

November 2021

## REGULATED PRODUCTS AND FACILITIES

- FDA is responsible for the oversight of more than \$2.7 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 6,700 different medical device product categories.
- There are about 1,600 FDA-approved animal drug products.
- There are about 621 FDA-licensed biologics products.
- FDA oversees over 100,000 tobacco products, not including ENDS products.

### FDA-Registered Facilities

Program	Domestic	Foreign	Total
Animal Drugs	1,858	1,103	2,961
Animal Food	17,523	7,394	24,917
Biologics	4,944	556	5,500
Human Drugs	6,799	6,318	13,117
Human Food	81,588	116,344	197,932
Medical Devices	13,010	12,891	25,901
Tobacco	2,391	0	2,391
<b>Total</b>	<b>128,113</b>	<b>144,606</b>	<b>272,719</b>

- 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 275,000 registered facilities, more than half of which are outside the U.S.
- About 78 percent of active pharmaceutical ingredient manufacturers are located outside of the U.S.
- FDA-regulated products account for 15 percent of U.S. imports and 15 percent of exports.

### U.S. Imports and Exports by FDA Program

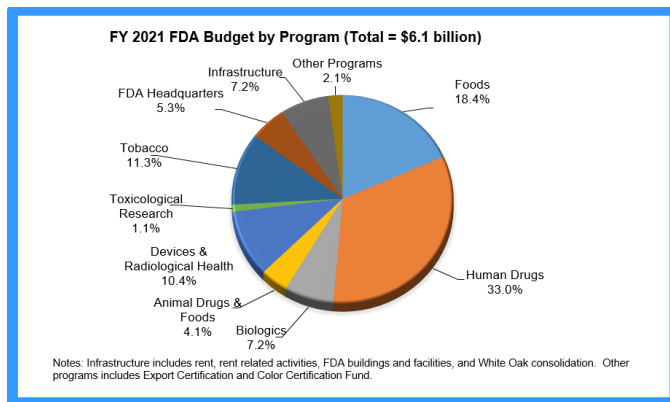
Program	Imports (Billions)	Exports (Billions)
Animal Food	\$2.79	\$5.49
Biologics	\$42.73	\$25.42
Human & Animal Drugs	\$93.62	\$31.67
Human Food & Cosmetics	\$158.90	\$122.90
Medical Devices	\$68.01	\$58.69
Tobacco	\$1.58	\$1.05
<b>FDA Total</b>	<b>\$367.63</b>	<b>\$245.22</b>
<b>USA Total</b>	<b>\$2,493.74</b>	<b>\$1,642.82</b>

- About 84 percent of biologics sales are imports.
- About 57 percent of fresh fruit, 34 percent of vegetables, and 91 percent of seafood consumption by volume are imports.
- About 44 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.

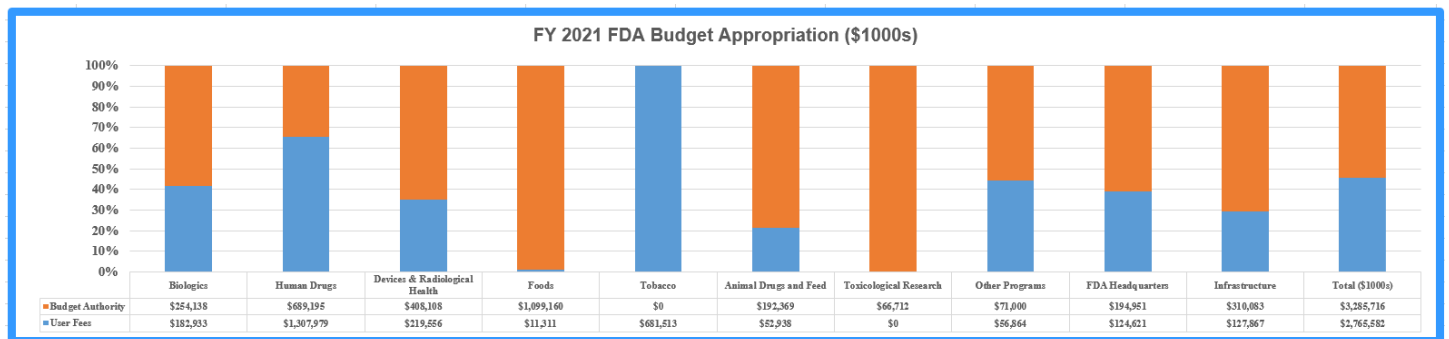
For more information, please contact the Office of Economics and Analysis at [Economics@fda.hhs.gov](mailto:Economics@fda.hhs.gov).

## PROGRAM FUNDING

- FDA's budget for Fiscal Year 2021 is \$6.1 billion.
- About 54 percent, or \$3.3 billion, of FDA's budget is provided by federal budget authorization. The remaining 46 percent, or \$2.8 billion, is paid for by industry user fees.
- The FDA budget is equivalent to \$10.01 per American per year.
- The FDA budget includes 18,062 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; 35 percent of these activities are paid for by industry user fees.
- Foods regulatory activities account for about 18 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; 42 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; 22 percent of these activities are paid for by industry user fees.
- Excluding tobacco user fees, federal budget authorization funds about 61 percent of FDA's budget. The remaining 39 percent is paid for by industry user fees.



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