FDA REGULATED PRODUCTS AND FACILITIES

FDA oversee 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

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

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

FDA regulates about 78% of the U.S. food supply, except meat, poultry, and some egg products.

About 60% of fresh fruit, 39% of vegetables, and 92% of seafood consumption by volume are imports.

FDA regulations cover about:
- 35,000 produce farms
- 300,000 restaurant food establishments

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

About 60% of fresh fruit, 39% of vegetables, and 92% of seafood consumption by volume are imports.

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

U.S. Imports and Exports by FDA Program

<table>
<thead>
<tr>
<th>Program</th>
<th>Imports (Billions)</th>
<th>Exports (Billions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal Food</td>
<td>$4.50</td>
<td>$7.24</td>
</tr>
<tr>
<td>Biologics</td>
<td>$46.91</td>
<td>$34.85</td>
</tr>
<tr>
<td>Human &amp; Animal Drugs</td>
<td>$107.90</td>
<td>$34.26</td>
</tr>
<tr>
<td>Human Food &amp; Cosmetics</td>
<td>$217.10</td>
<td>$151.20</td>
</tr>
<tr>
<td>Medical Devices</td>
<td>$83.04</td>
<td>$49.27</td>
</tr>
<tr>
<td>Tobacco</td>
<td>$1.82</td>
<td>$0.23</td>
</tr>
<tr>
<td>FDA Total</td>
<td>$461.27</td>
<td>$277.05</td>
</tr>
<tr>
<td>USA Total</td>
<td>$3,254.27</td>
<td>$1,747.05</td>
</tr>
</tbody>
</table>
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.

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

- **Human Drugs**
  - Budget Authority: 33.3%
  - User Fees: 66.7%
  - $2,283.7 (34%)

- **Foods**
  - Budget Authority: 99.0%
  - User Fees: 1.0%
  - $1,207.9 (18%)

- **Tobacco**
  - Budget Authority: 0%
  - User Fees: 100.0%
  - $677.2 (10%)

- **Devices/Radiological Health**
  - Budget Authority: 60.2%
  - User Fees: 39.8%
  - $746.2 (11%)

- **Biologics**
  - Budget Authority: 55.5%
  - User Fees: 44.5%
  - $490.5 (7%)

- **Infrastructure**
  - Budget Authority: 69.7%
  - User Fees: 30.3%
  - $478.5 (7%)

- **FDA Headquarters**
  - Budget Authority: 61.5%
  - User Fees: 38.5%
  - $362.3 (5%)

- **Animal Drugs and Feed**
  - Budget Authority: 79.8%
  - User Fees: 20.2%
  - $288.4 (4%)

- **Other Programs**
  - Budget Authority: 45.4%
  - User Fees: 54.6%
  - $110.0 (2%)

- **Toxicology Research**
  - Budget Authority: 100%
  - User Fees: 0%
  - $76.9 (1%)

**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’s budget for Fiscal Year 2023 is:
- Approximately $6.7 billion.
- Provided by federal budget authorization (53% or $3.6 billion) and industry user fees (47% or $3.1 billion).
- Equivalent to $10.78 per American per year.
- Inclusive of 18,654 full time equivalents (FTEs).

The share of a program’s funding paid by industry user fees varies from about 1% for Foods to 100% of Tobacco regulatory activities.