

BIOLOGICS

	FY 2013		FY 2014	FY 2015	FY 2015
	Final	Actual	Enacted	President's Budget	+/- FY2014
Biologics	308,010	296,866	337,543	342,639	5,096
Budget Authority	194,673	194,638	210,928	209,754	-1,174
User Fees	113,337	102,228	126,615	132,885	6,270
Center	266,608	257,415	292,586	297,773	5,187
Budget Authority	157,571	157,570	170,744	169,890	-854
User Fees	109,037	99,845	121,842	127,883	6,041
Prescription Drug (PDUFA)	98,932	89,720	109,993	115,493	5,500
Medical Device (MDUFA)	9,369	10,125	10,301	10,549	248
Generic Drug (GDUFA)	---	---	774	1,052	278
Biosimilars (BsUFA)	736	---	774	789	15
Field	41,402	39,451	44,957	44,866	-91
Budget Authority	37,102	37,068	40,184	39,864	-320
User Fees	4,300	2,383	4,773	5,002	229
Prescription Drug (PDUFA)	4,121	1,926	4,581	4,810	229
Medical Device (MDUFA)	179	457	192	192	---
Medical Products Reinspection	---	---	---	---	---
FTE		1,342	1,384	1,385	1

Authorization Legislation: Public Health Service Act; Federal Food, Drug, and Cosmetic Act; Medical Device Amendments of 1976; Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 201); Safe Medical Devices Act of 1990; Medical Device Amendments of 1992; Food and Drug Administration Modernization Act of 1997; Medical Device User Fee and Modernization Act of 2002; Public Health Security and Bioterrorism Preparedness Response Act of 2002; Project BioShield Act of 2004; Medical Device User Fee Stabilization Act of 2005; Food and Drug Administration Amendments Act of 2007; Patient Protection and Affordable Care Act of 2010; Food and Drug Administration Safety and Innovation Act of 2012; and Drug Quality and Security Act of 2013.

Allocation Method: Direct Federal/Intramural

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

The Biologics Program was established in 1902 with the passage of the Biologics Control Act in the Department of Treasury's Hygienic Laboratory and later became part of the National Institutes of Health (NIH) in 1930. In 1972, the Biologics Program was transferred from NIH to FDA and became the Bureau of Biologics. In 1988, the Bureau became the Center for Biologics Evaluation and Research (CBER) which, with the Office of Regulatory Affairs' (ORA) field investigation program, comprises the FDA

Biologics Program.

FDA is responsible for protecting and enhancing public health by ensuring the safety, purity, potency and effectiveness of biological products including vaccines and allergenic products, blood and blood products, cells, tissues, and gene therapies for the prevention, diagnosis, and treatment of human diseases, conditions, or injuries. FDA encompasses the review and approval of safe and effective biological products and works with other Federal agencies, foreign governments and their national regulatory authorities, and international organizations such as the World Health Organization (WHO).

FDA regulates complex biological entities including live agents and cells that involve novel and cutting-edge technologies and evolving science. The Biologics Program also plays an important role in protecting the public against the threat of emerging infectious diseases, neglected tropical diseases, and potential bioterrorism agents.

FDA's strategic goal to Advance Biologics Safety and Effectiveness is focused on four long-term objectives:

- ensure the safety of biological products
- enhance the ability of advances in science and technology facilitate development of safe and effective biological products
- increase the Nation's preparedness to address threats as a result of bioterrorism, pandemic, and emerging infectious diseases
- improve global public health through international collaboration, including research and information sharing.

Major accomplishments for FY 2013 through FY 2014 include:

- issuing a long-term strategic plan and proposed rule concerning drug and biologic product shortages, ensuring safe and effective influenza vaccines are available
- enhancing patient access to new medical treatments for serious conditions by issuing draft guidance that provides a comprehensive reference for industry on fast track designation, accelerated approval, breakthrough designation, and priority review.

Ensure the Safety of Biological Products

FDA ensures the safety of biological products throughout their lifecycle. Under FDAAA, FDA gained additional authorities to enhance product safety through required post-market studies, safety labeling changes, and risk evaluation and mitigation strategies. Implementing these tools, FDA carries out surveillance, compliance, and enforcement activities to ensure product safety.

In March 2013, FDA issued an Order to Cease Manufacturing to a fertility clinic responsible for determining the eligibility of anonymous and directed donors of reproductive human cells, tissues, and cellular and tissue-based products. Inspections revealed that the firm failed to provide adequate protections against the risks of communicable disease transmission.

In May 2013, the Biologics Program approved iTrace for Blood Centers, the first device employing Radio Frequency Identification technology cleared for use in blood establishments to track and monitor blood products, in conjunction with barcode identification and labeling processes in place. iTrace enhances blood safety and surveillance by streamlining blood collection and processing and aiding in product tracking and reconciliation, thus preventing the release of unsuitable blood products.

In May 2013, FDA also held a public workshop with NIH and the scientific-medical community to discuss scientific and regulatory challenges associated with the use of Fecal Microbiota for Transplantation (FMT). As a result of discussion during the workshop, the Biologics Program published a final guidance for industry.

In June 2013, the Biologics Program required safety labeling changes for immune globulin products "Immune Globulin Products (Human) intravenous, subcutaneous, and intramuscular." FDA also required safety labeling changes for Rotateq, a rotavirus vaccine, after assessing new safety data from its

evaluation of rotavirus vaccines and intussusception. This evaluation was the first protocol-based assessment completed under the Mini- Sentinel Post-Licensure Rapid Immunization Safety Monitoring (PRISM) program, and it demonstrated FDA's enhanced capability to integrate safety signal identification and evaluation with regulatory decision-making. PRISM is evaluating febrile seizures and influenza vaccines, venous thromboembolism and Gardasil (a human papilloma virus vaccine), Kawasaki Disease and Prevnar 13 (a pneumococcal conjugate vaccine). PRISM is also assessing the feasibility of addressing pregnancy and birth outcomes after influenza vaccines.

In September 2013, FDA collaborated with the Centers for Medicare and Medicaid Services (CMS) to monitor Guillain-Barré syndrome after seasonal influenza vaccines among Medicare beneficiaries in near real time using healthcare claims data; the results of the evaluation of Guillain-Barré syndrome after the 2009 H1N1 vaccine using medical chart confirmation in Medicare beneficiaries were published in the American Journal of Epidemiology. The Biologics Program continued development of the Blood Safety Continuous Active-Surveillance Network (BloodSCAN), to create an active pharmacovigilance system for blood and blood products by launching a protocol based evaluation of thromboembolic events and Immune Globulin Products (Human).

The Biologics Program also monitors recalls of biological products and ensures the effectiveness of the firm's recall to remove the defective product from commerce. In FY 2013, FDA classified 4 Class I, 1103 Class II, and 426 Class III biologic recall events

In October 2013, FDA issued a long-term strategic plan to improve the agency's response to imminent or existing shortages, and for longer term approaches for addressing the underlying causes of drug and biologic product shortages and highlighting opportunities for manufacturers and others to prevent shortages by promoting and sustaining quality manufacturing. FDA issued a proposed rule requiring all manufacturers of biologic products to notify FDA of a permanent discontinuance or a temporary interruption of manufacturing likely to disrupt their supply.

In November 2013, FDA issued a Safety Communication and required a change to product labeling for hydroxyethyl starch solutions "Boxed Warning on increased mortality and severe renal injury, and additional warning on risk of the bleeding, for use of hydroxyethyl starch solutions in some settings."

Enhance the Ability of Advances in Science and Technology to Facilitate Development of Safe and Effective Biological Products

The Biologics Program addresses the use of advanced technologies, methods, and relevant scientific discoveries, such as newly identified clinical biomarkers, adaptive clinical trial designs, and genomics in regulatory guidance for industry. The program advances regulatory research that supports product review and the corresponding review processes to reflect the new generation of product evaluation tools and the innovative products FDA expects to see over the next decade. Accomplishments in the development of safe and effective biological products include the following items.

FDA issued draft guidance, "Expedited Programs for Serious Conditions – Drugs and Biologics," which provides a single source for industry on fast track, priority review, accelerated approval, and breakthrough designation, to help enhance accelerated patient access to new medical treatments for serious conditions. Also this year, CBER published seven draft and seven final guidances and provided input to over a dozen Agency guidances intended to facilitate development of safe and effective biological products, while

taking into account advances in science and technology.¹⁴

In March 2013, FDA developed and validated a quantitative risk assessment on the risk of transmitting variant Creutzfeldt-Jakob disease (vCJD) in the United States by transfusion of red blood cells, drawing on recommendations made by FDA's Transmissible Spongiform Encephalopathy Advisory Committee (TSEAC). Results were presented to TSEAC.

In April 2013, the Biologics Program approved Kcentra for the urgent reversal of vitamin K antagonist (VKA) anticoagulation in adults with acute major bleeding. Unlike plasma, Kcentra does not require blood group typing or thawing allowing it to be administered more quickly than frozen plasma. FDA held a Workshop on the Application of Advances in Nucleic Acid and Protein Based Detection, to hear scientific advances and encourage manufacturers to bring this technology for multiplex detection of transfusion- transmissible agents forward for approval.

In May 2013, FDA approved Allocord (St. Louis Cord Blood Bank of the SSM Cardinal Glennon Children's Medical Center) and approved HPC, Cord Blood, in June 2013 (LifeSouth Community Blood Centers, Inc.), increasing the total to five cord blood products available to treat patients with disorders affecting the hematopoietic system.

In June 2013, FDA approved RIXUBIS the first recombinant Factor IX product indicated for prophylaxis to reduce the frequency of bleeding events and the likelihood of disabling joint disease. It is also the second approved recombinant Factor IX product, adding to choices for treatment for Factor IX deficient patients and reducing the likelihood of shortages

In July 2013, the Biologics Program approved the second U.S. licensed blood typing and antibody detection and identification system using gel column agglutination technology; this system helps with the resolution of blood typing discrepancies. This approval was based on the review of sixteen Biologics License Applications (BLAs), one efficacy supplement, seven Prior Approval Supplements, and four 510(k)s for S.A. DGGel® cards.

In August 2013, FDA approved the first rapid diagnostic test to detect both Human Immunodeficiency Virus (HIV)-1 antigen and HIV-1/2 antibodies. The Alere Determine HIV1/2 Ag/Ab Combo Test is the first FDA-approved test that distinguishes test results for HIV-1 p24 antigen and HIV-1/2 antibodies in a single test and helps diagnose HIV infection at an earlier time point in outreach settings, allowing infected individuals to seek medical care.

In December 2013, FDA approved Tretten, Coagulation Factor XIII A-Subunit (Recombinant), the first recombinant product for use in the routine prevention of bleeding in adults and children who have a serious, rare clotting disorder, known as congenital Factor XIII A-subunit deficiency.

In January 2014, the Biologics Program held workshops entitled "Strategies to Address Hemolytic Complications of Immune Globulin Infusions" and "Complex Issues in Developing Drug and Biological Products for Rare Diseases," to discuss complex issues in clinical trials for developing drug and biological products for rare diseases. In addition, FDA approved the first Humanitarian Device Exemption (HDE) for the CliniMACS CD34 Reagent System intended for use in a sub-population of patients with Acute Myeloid Leukemia who are in first remission undergoing myeloablative transplant (depletion of bone marrow cells) from a matched sibling donor.

Increase the Nation's Preparedness to Address Threats as a Result of Bioterrorism,

¹⁴ Complete information on CBER guidances can be found at:
<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances>

Pandemic, and Emerging Infectious Diseases

FDA responds to the challenges of bioterrorism, pandemic and emerging infectious diseases by being proactive in preparing for and facilitating product development to protect the public against these threats and approving products that have been demonstrated to be safe and effective. To increase preparedness, the Biologics Program facilitates the development of both seasonal and pandemic influenza vaccines through expedited regulatory pathways. FDA also supports efforts to increase manufacturing capacity using both new and existing technologies and to develop faster methods for testing the potency of influenza vaccines. Accomplishments in increasing the Nation's preparedness to bioterrorism, pandemic and emerging infectious disease threats include the following items.

The Biologics Program prepared potency reagents and provided them to vaccine manufacturers and other global partners, for the U.S. federal public health response to the appearance of H7N9, a novel avian influenza virus with pandemic potential. The Biologics Program collaborated with NIH to develop a protocol for the conduct of human clinical trials to obtain preliminary safety and immunogenicity data which will inform use of the vaccine in populations.

To date, FDA has approved 15 seasonal influenza vaccines for the United States, including Flucelvax and Flublok, two vaccines that do not use egg-based technology in their manufacturing, which offer the potential for faster start-up of the vaccine manufacturing process in the event of a pandemic. Three new Quadrivalent vaccines were approved, bringing the total licensed to four that increase the likelihood of adequate protection against circulating influenza B strains.

The Biologics Program approved the first adjuvant vaccine for the prevention of H5N1 influenza, commonly known as avian or bird flu. This vaccine could be used in the event that the H5N1 avian influenza virus develops the capability to spread efficiently from human-to-human, resulting in the rapid spread of disease across the globe and will be included within the National Stockpile for distribution by public health officials if needed.

FDA initiated a study, in collaboration with CMS and the Center for Disease Control, to compare the effectiveness of Fluzone High-Dose vaccine and the standard dose among the elderly in the United States.

FDA collaborates and provides technical assistance to the Biological Advanced Research and Development Authority and HHS on multiple medical countermeasure initiatives including using mass spectrometry for influenza vaccine potency testing, assessing the potential for the UK Anthrax Vaccine Precipitated production facility to supply vaccines for use in the United States, and establishing Centers for Innovation in Advanced Development and Manufacturing to increase medical countermeasures and pandemic influenza manufacturing capabilities in the United States.

The Biologics Program published promising research on vaccines in peer reviewed publications. One publication showed that baboons provide an excellent model of clinical pertussis; therefore allowing researchers to investigate how *Bordetella pertussis* bacteria cause disease, how it is spread in a population, how it is prevented by existing vaccines and how those vaccines and their evaluation may be improved in the future. In follow-up to this study, the Biologics Program conducted additional important research that helps provide an understanding of the rising rates of pertussis disease and response to vaccination. In addition, FDA Co-authored two landmark studies related to H1N1 influenza vaccination that provide critical new evidence on the safety of existing vaccines and promising approaches to the development of a universal vaccine to protect against both H1N1 and H5N1 viruses.

In March 2013, FDA approved Botulism Antitoxin Heptavalent for treating patients with symptomatic botulism following exposure to botulinum neurotoxin serotypes A, B, C, D, E, F, or G. A few hundred cases of symptomatic botulism occur each year due to ingestion of bacterial spores or as a result of improperly canned foods. Botulinum is also a highly potent toxin that can be aerosolized as a bioterrorism agent and is the first biological product to be approved under the "animal rule" since human efficacy studies were not feasible or ethical.

Improve Global Public Health through International Collaboration, Including Research

and Information Sharing

As a part of improving public health through international collaboration, the Biologics Program promotes research and information-sharing globally to address diseases and emerging threats impacting human populations; facilitates global access to vaccines and biological products that address critical health needs; harmonizes existing regulatory standards, where feasible to promote global public health; and participates in international scientific efforts to establish and maintain reference materials and standards for biologics. Accomplishments in improving global health include the following items.

FDA conducts regulatory science research and shares results with other WHO Collaborating Centers and the global community to advance product development. FDA contributes to the development of international standards for Dengue Viruses and West Nile Virus, a consensus statement supporting the inclusion of whole blood and red blood cells on the WHO Model List of Essential Medicines, and a consensus position statement on blood donor deferral for men who have had sex with other men.

The Biologics Program worked with WHO Collaborating Centers and other national regulatory authorities to evaluate and select candidate materials that are used as reference standards for hematologic proteins such as Factor VIII and IX, and in the development of international reference preparations for hematological products and blood safety related In Vitro Diagnostics.

FDA developed data requirements for influenza virus vaccines to expedite importation. These requirements were implemented in May 2013 and letters were issued to manufacturers in July 2013 specifying data needed on entry documents to expedite vaccine imports into the United States.

Biologics Program staff members served as chair for two international working groups on gene therapy, the Regulators Forum Cell Therapy Group (RFCTG) and the Regulators Forum Gene Therapy Discussion Group, under the International Pharmaceutical Regulators Forum, including meeting with regulatory authorities of nine countries.

FUNDING HISTORY

Fiscal Year	Program Level	Budget Authority	User Fees
FY 2011 Actual	\$302,020,000	\$211,790,000	\$90,230,000
FY 2012 Actual	\$308,620,000	\$212,298,000	\$96,322,000
FY 2013 Actual	\$ 296,866,000	\$ 194,638,000	\$ 102,228,000
FY 2014 Enacted	\$ 337,543,000	\$ 210,928,000	\$ 126,615,000
FY 2015 Budget Request	\$ 342,639,000	\$ 209,754,000	\$ 132,885,000

BUDGET REQUEST

The FY 2015 Budget for the Biologics Program is \$342,639,000, of which \$209,754,000 is budget authority and \$132,885,000 is user fees. This is \$5,096,000 above the FY 2014 Enacted level. The Center portion is \$297,773,000 and the Field portion is \$44,866,000.

FDA is committed to advancing public health through innovative regulation that promotes the safety, effectiveness, and timely delivery of biological products to patients.

In FY 2015, the Biologics Program will address threats as a result of bioterrorism, pandemic, and emerging infectious diseases, including facilitating development, evaluation, and availability of high-priority medical products and countermeasures. FDA will develop reagents, evaluate new methods, implement policies, engage with industry on emerging scientific and regulatory issues, and develop models to better understand disease pathogenesis and response.

The Biologics Program will improve global public health through international collaboration by facilitating global access to vaccines and biological products that address critical health needs, including

promoting research and sharing information to address global diseases and emerging threats impacting human populations.

FDA is strategizing to harmonize existing regulatory standards and cooperate with international scientific efforts to establish and maintain reference materials and standards for biologics.

The Biologics Program will advance science and technology to bring products to market by developing and issuing guidance and regulations to communicate scientific and regulatory requirements, provide recommendations and frameworks for product development, develop policy and take appropriate regulatory actions on premarket product submissions. In addition, FDA will advance regulatory research to facilitate product review, including development of animal models, genomics, proteomics, high-sensitivity gene sequencing, biomarkers to improve the evaluation of effectiveness of products in clinical trials, and other cutting-edge scientific technologies.

FDA is striving to ensure safety of biological products by conducting a robust post-market program after products are approved and evaluate the results of clinical studies, including use of healthcare data to move to active surveillance, enhance statistical data analysis and mathematical models for improved epidemiological and risk assessment of regulated products.

Medical Product Safety

Pharmacy Compounding: Inspections and Enforcement and Policy Development Coordination (+\$454,000)

The Pharmacy Compounding Initiative component of the Biologics Program is part of a multi-program initiative to provide more appropriate and effective oversight of pharmacy compounding through investments in inspections and enforcement, policy development, and state coordination. This initiative will support inspections and enforcement of high-risk pharmacy compounding facilities regulated by the Biologics Program. Also, the Biologics Program will participate in policy development activities with the Human Drugs Program with emphasis on cases and policies that affect biological products regulated by the Biologics Program. Further details on this initiative as well as the other organizations involved in this initiative appear in the Overview of the Budget Request narrative, Human Drugs Program narrative, Animal Drugs and Feeds Program narrative, Office of Regulatory Affairs narrative, and FDA Headquarters narrative.

PERFORMANCE

The Biologics Program’s performance measures focus on biological product review, manufacturing diversity and capacity for influenza vaccine production and post-market inspections for ensuring the safety, purity, potency, and effectiveness of biological products, as detailed in the following table.

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2014 Target	FY 2015 Target	FY 2015 +/- FY 2014
233207: Review and act on standard New Molecular Entity (NME) New Drug Application (NDA) and original BLA submissions within 10 months of the 60 day filing date. (Output)	NA New Goal	90%	90%	maintain
233208: Review and act on priority NME NDA and	NA New Goal	90%	90%	maintain

original BLA submissions within 6 months of the 60 day filing date. (Output)				
233209: Review and act on standard non-NME original NDA submissions within 10 months of receipt. (Output)	NA New Goal	90%	90%	maintain
233210: Review and act on priority non-NME original NDA submissions within 6 months of receipt. (Output)	NA New Goal	90%	90%	maintain
233203: Complete review and action on standard PDUFA efficacy supplements within 10 months of receipt. (Output)	FY 2012: 100% Target: 90% (Target Exceeded)	90%	90%	maintain
Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2014 Target	FY 2015 Target	FY 2015 +/- FY 2014
233205: Complete review and action on complete blood bank and source plasma BLA submissions within 12 months after submission date. (Output)	FY 2012: 100% Target: 90% (Target Exceeded)	90%	90%	maintain
233206: Complete review and action on complete blood bank and source plasma BLA supplements within 12 months after submission date. (Output)	FY 2012: 99% Target: 90% (Target Exceeded)	90%	90%	maintain
234101: Increase manufacturing diversity and capacity for influenza vaccine production. (Output)	FY 2013: Developed and evaluated new methods to produce high-yield influenza vaccine reference strains.(Target Met)	Continue evaluation of new methods to produce high-yield influenza vaccine reference strains.	Continue evaluation of new methods to produce high-yield influenza vaccine reference strains.	maintain
234202: Number of registered domestic blood bank and biologics manufacturing inspections. (Output)	FY 2013: 1,031 Target: 1,000 (Target Exceeded)	1,000	1,000	maintain
234203: Number of human foreign and domestic tissue establishment inspections. (Output)	FY 2013: 669 Target: 533 (Target Exceeded)	570	570	maintain

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

Review Goals

FDA continues to exceed the standard PDUFA efficacy supplements and blood bank and source plasma review goals. Review Goals 233207, 233208, 233209 and 233210 were added in FY 2013 to align with the new PDUFA V performance commitments. Performance results will not be available until November 2014, when the review of the applications for the FY 2013 Cohort is complete. In October 2013, CBER

approved its first product under PDUFA V. CBER approved Novoeight, Antihemophilic Factor (Recombinant), for use in adults and children with hemophilia A for control and prevention of bleeding episodes, perioperative management, and routine prophylaxis to prevent or reduce the frequency of bleeding episodes. No material of human or animal origin is used in the establishment of the production cell line, cell culture, purification, or formulation of Novoeight.

Influenza Goal

This performance goal supports the Department's national preparedness efforts in combating the seasonal influenza outbreak, by increasing manufacturing diversity and capacity for influenza vaccine production. Further information on this goal can be found in the Department's Online Performance Appendix.

In FY 2013, FDA met the target to develop and evaluate new methods to produce high-yield influenza vaccine reference strains. Activities to meet this target include the following examples.

- FDA evaluated multiple assays to determine the best methods for assessing vaccine reference strain yield. The results indicated that a single method was insufficient for an accurate assessment of a candidate vaccine's potential for vaccine manufacturing and that multiple methods should be utilized.
- FDA approved further modifications to previously developed influenza vaccine reference strains for the 2009 H1N1 pandemic strain, increasing hemagglutinin (HA) yield. HA yield is important to produce the needed quantity of vaccine and helps to ensure rapid availability of vaccines.
- One new influenza reference strain was developed as a possible vaccine candidate for the H7N9 influenza virus that emerged in China during 2013. This reference strain has been shared with the WHO collaborating centers.

PROGRAM ACTIVITY DATA

Biologics Program Activity Data (PAD)¹

Workload and Outputs	FY 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
Original Biologics License Applications (BLA)			
Workload ^{/2}	25	25	25
Total Decisions ^{/3}	60	60	60
Approved	32	32	32
BLA Efficacy Supplements			
Workload ^{/2}	16	16	16
Total Decisions ^{/3}	15	15	15
Approved	11	11	11
BLA Manufacturing Supplements			
Workload ^{/2}	1,201	1,201	1,201
Total Decisions ^{/3}	1,470	1,470	1,470
Approved	1,129	1,129	1,129
BLA Labeling Supplements			
Workload ^{/2}	208	208	208
Total Decisions ^{/3}	245	245	245
Approved	221	221	221
Original New Drug Application (NDA)			
Workload ^{/2}	0	0	0
Total Decisions ^{/3}	2	2	2
Approved	2	2	2
NDA Efficacy Supplements			
Workload ^{/2}	2	2	2
Total Decisions ^{/3}	1	1	1
Approved	1	1	1
NDA Manufacturing Supplements			
Workload ^{/2}	49	49	49
Total Decisions ^{/3}	87	87	87
Approved	15	15	15
NDA Labeling Supplements			
Workload ^{/2}	13	13	13
Total Decisions ^{/3}	12	12	12
Approved	5	5	5
Original Abbreviated New Drug Application (ANDA)			
Workload ^{/2}	0	0	0
Total Decisions ^{/3}	1	1	1
Approved	0	0	0
ANDA Efficacy Supplements			
Workload ^{/2}	0	0	0
Total Decisions ^{/3}	0	0	0
Approved	0	0	0
ANDA Manufacturing Supplements			
Workload ^{/2}	2	2	2
Total Decisions ^{/3}	6	6	6
Approved	1	1	1
ANDA Labeling Supplements			
Workload ^{/2}	1	1	1
Total Decisions ^{/3}	2	2	2
Approved	1	1	1
Device 510Ks			
Workload ^{/2}	59	59	59
Total Decisions ^{/3}	56	56	56
Final Decision - SE	43	43	43

Biologics Program Activity Data (PAD)¹

Workload and Outputs	FY 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
Device Premarket Applications (PMA)			
Workload ^{/2}	1	1	1
Total Decisions ^{/3}	2	2	2
Approved	2	2	2
Device Premarket Applications (PMA) Supplements			
Workload ^{/2}	48	48	48
Total Decisions ^{/3}	50	50	50
Approved	24	24	24
Investigational New Drugs (IND)			
Receipts: IND (new)	424	424	424
Receipts: IND Amendments	8,821	8,821	8,821
Total Active IND ^{/4}	2,010	2,010	2,010
Investigational Device Exemptions (IDE)			
Receipts: IDE (new)	12	12	12
Receipts: IDE Amendments	296	296	296
Total Active IDE ^{/4}	117	117	117
Patient Safety			
Adverse Event Reports Received ^{/5}	42,786	43,000	43,000
Biological Deviation Reports Received	54,716	55,000	55,000
Sponsor Assistance Outreach			
Meetings	403	403	403
Final Guidance Documents ^{/6}	37	30	30
Admin/Management Support			
Advisory Committee Meetings Held	16	17	17
FOI Requests Processed	335	350	350

^{1/} Please note that the PAD presentation changed from the FY 2014 Congressional Budget Submission to be consistent with the format of other medical product program PAD presentations.

^{2/} Workload includes applications received and filed.

^{3/} Total Decisions include approved, denied, withdrawn, approvable, approvable pending inspection, not approvable, exempt, major deficiency, substantially equivalent (SE), not substantially equivalent (NSE), de novo and complete response (CR).

^{4/} Total Active includes investigational applications received and existing applications for which CBER has received at least one amendment (IND) or supplement (IDE) during the FY being reported.

^{5/} Includes MedWatch, Foreign reports and VAERS reports. Does not include Fatality Reports or Medical Device Reports for CBER-regulated medical devices.

^{6/} Includes all FDA final guidances issued by CBER and other FDA centers that pertain to biological products.

Field Biologics Program Activity Data (PAD)

Field Biologics Program Workload and Outputs	FY 2013 Actual	FY 2014 Estimate	FY 2015 Estimate
<i>FDA WORK</i>			
DOMESTIC INSPECTIONS			
<i>UNIQUE COUNT OF FDA DOMESTIC BIOLOGICS ESTABLISHMENT INSPECTIONS</i>			
	2,004	2,047	2,047
Bioresearch Monitoring Program Inspections	89	100	100
Blood Bank Inspections	758	1,000	1,060
Source Plasma Inspections	186	194	194
Pre-License, Pre-Market Inspections	14	7	7
GMP Inspections	35	28	28
GMP (Device) Inspections	6	7	7
Human Tissue Inspections	669	661	661
FOREIGN INSPECTIONS			
<i>UNIQUE COUNT OF FDA FOREIGN BIOLOGICS ESTABLISHMENT INSPECTIONS</i>			
	74	47	47
Bioresearch Monitoring Program Inspections	24	11	11
Foreign Human Tissue Inspections	2	0	0
Blood Bank Inspections	8	8	8
Pre-License, Pre-market Inspections	8	2	2
GMP Inspections (Biologics & Device)	30	20	20
<i>TOTAL UNIQUE COUNT OF FDA BIOLOGIC ESTABLISHMENT INSPECTIONS</i>	2,078	2,094	2,094
IMPORTS			
Import Field Exams/Tests	37	45	45
Import Line Decisions	74,402	97,198	97,198
Percent of Import Lines Physically Examined	0.05%	0.05%	0.05%
<i>GRAND TOTAL BIOLOGICS ESTABLISHMENT INSPECTIONS</i>	2,078	2,094	2,094