

**FDA FY 2013 Budget  
Protecting Patients  
Budget Authority: +\$25,148,000 / -3FTE  
Proposed User Fees: +\$338,521,000,000 / 596 FTE**

The following table displays the FDA budget for the Protecting Patients initiative in the FY 2013 Congressional budget justification.

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(Dollars in Millions)<sup>1</sup>

Program	FY 2011 Enacted	FY 2012 Enacted	FY 2013 Request	+/- FY 2012 Enacted
<b>Budget Authority:</b>				
<b>Human Drugs</b>	<b>\$474.889</b>	<b>\$473.054</b>	<b>\$471.309</b>	<b>-\$1.745</b>
Center	344.076	343.061	341.977	-1.084
Field Activities	130.813	129.993	129.332	-0.661
<b>Biologics</b>	<b>\$210.593</b>	<b>\$210.250</b>	<b>\$209.476</b>	<b>-\$0.774</b>
Center	169.735	169.737	169.172	-0.565
Field Activities	40.857	40.513	40.303	-0.210
<b>Animal Drugs and Feeds</b>	<b>\$28.738</b>	<b>\$28.923</b>	<b>\$28.796</b>	<b>-\$0.127</b>
Center	25.917	26.257	26.142	-0.114
Field Activities	2.821	2.666	2.653	-0.013
<b>Devices and Radiological Health</b>	<b>\$318.369</b>	<b>\$319.675</b>	<b>\$318.258</b>	<b>-\$1.417</b>
Center	236.761	238.478	237.485	-0.993
Field Activities	81.609	81.197	80.773	-0.424
<b>National Center for Toxicological Research</b>	<b>\$48.077</b>	<b>\$49.832</b>	<b>49.602</b>	<b>-\$0.230</b>
<b>FDA Headquarters</b>	<b>\$93.564</b>	<b>\$89.358</b>	<b>\$94.59</b>	<b>\$5.231</b>
<b>White Oak Consolidation</b>	<b>\$38.459</b>	<b>\$40.386</b>	<b>\$58.044</b>	<b>\$17.658</b>
<b>Other Rent and Rent Related</b>	<b>\$29.161</b>	<b>\$34.951</b>	<b>\$36.851</b>	<b>\$1.900</b>
<b>GSA Rental Payments</b>	<b>\$80.366</b>	<b>\$85.847</b>	<b>\$90.500</b>	<b>\$4.653</b>
<b>Total, Budget Authority, Salaries and Expenses</b>	<b>\$1,283.757</b>	<b>\$1,332.276</b>	<b>\$1,357.424</b>	<b>\$25.148</b>
<b>Biosimilars User Fee<sup>2</sup></b>	<b>\$0.000</b>	<b>\$0.000</b>	<b>\$20.242</b>	<b>\$20.242</b>
<b>Generic Drug User Fee<sup>2</sup></b>	<b>\$0.000</b>	<b>\$0.000</b>	<b>\$299.000</b>	<b>\$299.000</b>
<b>Medical Products Reinspection Fee<sup>2</sup></b>	<b>\$0.000</b>	<b>\$0.000</b>	<b>\$14.746</b>	<b>\$14.746</b>
<b>International Courier User Fee<sup>2</sup></b>	<b>\$0.000</b>	<b>\$0.000</b>	<b>\$4.533</b>	<b>\$4.533</b>
<b>Total, Program Level</b>	<b>\$1,283.757</b>	<b>\$1,332.276</b>	<b>\$1,695.945</b>	<b>\$363.669</b>

<sup>1</sup> The FY 2013 request displayed in this table reflects increases for commissioned corps pay and increases and absorptions for FY 2013 rent activities. In addition to the amounts displayed in this table, the amounts shown in other FDA FY 2013 business case papers also contribute to the total resources available to FDA programs. The FY 2013 column does not include the Administrative savings proposed in the FY 2013 Budget.

<sup>2</sup> FDA proposes these user fees in the FY 2013 President's Budget. The amounts in this table include program support and associated rent activities.

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## **1. Initiative Summary**

In this initiative, FDA proposes new user fees to support:

- the activities of the Generic Drug Program
- the development and review of biosimilar products<sup>1</sup>
- surveillance of FDA-regulated commodities at express courier hubs
- expansion of the current Reinspection Fee authority for food and feed establishments
- reinspections of medical product establishments.

In this initiative, FDA also requests new budget authority to increase its capacity to detect and address the risks of products and ingredients manufactured in China and to assure that these products do not result in harm to Americans.

This initiative also contains new budget authority to equip state-of-the-art laboratory facilities on FDA's White Oak, Maryland, campus that will support essential research to protect patients and consumers.

Finally, this initiative also provides new budget authority to support the pay increase for Commissioned Corps personnel that serve at FDA.

## **2. Why is this funding necessary?**

**A. Generic Drug User Fee:** The growth in generic drug applications has outpaced FDA resources, resulting in an application backlog and an increase in time to approval. Generic drugs are now increasingly complex, and product testing and manufacturing often occurs in overseas facilities.

To keep pace with the increase in applications and to respond to changes in the industry, FDA is proposing increased resources in the form of user fees. These fees will:

- strengthen the FDA generic drugs program
- enhance the application review process
- allow FDA to increase post-market safety and overseas inspection activities.

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<sup>1</sup> Biosimilar products are structurally and therapeutically similar to biological products manufactured by an innovator company.

Without these fee resources, FDA cannot respond to the growing demand from patients, payers, and the generic drug industry. The generic industry supports this user fee proposal.

Generic drugs are widely known to provide cost-effective treatment. According to industry estimates, generic drugs saved consumers approximately \$931 billion between 2001 and 2010. In 2010, generic drugs generated savings of \$158 billion, or an average of \$3 billion per week.

With each new generic version of a brand-name drug that FDA approves, consumers have an additional option to save money on their prescription needs. The proposed user fee investments in FDA's generic drug program will generate additional savings by bringing more generics to market sooner, which will benefit more American patients.

Health care payers and plans, including Medicare, Medicaid, the Department of Veterans Affairs and the Department of Defense, as well as private health care plans will experience savings from greater availability of generic drugs. A greater availability of generic drugs will also mitigate some risks associated with drug shortages, thereby ensuring that patients have access to the drugs they need.

**B. Biosimilars User Fee:** Biosimilars offer the potential to reduce the costs of and promote greater patient access to biological products. With this proposed user fee, FDA will establish efficient pathways for approving biosimilars, which will encourage development of important therapies that will benefit patients and allow industry sponsors to bring new products to market more quickly and efficiently.

Savings will also accrue to Federal health programs such as Health care payers and plans, including Medicare, Medicaid, the Department of Veterans Affairs and the Department of Defense. Private sector health plans, upon which millions of Americans depend, will also experience savings from the availability of biosimilars, while providing important patient access to a wider range of therapeutic alternatives.

Biological products cost \$15,000 to \$150,000 or more per patient per year. These high costs represent a disproportionately large share of Federal government and private sector pharmaceutical costs. In light of these high costs, the Congressional Budget Office (CBO) has estimated that federal savings associated with biosimilars could equal \$7 billion during the next decade. However, these savings will only materialize if FDA has the resources to conduct a biosimilar and interchangeable biological product review program and the resources to support the innovation required to spur biosimilar development.

**C. Drug Manufacturing Inspections in China:** Global production of goods that FDA regulates has increased dramatically during the past decade. In addition to

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importing more finished products, manufacturers increasingly use imported materials and ingredients in their U.S. production facilities. This trend makes the distinction between domestic and imported products obsolete.

This trend is increasingly evident in trade between the U.S. and China. China is the source of a large and growing volume of imported drugs and drug ingredients.

This FDA initiative supports a prevention-focused import safety program in China. With this FY 2013 initiative, FDA will increase its capacity to detect and address risks of drugs and drug ingredients manufactured in China and to assure that these products do not result in harm to Americans. The initiative will place greater responsibility on Chinese manufacturers to institute measures to assure that drugs and drug ingredients imported to the United States are safe and meet FDA standards. There is a parallel component to this initiative related to foods in the FDA Transforming Food Safety business case paper.

**D. Life Sciences – Biodefense Laboratory Complex:** During the past two decades, an unprecedented level of investment has led to revolutionary advances in the biomedical sciences. To fulfill its mission to protect patients and consumers, FDA's scientific infrastructure must keep pace with these advances.

The 2007 report on *FDA Science and Mission at Risk* concluded that FDA is unable fulfill its mission, in part because it lacks modern science facilities. Funding the CBER-CDER Life Sciences-Biodefense Laboratory will provide safe, certified laboratory capacity for FDA to perform its medical product safety and review responsibilities.

On August 18, 2010, the General Services Administration (GSA) awarded the construction contract for the new laboratory complex at White Oak, and construction is underway. With the resources requested in this initiative, FDA will outfit the CBER-CDER Life Sciences-Biodefense Laboratory complex. FDA must make this investment now to ensure that the laboratory is operational and ready for occupancy in FY 2014.

**E. International Courier User Fee:** For FY 2013, FDA is proposing a new International Courier User Fee. The proposed fee will support activities associated with increased surveillance of FDA-regulated commodities, predominantly medical products, at express courier hubs.

Current FDA staffing does not match the current workload and expected growth in import volume arriving through international express courier facilities. Express couriers and other couriers have indicated that they expect dramatic growth in shipments, further taxing FDA resources. To address the growing volume of imports entering through international couriers, FDA is proposing to pay the cost of its international courier activities through user fees.

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**F. Reinspection User Fee:** The FDA Food Safety Modernization Act, which Congress enacted in December 2010, authorized Reinspection Fees for reinspections of food and feed establishments. FDA is proposing to expand this authority to medical product establishments. With this change, medical product establishments will pay the full cost of reinspections and associated follow-up work. FDA will impose the user fee when FDA reinspects facilities due to a failure to meet Good Manufacturing Practices (GMPs) or other important FDA requirements.

**G. Pay Costs (Commissioned Corps):** FDA can only fulfill its public health responsibilities if it has sufficient resources to pay the workforce that conducts FDA medical product safety programs. To maintain its Commissioned Corps workforce, who provide scientific, professional, and technical expertise to all programs, FDA must continue to meet the full cost of the workforce payroll, including the proposed pay increase.

### **3. What activities will the funds support?**

The following information displays estimates for the activities funded with the FY 2013 increases for Protecting Patients. In the case of the new user fee programs to support generic drug and biosimilar review, as FDA continues to plan for and implement these programs and as the fee programs mature, FDA will adjust the allocation of funds to support generic drug and biosimilar program activities based on the anticipated workload and the fee revenue that FDA receives.

#### **A. Generic Drug User Fee (+ \$268,218,000 / 410 FTE)<sup>2</sup> (All UF)**

With the proposed user fee resources, FDA will enhance the generic drug review process and increase FDA's capacity to conduct reviews of Abbreviated New Drug Applications (ANDA) with greater efficiency and transparency. FDA will conduct additional pre-approval and bioequivalence inspections to verify manufacturing compliance with Current Good Manufacturing Practices (CGMP) for generic drug products.

*CDER: \$166,938,000 / 200 FTE*

*ORA: \$ 16,311,000 / 46 FTE*

*FDA HQ: \$ 13,676,000 / 10 FTE*

FDA will increase inspections of foreign facilities involved in manufacturing generic drug products.

*CDER \$13,757,000 / 19 FTE*

*ORA: \$35,500,000 / 104 FTE*

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<sup>2</sup> In addition to the amounts displayed here, additional amounts to support this activity are also displayed within the Program Support and Rent Activities section of this document.

FDA will also increase post-market safety and surveillance activities related to generic drug products.

*CDER: \$22,036,000 / 31 FTE*

## **B. Biosimilars User Fee (+\$17,626,000 / 68 FTE)<sup>3</sup> (All UF)**

In FY 2011, FDA's Center for Drug Evaluation and Research (CDER) received an appropriation of \$1,852,000 from Congress to begin to develop and implement its biosimilars program. With these funds, FDA purchased equipment to support biosimilar characterization and funded contracts to support biosimilars program activities.

With the proposed user fee resources in FY 2013, FDA will review biosimilar biological product applications, supplements, and other submissions related to biosimilar products. This work will include biosimilar product development meetings and activities related to investigational new drug applications (INDs). FDA will issue action letters that communicate decisions on biosimilar product applications and hire investigators to conduct 30 domestic biosimilars pre-approval inspections in FY 2015 and 12 foreign biosimilars pre-approval inspections in FY 2016. Full performance will not be reached until the out-years, since investigators need intensive training before conducting inspections.

*CDER: \$9,886,000 / 38 FTE*

*CBER: \$ 516,000 / 2 FTE*

*ORA: \$1,290,000 / 5 FTE*

*FDA HQ: \$ 129,000 / 0.5 FTE*

FDA will also develop regulations and guidance documents to foster the development of biosimilars.

*CDER: \$5,418,000 / 21 FTE*

*CBER: \$ 258,000 / 1 FTE*

*FDA HQ: \$ 129,000 / 0.5 FTE*

## **C. Drug Manufacturing Inspections in China (+\$5,287,500 / 11 FTE)<sup>4</sup> (All BA)**

With the resources requested in this initiative, FDA will perform additional foreign inspections in China, focusing on facilities that produce drugs and drug ingredients that potentially pose the greatest risks to patients in the United States. FDA will also conduct outreach and education activities for Chinese manufacturers on implementing measures to meet FDA manufacturing quality and good manufacturing practices.

*FDA HQ: \$4,725,000 / 9 FTE*

<sup>3</sup> In addition to the amounts displayed here, additional amounts to support this activity are also displayed within the Program Support and Rent Activities section of this document.

<sup>4</sup> In addition to the amounts displayed here, additional amounts to support this activity are also displayed within the Program Support section of this document.

FDA will expand risk modeling and risk analysis to improve FDA's ability to better target inspection resources to high-risk drugs and drug ingredients manufactured in China.

*FDA HQ: \$562,500 / 2 FTE*

**D. Life Sciences-Biodefense Laboratory Complex  
(+\$17,658,000 / 0 FTE) (All BA)**

As the General Services Administration completes construction of the Life Sciences-Biodefense Laboratory complex, FDA's FY 2013 budget request contains resources to make the facilities operational and to properly certify the new laboratory. The new laboratory will allow FDA to support more efficient development of new and innovative medical products and to better assess product safety and effectiveness. With these resources, FDA can operate in modern laboratory facilities that are essential to protect patients and consumers and to accomplishing FDA's public health mission.

**E. International Courier User Fee: +\$4,087,000 / 17 FTE<sup>5,6</sup> (All UF)**

The user fee will address the growing volume of imports that enter the United States through international couriers. The fee revenue will support the cost of FDA import operations to conduct FDA work at international courier facilities. Funding generated from this user fee program will allow FDA to:

- conduct import entry reviews
- collect samples and conduct physical exams to determine whether a product can be admitted into the United States
- initiate compliance actions to prevent the release of unsafe products
- establish import controls to prevent future imports of unsafe products from reaching U.S. consumers.

**F. Reinspection User Fee: +\$12,277,000 / 53 FTE<sup>7</sup> (All UF)**

When FDA identifies violations during an inspection or issues a warning letter following an inspection, FDA conducts follow-up inspections to verify that the problem was corrected. FDA procedures usually require that FDA conduct a follow-up inspection of the firm within six months of issuing a warning letter.

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<sup>5</sup> In addition to the amounts displayed here, additional amounts to support this activity are also displayed within the Program Support and Rent Activities sections of this document.

<sup>6</sup> The food safety portion of this user fee, totaling \$1,047,000, is found in the Transforming Food Safety business case paper.

<sup>7</sup> In addition to the amounts displayed here, additional amounts to support this activity are also displayed within the Program Support and Rent Activities sections of this document.

Of the total FTE increase for this activity, FDA will hire 21 new investigators. When the new investigators are fully trained, FDA will have the capacity to conduct an estimated 329 domestic medical product reinspections.

**G. Pay Costs (Commissioned Corps): (+\$799,000) (All BA)**

For medical product safety programs, the FY 2013 budget authority amount for higher Commissioned Corps pay costs is \$799,000. For all FDA programs, pay cost will increase by \$1,502,000.

**H. Program Support for the FY 2013 Protecting Patients Initiative  
+12,995,500 / 55 FTE (\$337,500 / 0 FTE BA; \$12,658,000 / 48 FTE UF)**

The FY 2013 Protecting Patients Initiative includes resources to ensure that FDA medical product programs that participate in this initiative receive the support necessary to achieve their public health outcomes. Program support activities include finance and budgeting, human resource assistance, contracting, billing, legal counsel, communication, ethics, headquarters coordination and related support functions.

<i>Biosimilars User Fee:</i>	+\$ 1,032,000 / 4 FTE
<i>Generic Drug User Fee:</i>	+\$10,520,000 / 40 FTE
<i>Drug Manufacturing Inspections—China: (BA):</i>	+\$ 337,500 / 0 FTE
<i>International Courier User Fee (Medical Products):</i>	+\$ 185,000 / 1 FTE
<i>Reinspection User Fee</i>	+\$ 921,000 / 3 FTE

**I. Rent Activities for FDA Medical Product Programs  
(+24,722,000 / -14 FTE) (\$1,067,000 BA; \$23,655,000 UF)**

The FY 2013 Protecting Patients Initiative includes resources to pay the GSA Rent and the Other Rent and Rent-Related costs for the new employees hired under the FY 2013 Protecting Patients Initiative.

These funds will also allow FDA to pay a portion of the increased cost of GSA Rent and Other Rent and Rent-Related activities for the facilities that support FDA's base program. To fully meet its rent obligations, FDA must also redirect program resources to cover its rent costs.

The GSA Rent account includes funds for FDA payments to GSA for FDA's office and laboratory facilities. GSA rent also includes funds for payments to the Department of Homeland Security for guard services and the operation of security systems at FDA facilities. The Other Rent and Rent-Related account includes funds for commercial rent and other payments related to leased facilities that are not part of the GSA building inventory.

<i>Inflationary Rent (BA):</i>	<i>+\$ 1,067,000 / 0 FTE</i>
<i>Biosimilars User Fee Initiative Rent:</i>	<i>+\$ 1,584,000 / 0 FTE</i>
<i>Generic Drugs User Fee Initiative Rent:</i>	<i>+\$20,262,000 / 0 FTE</i>
<i>International Courier User Fee (Medical Products) Initiative Rent:</i>	<i>+\$ 261,000 / 0 FTE</i>
<i>Reinspection User Fee Initiative Rent:</i>	<i>+\$ 1,548,000 / 0 FTE</i>

In addition to the amounts displayed above, FDA will also redirect the following amount from medical product programs to pay the remaining FY 2013 costs for rent activities.

*Inflationary Rent Absorption (BA):*                    *-\$5,486,000 (non-add) / -14 FTE*

**4. How does this initiative support important public health priorities?**

The Generic Drug and Biosimilar User Fees support the FDA mission of promoting and protecting the public health by supporting the review of product applications for safety and efficacy, and by making affordable treatments available to patients. The generic drug user fee and the biosimilars user fee will also foster innovation and improve health care quality.

Funding for drug manufacturing inspections in China will enable FDA to strengthen the supply chain for drugs and drug ingredients manufactured in China. This initiative has the potential to reduce import safety emergencies, reduce the number of adverse events and allow FDA to identify safety problems associated with drugs and ingredients manufactured in China earlier in the supply chain.

The funding request for the Life Sciences-Biodefense Laboratory Complex will allow FDA to harness the power of science to improve the health of Americans. The new laboratory complex will also have an essential role in fulfilling FDA responsibilities for drug and biologic safety. The Life Sciences-Biodefense Laboratory Complex supports important priorities such as:

- protecting American’s health and safety during public health emergencies
- transforming health care
- implementing personalized medicine
- using scientific discovery to improve patient care.

The International Courier and the Reinspection user fee programs proposed in this initiative support the core public health priority of improving health care quality and patient safety.

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The increases for Commissioned Corps pay costs, Program Support and Rent Activities proposed in this initiative support FDA mission critical activities within FDA medical product programs.

**5. What are the risks of not proceeding with this initiative?**

**A. Generic Drug User Fee:** Without additional resources from the proposed Generic Drug User Fee, FDA will not be able to address the growing number of pending generic drug applications and ensure more timely availability of generic drugs. Without these improvements, patients may continue to struggle to afford medical treatments that they need and health care payers will face increased drug costs.

Delays in the availability of less-expensive generic drugs will result in higher costs for patients – some of whom may forego critical medicines if their drugs are unaffordable – leading to poorer health outcomes. Without the user fees, FDA will not be able to respond to important changes in generic manufacturing, including the increasing complexity of some products and the shift to overseas manufacturing.

**B. Biosimilars User Fee:** Failure to establish a user fee program for biosimilar biological products will significantly delay patient access to new, affordable medical products. Failure to establish this new fee program will limit the opportunities for an important new industry and limit the availability of the products that provide affordable alternatives for patients. This will adversely affect health care and limit opportunities for new, high-quality U.S. jobs associated with this new biotechnology industry. Finally, the Federal government will miss the opportunity to generate significant savings, estimated by CBO at \$7 billion by the end of the decade.

**C. Drug Manufacturing Inspections in China:** Without this initiative, FDA will not have the resources to adequately identify and address risks associated with drugs and drug ingredients imported from China. Not funding the initiative could result in preventable harm to patients in America.

**D. Life Sciences-Biodefense Laboratory Complex:** Without this investment, FDA pay double rent for the new lab it cannot occupy and for the old lab it cannot vacate. FDA also will not have the needed infrastructure to enable sound, science-based regulatory decisions that support new markets for new medical products and that protect the health of patients.

**E. International Courier User Fee:** Without the resources for the proposed International Courier User Fee, FDA cannot adequately protect the health of Americans. Without this user fee, FDA cannot:

- reduce the risk of unsafe or contaminated imports from reaching U.S. consumers
- prevent harm from counterfeit and unsafe products
- reduce the time between detection and appropriate risk management response.

**F. Reinspection User Fee:** The Reinspection User Fee ensures that facilities that fail to comply with health and safety standards bear the cost of the reinspection. If facilities that fail to comply with FDA regulations do not pay for reinspections, FDA must shift resources from priority public health activities to conduct facility reinspections. The proposed Reinspection User Fee will also make this activity consistent with the Reinspection User Fee for food and feed.

**G. Pay Increase (Commissioned Corps), Rent Activities and Program Support for Medical Product Programs:** Pay, rent, utilities and other costs to support the FDA workforce are fixed costs that FDA does not control. If FDA does not receive the increases for Commissioned Corps pay and for rent costs, FDA will fail to maintain its staff of investigators, epidemiologists, safety experts and other professionals that are the backbone of FDA's medical product safety workforce. The FY 2013 Protecting Patients Initiative includes resources for Program Support to ensure that FDA medical product initiatives for FY 2013 receive the support necessary to achieve their public health outcomes.

## **6. What will FDA accomplish with the initiative?**

**A. Generic Drug User Fee:** This initiative will enable FDA to address the increased number of generic drug applications, as well as the increasing complexity of generic drug products. Moreover, FDA will have limited ability to respond to changes in the generic drug industry, particularly the dramatic growth of foreign manufacturing.

The proposed fee resources will result in more timely availability of generic drugs. The user fee program will supplement the existing generic drug program and will result in measurable improvements in FDA performance. The user fee agreement includes several performance targets that FDA expects to achieve by the end of FY 2017:

- Review and act on 90 percent of all ANDAs, ANDA amendments, and ANDA prior approval supplements regardless of current review status, pending on October 1, 2012
- Review and act on 90 percent of complete electronic ANDAs within 10 months after the date of submission
- Conduct inspections of foreign facilities on a risk-adjusted biennial basis, on parity with inspections at domestic facilities.

**B. Biosimilars User Fee:** This initiative will enable FDA to continue to reduce the scientific, legal and regulatory uncertainty surrounding the development of biosimilars. Reducing this uncertainty will increase investments in this promising area and lead to quicker development and launch of biosimilars, resulting in lower costs for life-saving treatments for many Americans.

The biosimilars user fee will supplement base spending from appropriations and enable FDA's biosimilar program to support this emerging industry. FDA will use these resources to continue to identify scientific, regulatory, and policy issues surrounding biosimilar biological product development.

The user fee agreement with industry included the following performance targets for FY 2013:

- Review and act on 70 percent of original biosimilar biological product application submissions within 10 months of receipt
- Review and act on 70 percent of resubmitted original biosimilar biological product application submissions within 6 months of receipt.

By September 30, 2013, FDA's Office of Regulatory Affairs will complete the hiring of five additional employees and will begin to train these employees. By September 30, 2015, once the new employees are fully trained, ORA will conduct an additional 30 domestic biosimilars pre-approval inspections, and by September 30, 2016, ORA will conduct 12 additional foreign biosimilars pre-approval inspections.

**C. Drug Manufacturing Inspections in China:** The investment will allow FDA to hire the staff needed to support additional foreign inspections in China.

**D. Life Sciences-Biodefense Laboratory Complex:** This investment is critical for FDA to be an active participant in 21<sup>st</sup> century medical product development and to fulfill its mission to patients and consumers. The investment supports FDA efforts to develop and maintain a world-class science workforce and brings much needed core scientific capacities to FDA.

This initiative will benefit every American by increasing access to new medical technologies that treat serious illnesses and improve quality of life. It will increase the accuracy and efficiency of FDA review, thereby reducing adverse health events, regulatory costs, and the time-to-market for new medical technologies.

**E. International Courier User Fee:** Express couriers have indicated that they expect significant growth in shipments during the next year, further taxing FDA resources. These fees will help FDA increase staffing levels to

protect public health and meet the expected increase. This increase will support import controls to prevent unsafe products from entering the United States.

**F. Reinspection User Fee:** The Reinspection User Fee ensures that facilities that fail to comply with health and safety standards bear the cost of the reinspection.

***FY 2013 Protecting Patients Performance Tables:***

FDA is using FDA-TRACK, our agency-wide performance management system, to track, analyze, and report monthly and quarterly performance measures, progress and accomplishments for FDA’s most important initiatives. These initiatives include ongoing efforts as well as new efforts as showcased in the following FY 2013 performance tables. Upon finalization and receipt of the FY 2013 request, FDA will be developing performance measures and/or key project milestones for the funded initiatives. You will find these measures, milestones, and progress on the FDA-TRACK website - [www.fda.gov/fdatrack](http://www.fda.gov/fdatrack).

The following tables contain performance items associated with this initiative.

<b>Performance Measures</b>	<b>FY 2012 Enacted Performance Level</b>	<b>FY 2013 Performance Level +/- FY 2011 Enacted</b>	<b>Most Recent Actual</b>
Begin to establish an abbreviated regulatory review pathway for biosimilar and interchangeable biological products.	Identify scientific, legal, and policy issues related to biosimilar and interchangeable biological products, and establish the regulatory review pathway for biosimilar and interchangeable biological products.	+2 guidance documents	N/A
Percentage of original biosimilar biological product application submissions reviewed and acted on within 10 months	N/A	70 percent	N/A
Percentage of resubmitted original biosimilar biological product applications reviewed and acted on within 6 months	N/A	70 percent	N/A

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<b>Performance Measures</b>	<b>FY 2012 Enacted Performance Level</b>	<b>FY 2013 Performance Level +/- FY 2011 Enacted</b>	<b>Most Recent Actual</b>
Domestic and Foreign Biosimilar Inspections	0	Hire and train 5 FTE in 2013. (+30 domestic inspections in FY 2015; +12 foreign inspections in FY 2016)	N/A
Foreign In-Country Human Drug Inspections	0	Hire and train 9 FTE in 2013. (+120 in-country inspections in FY 2015)	N/A
Enhance the safety or efficacy of drugs and biologics by conducting state-of-art laboratory tests	N/A	When fully constructed and operational, the CDER/CBER Life Science Lab will allow FDA to: <ul style="list-style-type: none"> <li>• Develop improved assays, standards and tests for medical products</li> <li>• Use state-of-the-art technologies to aid in medical product evaluation.</li> </ul>	N/A