



AT A GLANCE



April 2017

FDA-REGULATED PRODUCTS AND FACILITIES

- FDA is responsible for the oversight of more than \$2.4 trillion in consumption of medical products, food and tobacco.
- FDA-regulated products account for about 20 cents of every dollar of annual spending by U.S. consumers.
- FDA regulates about 75 percent of the U.S. food supply. This includes everything we eat except for meat, poultry, and some egg products.
- There are over 17,000 prescription drug products approved for marketing.
- FDA has oversight of at least 6,000 different medical device product categories.
- There are at least 1,600 FDA-approved animal drug products.
- There are approximately 320 FDA-licensed biologics products.
- FDA has oversight of more than 4,500 tobacco products.
- There are about 35,000 produce farms, 300,000 restaurant chain establishments, and 10,500 vending machine operators covered under FDA regulations.

Facilities Registered with FDA

Program	Domestic	Foreign	Total
Animal Drugs	1,448	393	1,841
Animal Food	16,921	7,935	24,856
Biologics	6,110	621	6,731
Human Drugs	3,049	3,679	6,728
Human Food	86,171	127,798	213,969
Medical Devices	13,062	10,684	23,746
Tobacco	92	0	92
Total	126,853	151,110	277,963

- FDA-regulated products now account for approximately 11 percent of all U.S. imports.
- FDA-regulated products account for 15 percent of all U.S. exports.

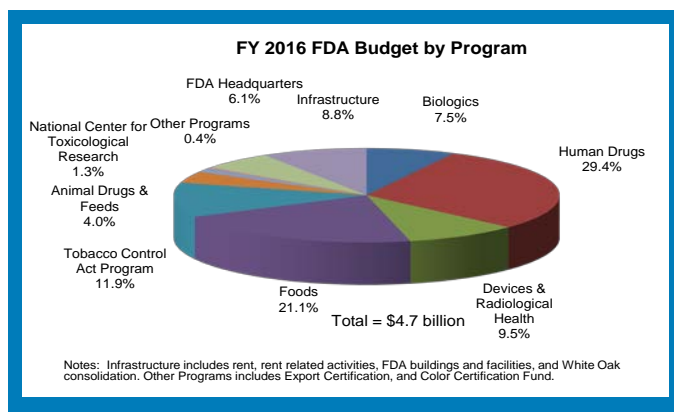
U.S. Imports and Exports by FDA Program

Program	Imports (\$Billions)	Exports (\$Billions)
Animal Food	\$2.43	\$4.76
Biologics	\$17.02	\$17.67
Human and Animal Drugs	\$70.49	\$34.92
Human Food	\$94.90	\$103.16
Medical Devices	\$52.74	\$55.24
Tobacco	\$1.33	\$0.92
FDA Total	\$238.91	\$216.67
USA Total	\$2,248.23	\$1,502.57

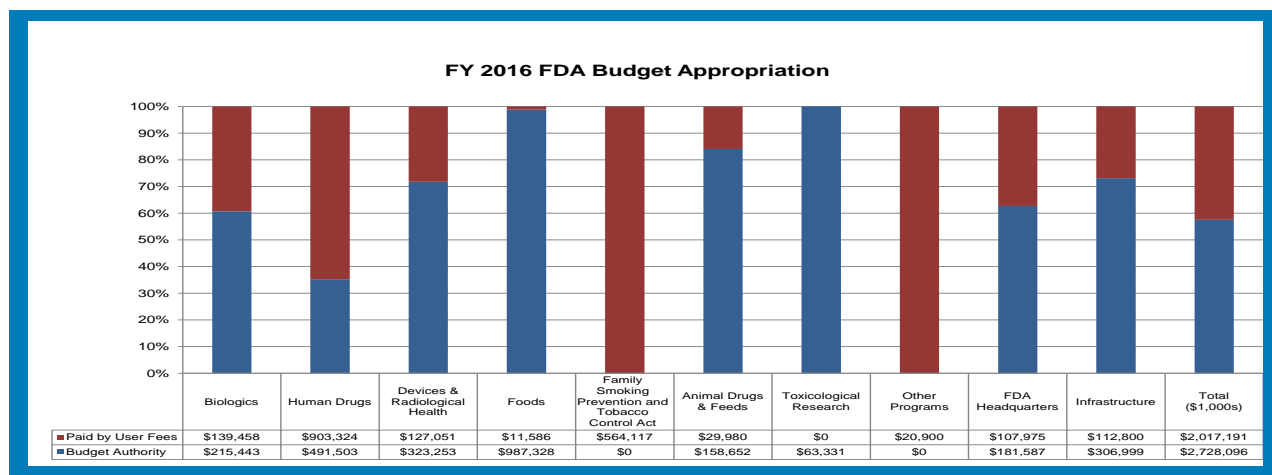
- FDA products are manufactured or handled at nearly 300,000 registered facilities, more than half of which are overseas.
- Approximately 80 percent of active pharmaceutical ingredients manufacturers are located outside of the U.S.
- Based on dollar values, about 55 percent of biologics are imported.
- Other countries now supply 51 percent of fresh fruit, 28 percent of vegetables, and at least 95 percent of seafood consumption by volume in the U.S.
- Based on dollar values, at least 30 percent of all medical devices used in this country are imported.
- Based on dollar values, nearly 4 percent of animal product consumption is imported.
- Based on dollar values, nearly 3 percent of U.S. tobacco consumption is imported.

FDA PROGRAM FUNDING

- The FDA budget of \$4.7 billion for FY 2016 includes 16,205 full time equivalents (FTEs).
- Approximately 42.5 percent, or \$2 billion, of FDA’s budget is paid for by industry user fees. The remainder is provided by appropriations from the general fund of the Treasury.
- The budgeted amount set aside for FDA is \$8.49 per American per year.



- The Tobacco Control Act Program is paid for entirely by industry user fees.
- Human Drugs regulatory activities account for 29 percent of FDA’s budget; 65 percent of these activities are paid for by industry user fees.
- Regulatory activities associated with Devices & Radiological Health account for 9.5 percent of FDA’s budget; 28 percent of this share is paid for by industry user fees.
- Regulatory activities associated with Foods account for 21 percent of FDA’s budget; 1 percent of this share is paid for by industry user fees.
- Regulatory activities associated with Biologics account for 7.5 percent of FDA’s budget; 39 percent of this share is paid for by industry user fees.
- Animal Drugs and Feeds regulatory activities account for 4 percent of FDA’s budget; 16 percent of these activities are paid for by industry user fees.



The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by ensuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, and products that give off electronic radiation, and for regulating tobacco products.