

REGULATED PRODUCTS AND FACILITIES

- FDA is responsible for the oversight of more than \$2.8 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 78 percent of the U.S. food supply. This includes everything we eat except for meat, poultry, and some egg products.
- There are over 20,000 prescription drug products approved for marketing.
- FDA oversees over 6,500 different medical device product categories.
- There are about 1,600 FDA-approved animal drug products.
- There are about 300 FDA-licensed biologics products.
- FDA oversees over 90,000 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 food 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 outside the U.S.
- About 80 percent of active pharmaceutical ingredient manufacturers are located outside of the U.S.
- FDA-regulated products account for 14 percent of U.S. imports and 15 percent of exports.

U.S. Imports and Exports by FDA Program

| Program | Imports (Billions) | Exports (Billions) |
|------------------------|--------------------|--------------------|
| Animal Food | \$2.79 | \$5.49 |
| Biologics | \$42.70 | \$25.41 |
| Human & Animal Drugs | \$93.67 | \$31.64 |
| Human Food & Cosmetics | \$147.00 | \$120.77 |
| Medical Devices | \$68.12 | \$58.72 |
| Tobacco | \$1.58 | \$1.05 |
| FDA Total | \$355.86 | \$243.08 |
| USA Total | \$2,497.53 | \$1,643.16 |

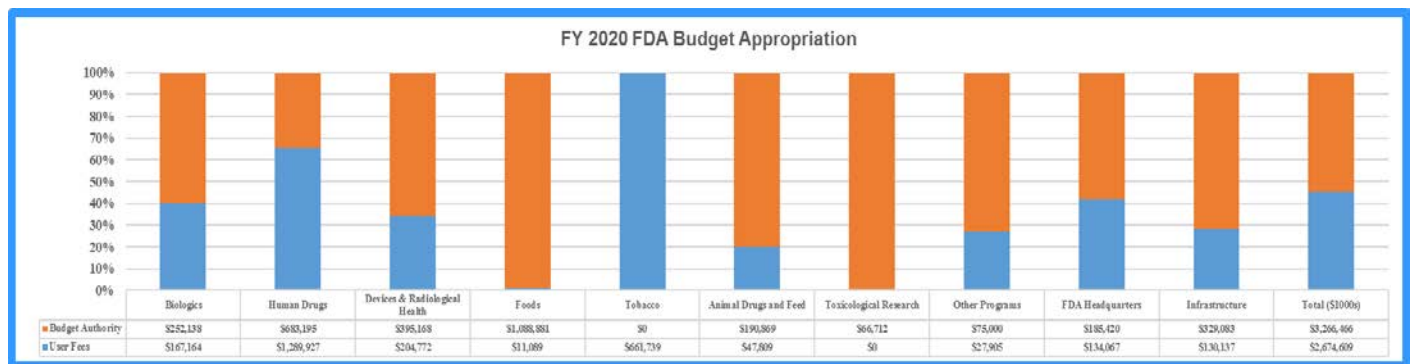
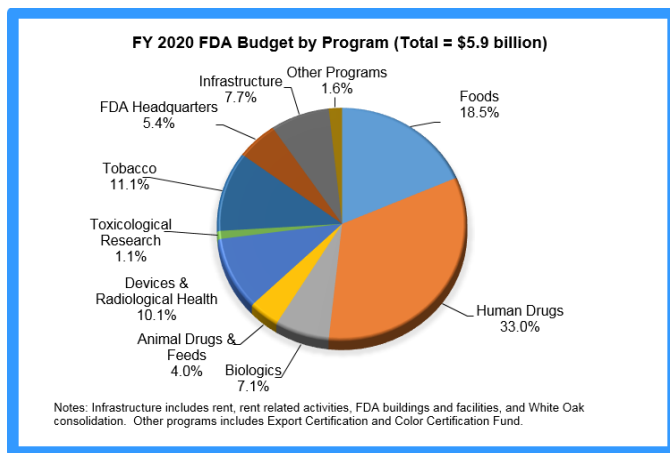
- About 87 percent of biologics sales are imports.
- About 57 percent of fresh fruit, 31 percent of vegetables, and 93 percent of seafood consumption by volume are imports.
- About 39 percent of medical devices used in this country are imports.
- About 5 percent of animal product sales are imports.
- About 3 percent of tobacco product sales are imports.

FDA-Registered Facilities

| Program | Domestic | Foreign | Total |
|-----------------|----------------|----------------|----------------|
| Animal Drugs | 1,608 | 1,156 | 2,764 |
| Animal Food | 40,826 | 25,023 | 65,849 |
| Biologics | 5,112 | 467 | 5,579 |
| Human Drugs | 3,568 | 3,970 | 7,538 |
| Human Food | 90,646 | 131,844 | 222,490 |
| Medical Devices | 13,010 | 12,854 | 25,864 |
| Tobacco | 3,067 | 0 | 3,067 |
| Total | 157,837 | 175,314 | 333,151 |

PROGRAM FUNDING

- FDA’s budget for Fiscal Year 2020 is \$5.9 billion.
- About 55 percent, or \$3.2 billion, of FDA’s budget is provided by federal budget authorization. The remaining 45 percent, or \$2.7 billion, is paid for by industry user fees.
- The FDA budget is equivalent to \$9.95 per American per year.
- The FDA budget includes 17,686 full time equivalents (FTEs).
- The Tobacco Control Act Program is paid for entirely by industry user fees.
- Human Drugs regulatory activities account for 33 percent of FDA’s budget; 65 percent of these activities are paid for by industry user fees.
- Devices & Radiological Health regulatory activities account for 10 percent of FDA’s budget; 34 percent of these activities are paid for by industry user fees.
- Foods regulatory activities account for about 19 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; 20 percent of these activities are paid for by industry user fees.
- Excluding tobacco user fees, federal budget authorization funds about 62 percent of FDA’s budget. The remaining 38 percent is paid for by industry user fees.



For more information, please contact Economics@fda.hhs.gov.

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.