



REGULATED PRODUCTS AND FACILITIES

- FDA is responsible for the oversight of more than \$2.5 trillion in consumption of food, medical products, and tobacco.
- FDA-regulated products account for about 20 cents of every dollar spent 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 19,000 prescription drug products approved for marketing.
- FDA oversees over 6,000 different medical device product categories.
- There are over 1,600 FDA-approved animal drug products.
- There are about 340 FDA-licensed biologics products.
- FDA oversees over 85,000 tobacco products, not including e-liquids. The estimated number of regulated products is continually assessed for accuracy and reliability.

- FDA regulations cover about 35,000 produce farms, 300,000 restaurant chain establishments, and 10,500 vending machine operators.
- FDA products are manufactured or handled at nearly 270,000 registered facilities, more than half of which are overseas.
- About 80 percent of active pharmaceutical ingredients manufacturers are located outside of the U.S.
- FDA-regulated products account for 12 percent of U.S. imports and 16 percent of U.S. exports.

U.S. Imports and Exports by FDA Program

Program	Imports (\$Billions)	Exports (\$Billions)
Animal Food	\$2.43	\$4.76
Biologics	\$16.92	\$17.66
Human and Animal Drugs	\$75.63	\$34.74
Human Food and Cosmetics	\$124.48	\$120.37
Medical Devices	\$52.60	\$55.24
Tobacco	\$1.33	\$0.92
FDA Total	\$273.39	\$233.69
USA Total	\$2,248.18	\$1,503.10

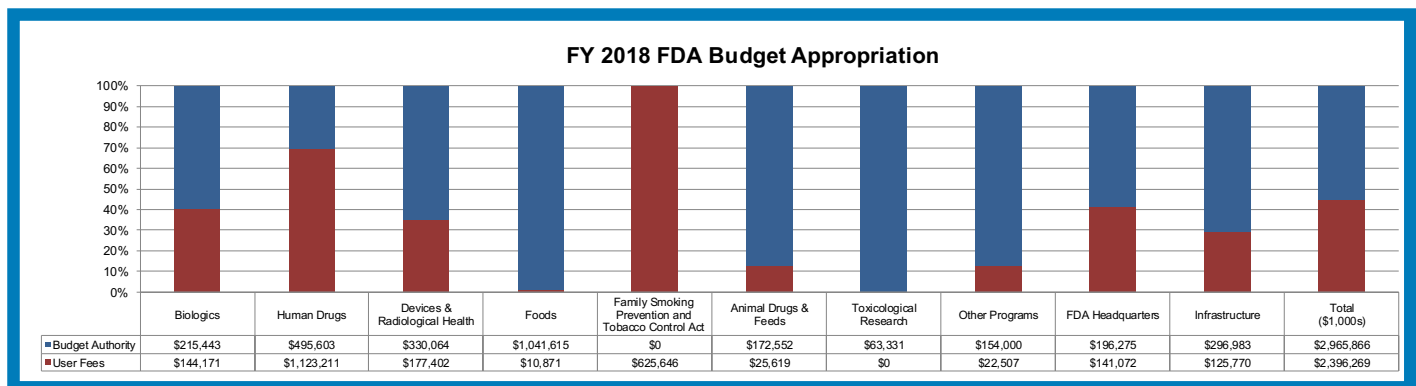
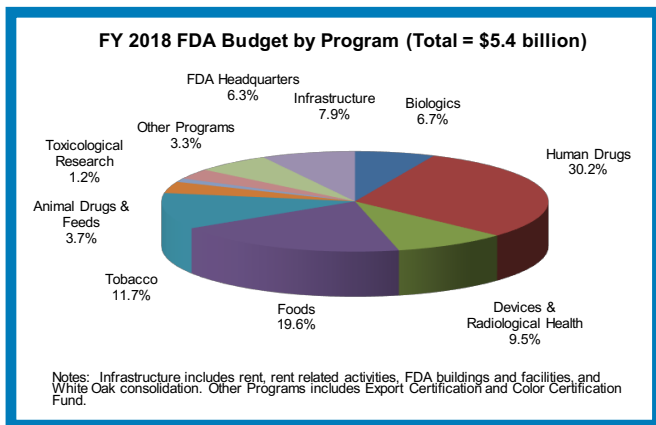
FDA-Registered Facilities

Program	Domestic	Foreign	Total
Animal Drugs	1,403	385	1,788
Animal Food	17,941	6,636	24,577
Biologics	6,336	660	6,996
Human Drugs	3,204	7,147	10,351
Human Food	84,838	108,539	193,377
Medical Devices	13,790	13,110	26,900
Tobacco	3,039	0	3,039
Total	130,551	136,477	267,028

- About 64 percent of biologics sales are imports.
- About 53 percent of fresh fruit, 29 percent of vegetables, and 93 percent of seafood consumption by volume are imports.
- About 35 percent of medical devices used in this country are imports.
- About 4 percent of animal product sales are imports.
- About 3 percent of tobacco product sales are imports.

PROGRAM FUNDING

- The FDA budget for FY 2018 is \$5.4 billion.
- About 55 percent, or \$3 billion, of FDA’s budget is provided by federal budget authorization. The remaining 45 percent, or \$2.4 billion, is paid for by industry user fees.
- The FDA budget is equivalent to \$9.11 per American per year.
- The FDA budget includes 17,803 full time equivalents (FTEs).
- The Tobacco Control Act Program is paid for entirely by industry user fees.
- Human Drugs regulatory activities account for 30 percent of FDA’s budget; 69 percent of these activities are paid for by industry user fees.
- Devices and Radiological Health regulatory activities account for 10 percent of FDA’s budget; 35 percent of these activities are paid for by industry user fees.
- Foods regulatory activities account for 20 percent of FDA’s budget; 1 percent of these activities are paid for by industry user fees.
- Biologics regulatory activities account for 7 percent of FDA’s budget; 40 percent of these activities are paid for by industry user fees.
- Animal Drugs and Feeds regulatory activities account for 4 percent of FDA’s budget; 13 percent of these activities are paid for by industry user fees.
- Excluding tobacco user fees, federal budget authorization funds about 63 percent of FDA’s budget. The remaining 37 percent is paid for by industry user fees.



FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring 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.