

Food and Drug Administration
FY 2012 Congressional Budget Request
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BUILDINGS AND FACILITIES

The following table displays funding levels for FY 2010 through FY 2012.

FDA Program Resources Table
(Dollars in Thousands)

	FY 2010 Enacted	FY 2010 Actuals	FY 2011 Cont.Res	FY 2012 Request	+/- FY 2010 Enacted
Program Level	\$15,930	\$22,111	\$15,930	\$13,055	-\$2,875
Budget Authority	\$15,930	\$22,111	\$15,930	\$13,055	-\$2,875
Building and Facilities	\$12,433	\$15,117	\$12,433	\$13,055	\$622
Natural Products Center	\$3,497	\$6,994	\$3,497	\$0	-\$3,497

The FDA Building and Facilities program operates under the following legal authorities:

Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 321-399)
 Public Health Service Act (42 U.S.C. §238)
 Energy Policy Act of 2005 (P.L. 109-058)
 Chief Financial Officers Act of 1990 (P.L. 101-576)
 Federal Financial Management Act of 1994 (P.L. 103-356)
 Federal Property and Administrative Services Act of 1949, as amended (40 U.S.C. §§471 *et seq.*)
 National Historic Preservation Act of 1966 (P.L. 89-665; 16 U.S.C. 470 *et seq.*)
 Omnibus Appropriations Act of 2009 (P.L. 111-8, 123 Stat. 524)
 Energy Independence & Security Act of 2007 (P.L. 10-140, 121 Stat. 1492)

Allocation Method: Direct Federal; Contract

Program Description and Accomplishments

The Building and Facilities Program (B&F) is a critical element of FDA's real property asset management program. The B&F Program provides direct support that allows FDA to accomplish its public health mission.

B&F supports FDA's strategic goal of transforming administrative systems and infrastructure to support FDA operations. The B&F program funding is provided to construct mission critical laboratory, office and support space, and for renovations, repairs and improvements to 85 FDA-owned facilities located at six sites in the U.S. and Puerto Rico where FDA conducts operations that are critical to FDA's public health mission.

FDA uses the majority of its B&F funds for renovation, repair and improvement projects. Those projects can take multiple years to complete, based on the project size and

* Authorities under this Act do not appear in sequence in the U.S. Code. The authorities are codified as amended in scattered sections of 21 U.S.C.

complexity. For example, designing the project, procuring construction services and completing the actual renovations, repairs and improvements usually take more than 18 months.

The Department of Health and Human Services (HHS) developed a Real Property Asset Management Plan (AMP). AMP outlines a framework and holistic approach for acquiring, managing, and disposing of real property assets. AMP contains performance measures and benchmarks that monitor key real property asset management criteria, including mission criticality, utilization, facility condition and operating costs.

The physical condition of FDA-owned assets, which includes a substantial amount of laboratory facilities and site infrastructure, is critically important. A safe, suitable and reliable work environment is essential for FDA to protect the Nation's health, security, and economy. Improving and maintaining facilities often results in a positive effect on facility use and operating costs.

An important component of FDA real property asset management is conducting facility condition assessments on a three-year cycle. Facility condition assessments evaluate:

- site infrastructure such as utility distribution systems, roads, and sidewalks
- buildings, including the associated physical systems such as architectural, civil, mechanical, and electrical issues, as well as code compliance, life and other safety conditions, and finishes and aesthetics.

These periodic assessments of FDA facilities result in a list of maintenance and repair deficiencies with associated costs known as the Backlog of Maintenance and Repair (BMAR) for the site and its facilities. The BMAR includes a plant replacement value which is the cost to replace an infrastructure item or a facility, and a Facility Condition Index (FCI) score.

The BMAR identifies and estimates costs associated with addressing needed maintenance, repairs and replacement of equipment and building systems that are approaching, at, or past their useful life. At the end of FY 2010, FDA's total BMAR, which includes building deficiencies, site infrastructure deficiencies and required renewals, for its six owned sites was approximately \$100,500,000. BMAR information is used to identify and prioritize short- and long-term projects using B&F Program funding. The FCI score is calculated using the BMAR and plant replacement value. HHS established an FCI goal of 90 percent or greater for all owned facilities. Currently, approximately 63 percent of FDA-owned assets have an FCI score below the HHS established goal and require significant repairs and improvements.

FDA used B&F Program funding provided in FY 2010 and FY 2011 and plans to use the FY 2012 funds to accomplish several mission critical and BMAR driven projects at each of its six owned sites. The FY 2012 B&F projects will improve the condition of these assets and ensure that the assets can successfully support FDA's mission. The list below is representational and not comprehensive. Severe weather and other natural events can alter the list and its priorities.

FDA's Gulf Coast Seafood Laboratory site, located in Dauphin Island, Alabama, is used by the Center for Food Safety and Applied Nutrition (CFSAN) to conduct research programs related to seafood safety, especially seafood harvested from the Gulf of Mexico. During FY 2010, FDA completed numerous projects to ensure the continued functionality of this facility. These projects include:

- resurfacing the parking lot and roads
- replacing the boiler and windows
- installing crawl space insulation to improve the energy efficiency and ensure a comfortable work environment.

FDA also plans to replace the switchgear and parallel conductors in the main laboratory building.

The FDA Muirkirk Road Complex (MRC) located in Laurel, Maryland is a campus which is shared by CFSAN and the Center for Veterinary Medicine (CVM). At MRC, FDA conducts research programs related to food and animal drug safety, toxicology, microbiology, and molecular biology. In addition, FDA uses the laboratories at this site for the Laboratory and Food Emergency Response Networks.

At MRC, recent B&F projects include:

- designs to replace the aged and non-compliant fire alarm systems and exit signs
- a study for replacing two chillers for the aquaculture facility
- installing and updating ground fault circuit interrupter protection
- installing emergency and egress lighting
- retubing boilers
- overhauling cooling towers and chillers
- designing a replacement laboratory nitrogen manifold system
- replacing variable frequency drives for laboratory air handling units and exhaust fans
- replacing reheat coils
- repaving a bridge and repairing associated sinkholes.

These projects support FDA's ability to establish science-based regulatory standards and rapid responses to outbreaks.

FDA also plans to renovate the mission critical laboratory space for CVM in MOD2 to support program mission requirements. These renovations include:

- installing a new nitrogen gas delivery system for essential laboratory equipment in MOD2
- renovating the BRF Support Building for the Office of Regulatory Affairs (ORA)
- replacing the MRC MOD 1 Fire Alarm System.

FDA will initiate additional projects to address other facility deficiencies, including the essential replacement or repair of motor controls, HVAC controls and compressors in MOD1, which will improve the reliability of building systems to support essential animal research and laboratory operations.

Finally, FDA is evaluating whether to enter into a second utility energy service contract (UESC) at MRC and is considering an investment grade audit to provide a more accurate cost estimate and annual savings from the preliminary audit report performed earlier in the year. In addition to projects that will result in energy conservation, FDA is considering including facility improvement projects, such as the replacement of the aged switchgear at MOD1, as part of this UESC. UESCs provide an opportunity to finance projects over time through a contract with a local utility provider, which allows FDA to use its B&F funds to make other needed repairs and improvements in support of the mission at this site. FDA also plans to develop a Master Plan for this site.

The Jefferson Laboratories Complex (JLC) located in Jefferson, AR houses the National Center for Toxicological Research (NCTR) and Office of Regulatory Affairs' (ORA) Arkansas Regional Laboratory (ARL). NCTR conducts research at this site that focuses on risk assessment, investigating toxicity, and studying the extrapolation of data from animal studies to humans, all of which informs FDA regulatory policies. The ARL provides analytical laboratory support to ORA's regulatory mission in the Southwest Region.

At JLC, FDA recently funded the following projects:

- fit-out of one floor of Building 50, a key administrative building
- renovating existing space for critical research and neurotoxicology laboratories in Building 62
- replacing a boiler and its associated equipment and controls in Building 7 with one that is more energy efficient and reliable
- replacing a chiller in Building 26 with a larger more energy efficient chiller
- replacing HVAC equipment in Building 5 that supports critical research support areas with more energy efficient equipment.

FDA has designed projects such as repairs of critical campus wide electrical distribution infrastructure and future laboratory repairs in Building 14A and 14B. Repair and improvement projects include:

- replacing fire alarm systems and reworking the electrical distribution system at campus substation #3
- renovating research support rooms and dressing rooms in Building 5
- renovating laboratory space in Building 14.

Other key site and building infrastructure projects involve repairing processing area equipment in Building 5A that supports animal research and replacing emergency generators and associated controls, air handling units and electrical distribution systems. Designs for critical laboratory, conference room, and administrative space renovations, a water recycling project, natural gas and hot water piping repairs and HVAC system replacement projects will also be completed and actual repair and improvement work associated with some of these designs will begin. FDA also initiated a project to develop a Master Plan for the site.

The assets at FDA's San Juan District Office located in San Juan, PR are primarily used for specialized human drug testing and analysis. FDA completed the projects to replace the rooftop central air conditioning units and direct expansion units, as well as the conference room carpet and ceiling. FDA also funded projects to complete additional HVAC repairs, clean ductwork, replace the Hazmat/Chemical Storage Building, make improvements to ensure ADA compliance, and paint exterior doors identified as facility deficiencies. Additional projects for various electrical repairs throughout the site are scheduled.

FDA's Pacific Regional Laboratory Southwest is located in Irvine, CA. This space provides analytical laboratory support to ORA's regulatory mission in the Pacific Region. The facility also houses the Los Angeles District Office, which serves as ORA's inspection and compliance base in the Los Angeles area.

During FY 2010, FDA completed a mission-required office renovation at the Irvine facility as well as projects that included repainting exterior metal surfaces, repairing wall cracks and installing expansion control joints. FDA also plans to fund a UESC Investment Grade Audit, which will include energy, water and other sustainable design measures, such as the design and construction of solar screens to improve energy efficiency, ensure a comfortable work environment, and generate solar power for portions of the building.

The Winchester Engineering and Analytical Center located in Winchester, MA, is an ORA specialty laboratory used to test the safety and performance of medical devices, microwaves, and radiopharmaceuticals; to conduct radionuclide testing with food samples; and to ensure seafood freshness. FDA has substantially completed a project to upgrade the laboratory HVAC, plumbing, and electrical systems, and replace the domestic water heater, three fume hoods and the acoustical ceiling. FDA also funded a project to upgrade additional HVAC equipment and to correct emergency generator deficiencies. FDA plans to continue work on miscellaneous HVAC, electrical and structural repairs.

FDA completed feasibility studies that identified program needs and required facility modifications to develop core scientific research facilities for nanotechnology, flow cytometry and imaging programs at the MRC, JLC and White Oak Campus. FDA plans to fund facility condition and sustainability assessments for its owned assets that are less than 5,000 square feet, which is consistent with HHS policy.

Promoting Efficiency

FDA laboratories and the site infrastructure that supports laboratories are essential for FDA to achieve its mission. Many laboratory upgrades funded through the B&F account permit FDA to improve and repair building and site infrastructure deficiencies to ensure laboratories are operating as efficiently as possible in support of FDA science, which in turn leads to improved public health.

FDA also uses B&F funds to install more modern equipment to analyze and address food, drug and cosmetic safety and toxicity concerns and concerns about the other products that FDA regulates. Updated equipment produces more rapid, accurate and sophisticated results, allowing FDA to respond to threats to public health and prevent injury, illness or death. Faster and more accurate results give FDA the ability to identify which firms within an industry sector are responsible for contamination – and which are not – allowing firms to resume business operations more quickly.

Five Year Funding Table

The following table displays funding levels from FY 2007 through FY 2011.

Fiscal Year	Program Level	Budget Authority
FY 2007 Actual	\$10,382,000	\$10,382,000
FY 2008 Actual ¹	\$7,534,000	\$7,534,000
FY 2009 Actual	\$5,871,000	\$5,871,000
FY 2010 Actual ²	\$22,111,000	\$22,111,000
FY 2011 Continuing Resolution ³	\$15,930,000	\$15,930,000

¹ FY 2008 includes \$3,724,000 under FY 2008 Omnibus Appropriations Act General Provision Sec. 734 to the National Center for Natural Products Research for construction and renovation.

² FY 2010 includes \$6,994,000 to the National Center for Natural Products Research for construction and renovation.

³ FY 2011 C.R. level estimates \$3,497,000 to the National Center for Natural Products Research for construction and renovation.

Summary of the Budget Request

The FY 2012 budget request for the Buildings and Facilities Program is \$13,055,000. This amount includes a \$622,000 increase above the FY 2010 Enacted Level.

FDA will use the requested resources to fund various projects at its six mission critical, owned sites, facilitating FDA’s ability to achieve its mission, provide a safe and productive work environment, and sustain and improve the condition of its owned sites and associated buildings.

FDA initially prioritized a multitude of renovation, repair and improvement projects for both site infrastructure and buildings driven by mission requirements and the Backlog of Maintenance and Repair. FDA will utilize the FY 2012 funding to complete these priority projects. Conditions and mission needs at FDA sites may change after this prioritization process that may require FDA to modify its planned projects for FY 2012, including a

modification to funding allocations per site. Such flexibility is critical to ensure the highest level of support for the programs carrying out the FDA mission.

FDA plans to use FY 2012 B&F funding at its Jefferson Labs Complex (JLC) site to:

- repair the electrical distribution system at campus substations #1 and #2
- renovate critical laboratory and support space
- replace a second boiler with a new energy efficient low, nitrogen oxide emitting boiler
- replace HVAC and reheat piping systems in multiple buildings.

These projects are critical to ensure adequate, reliable site infrastructure and building operations in support of the FDA mission. This site provides analytical laboratory support to ORA's regulatory mission in the Southwest Region and houses ORA's only nanotechnology laboratory. JLC is also the home base for ORA's two mobile laboratories, and supports numerous analytical testing capabilities including dioxin testing and gulf oil spill testing.

The National Center for Toxicological Research also employs this site to support integrated research vital to regulatory decisions on products using new technologies such as nanomaterials and to increase understanding of the interaction between genetics, metabolism, nutrition, and disease susceptibility to develop dietary recommendations and individualized therapy regimens. This laboratory directly benefits public health by enabling enhanced and more efficient regulatory laboratory operations and providing the necessary environment to develop regulatory tools that facilitate premarket review, postmarket safety assurance, and rapid detection of food contamination.

Repairs and improvement projects planned for FY 2012 at the Muirkirk Road Complex (MRC) include:

- replacing pneumatic mechanical system controls with direct digital controls in multiple buildings and tying them to a single building system
- replacing the atrium glass in MOD1 that chronically leaks, repairing large portions of the asphalt roads and parking lots
- installing more efficient control valves in laboratory research areas to improve safety
- correcting various structural, life safety, lighting, HVAC and electrical deficiencies in multiple buildings.

The MRC provides laboratory support to assure the safety of animal food, animal-derived food and the safety and efficacy of animal health products. Maintenance repairs and improvements allow the facility to accommodate state of the art instrumentation and the laboratory processes currently required to apply quick, innovative, and decisive science to animal health and food safety problems to better protect public health. Repairs to the facility enable CVM scientists to meet the current and anticipated demand for applied research to support the regulatory needs of FDA.

B&F funding will be used at FDA's Irvine, CA site in FY 2012 for site infrastructure improvements to include:

- repairing a cracked walkway
- modifying the site security entrance
- resealing the parking lot
- modifying the slope at the loading dock to ensure water drains away from the building.

This site provides analytical laboratory support to ORA's regulatory mission in the Pacific Region and houses the Los Angeles District Office, which supports ORA's inspection and compliance activity in the Los Angeles area. Existing microbiological media preparation capabilities severely restrict timely FDA public health response in regulatory and analytical testing operations. B&F projects at this site will recommission the building to ensure that major systems are functioning as designed.

Improvements planned for the main laboratory at the Winchester, MA site include:

- upgrading the fire alarm and emergency lighting systems
- replacing exit signs, replacing HVAC equipment and controls
- painting, cleaning ductwork and testing and balancing the building
- upgrading the building management system,
- installing a fire suppression system in the ashing room.

FDA also plans to upgrade exterior lighting at the site. This site provides specialized analytical services in engineering and medical devices and is the only field laboratory providing radiation analyses for both the foods and medical products programs. The site supports comprehensive evaluation of medical devices and radiation emitting appliances and recently played a critical role regarding polonium testing in beef. It is the primary field laboratory that FDA's Center for Device and Radiological Health (CDRH) relies on for analytical services and temperature-critical laboratory testing.

FDA plans to improve the main laboratory at the San Juan, PR site by replacing chemical fume hoods and modifying or replacing entrance ramps. Improvements to various other buildings on the site include installing new handrails for Americans with Disabilities Act compliance, replacing exterior doors, and repairing various electrical deficiencies. This facility is the National Servicing Laboratory in PR and specializes in pharmaceutical testing and analyses. It is strategically located since Puerto Rico has a large concentration of pharmaceutical manufacturers that produce approximately 30 percent of the world's pharmaceuticals and about 60 percent of the human drugs consumed in the U.S. These renovations are essential to the infrastructure of this mission critical laboratory and necessary to ensure continued optimal laboratory functionality.

FDA will complete critical site infrastructure improvements at the Dauphin Island, AL site in FY 2012 including:

- installing an emergency domestic water storage tank and pumps
- improving electrical distribution from the site transformer to existing buildings

- replacing the hazardous waste storage building.

Projects planned for the main laboratory building include replacing worn fuel feed pumps and improving the HVAC system to support IT equipment. The Gulf Coast Seafood Laboratory located at this site is CFSAN's sole marine laboratory. Scientific staff at this location represents 80 percent of FDA research capacity for addressing seafood issues. B&F projects planned at this facility support work on existing, emerging, and potential seafood safety issues, including continuing recovery efforts and research related to the 2010 Deepwater Horizon oil spill.

The following table provides an allocation plan by site for use of the FY 2012 funds.

FY 2012 Buildings and Facilities Allocation Plan

Site/Initiative	Total
Jefferson Laboratories Complex (NCTR & ARL) - Jefferson, AR	\$6,900,000
Muirkirk Road Complex (MOD I, MOD II, BRF) – Laurel, MD	\$4,982,000
ORA Pacific Regional Laboratory SW – Irvine, CA	\$150,000
Winchester Engineering and Analytical Center – Winchester, MA	\$446,000
San Juan District Office – San Juan, PR	\$272,000
CFSAN Gulf Coast Seafood Laboratory	\$305,000
B&F PROJECT TOTAL	\$13,055,000

FDA's B&F Program funding for FY 2012 will continue to make meeting mission requirements and sustaining and improving the condition of owned real property assets a priority. Completion of these projects enhances FDA's ability to achieve its critical mission of protecting and promoting the health of the American public. In addition, several of these projects will contribute to HHS sustainability goals established in the HHS Strategic Sustainability Plan developed in accordance with Executive Order 13514, "Federal Leadership in Environmental, Energy and Economic Performance." More specifically, FDA's planned FY 2012 projects to replace aged, inefficient HVAC and electrical equipment at several locations; to replace a boiler that services the entire Jefferson Laboratories Complex; and to replace windows and atrium glass at the MOD I facility will help reduce Scope 1 and 3 greenhouse gas emissions.

Buildings and Facilities Program Activity Data¹

Facility	Average FCI Score		
	FY 2010 Actual	FY 2011 Estimate	FY 2012 Estimate
Gulf Coast Seafood Laboratory ²	92	95	97
Jefferson Laboratory Complex ³	81	83	84
Muirkirk Road Complex ⁴	86	89	90
Pacific Regional Laboratory Southwest ⁵	100	100	100
San Juan District Office and Laboratories ⁶	83	84	85
Winchester Engineering and Analytic Center ⁷	70	73	76

¹The Backlog of Maintenance and Repairs (BMAR) at each site is significant. Funding is allocated to projects at each site in an effort to reduce the BMAR and improve the average Facility Condition Index (FCI) for the site. Without ongoing repair and improvement projects, the increase in BMAR each year would result in no change or a decrease in the FCI rather than an increase.

²Based on funding levels in FY2011 and FY2012, the remaining BMAR for this site, approximately \$80K, will be eliminated. Surplus of approximately \$296K will be used for sustainment improvements and other mission related projects.

³Based on funding levels in FY2011 and FY2012 the BMAR for this site will decrease by approximately \$8.4M. Remaining BMAR total will be approximately \$57.5M.

⁴Based on funding levels in FY2011 and FY2012, the BMAR for this site will decrease by approximately \$4.9M. Remaining BMAR total will be approximately \$10.6M.

⁵Based on funding levels in FY2011 and FY2012, the remaining BMAR for this site, approximately \$66K, will be eliminated. Surplus of approximately \$564K will be used for sustainment improvements and other mission related projects as well as to subsidize a Utility Energy Service Contract (UESC) to help meet presidential mandates, executive orders and energy efficiency statutes.

⁶Based on funding levels in FY2011 and FY2012, the BMAR for this site will decrease by approximately \$268K. Remaining BMAR total will be approximately \$2.5M.

⁷Based on funding levels in FY2011 and FY2012, the BMAR for this site will decrease by approximately \$853K. Remaining BMAR total will be approximately \$3.4M.