

# FDA REGULATED PRODUCTS AND FACILITIES

FDA oversees the safety of more than

\$3.6 trillion

worth of food, tobacco, and medical products produced in the U.S. and abroad.







There are over 20,000 prescription drug products approved for marketing.

FDA oversees over 6,500 different medical device products.

> There are about 1,600 FDA-approved animal products.

There are about 896 FDA-licensed biologics products. About 82% of active pharmaceutical ingredient manufacturers are located outside of the U.S.

About 47% of medical devices used in the U.S. are imports.

About 8% of animal product sales are imports.

About 80% of biologics sales are imports.

FDA-regulated products are manufactured or handled at nearly 280,000 registered facilities, more than half of which are outside of the U.S.

#### **FDA-Registered Facilities**

Program	Domestic	Foreign	Total
Animal Drugs	985	720	1,705
Animal Food	17,969	8,204	26,173
Biologics	5,226	649	5,875
Human Drugs	4,577	3,843	8,420
Human Food	84,886	122,678	207,564
Medical Devices	13,010	12,891	25,901
Tobacco	1,559	0	1,559
Total	128,212	148,985	277,197



FDA-regulated products account for about **21 cents** of every dollar spent by U.S. consumers.







FDA regulates about 78%<br/>of the U.S. food supply;About 60% of fresh fruit,<br/>39% of vegetables, and 92%<br/>of seafood consumption by<br/>volume are imports.

FDA regulations cover about:

- 35,000 produce farms
- 300,000 restaurant food establishments
- 10,500 vending machine operators



FDA oversees over 100,000 tobacco products, not including ENDS.

About 4% of tobacco product sales are imports.

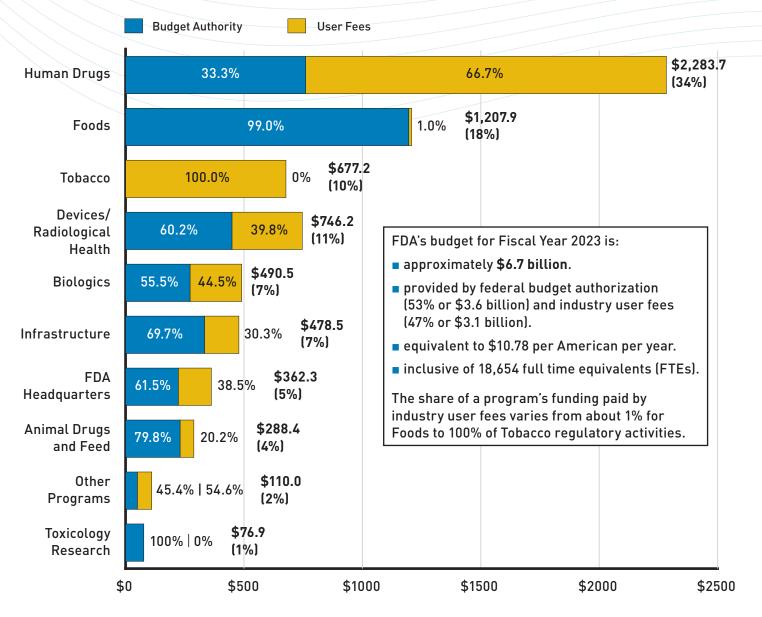
FDA-regulated products account for 14% of U.S. imports and 17% of exports.

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

Program Imp	orts (Billions)	Exports (Billions)
Animal Food	\$4.50	\$7.24
Biologics	\$46.91	\$34.85
Human & Animal Drugs	\$107.90	\$34.26
Human Food & Cosmetics	\$\$217.10	\$151.20
Medical Devices	\$83.04	\$49.27
Tobacco	\$1.82	\$0.23
FDA Total	\$461.27	\$277.05
USA Total	\$3,254.27	\$1,747.05

## FDA at a GLANCE

### **Distribution of FDA Budget by Program and Source** (millions of dollars)



Notes: Infrastructure includes rent, rent-related activities, FDA buildings and facilities, and White Oak consolidation. Other Programs includes Export Certification and Color Certification Fund.

FDA, an agency within the U.S. Department of Health and Human Services, protects public health by regulating human and veterinary drugs, vaccines and other biological products, medical devices, our nation's food supply, cosmetics, dietary supplements, electronic radiation emitting products, and tobacco products. FDA at a Glance is published annually by FDA's Office of Economics and Analysis (OEA), within the Office of Policy, Legislation, and International Affairs, Office of the Commissioner. OEA's mission is to provide public health, economic, and strategic analysis and evaluation to inform FDA's policy and rulemaking decisions.

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