Annualized CR level, which supports increased FTE levels associated with medical product user fees and facility costs related to real estate taxes, rental rates, maintenance, and utilities.

Proposed Appropriations Language Changes to Rent Cost Language

The FY 2018 President’s Budget proposes striking the “not to exceed” (NTE) language from FDA’s appropriation language for rent costs. A large majority of FDA’s owned buildings, including laboratories, were transferred to FDA from other federal agencies and these buildings as well as the associated site infrastructure were constructed between 30 to 60 years ago. Many of the buildings, including critical research and regulatory laboratories, are aged and the building systems, finishes, and layouts are past their useful life, creating unsafe and unhealthy work environments, which in turn compromises FDA’s ability to meet scientific needs. Historically funding for necessary major improvements for site infrastructure and building systems and equipment has been very limited and below the amount needed to even sustain the current poor condition. Accordingly, operations and maintenance costs are continuing to increase as more equipment and systems fail and more maintenance is needed to keep buildings operational. Major equipment failures could occur and the current “not to exceed” restriction severely limits FDA’s ability to address these needs as well as other increased maintenance costs to ensure FDA’s mission critical facilities remain operational. Without this flexibility, equipment and system failures will likely result in closing these critical buildings, which will have an immediate and significant impact on the FDA mission and the public health.

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 2018 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:

- **T**ransparency – provides interested parties an unprecedented look into how FDA performs its work
- **R**esults – highlights performance measures and results related to the agency’s public-health mission
- **A**ccountability – 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
- **C**redibility – 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
- **K**nowledge-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 53,000 visitors subscribe to the FDA-TRACK monthly updates.