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The following slides were presented during the educational portion of IFFGD's 2020 Virtual Advocacy Event. To view this presentation and the all videos available during this program, please visit https://bit.ly/Adv_Edu.

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Overview of the FDA

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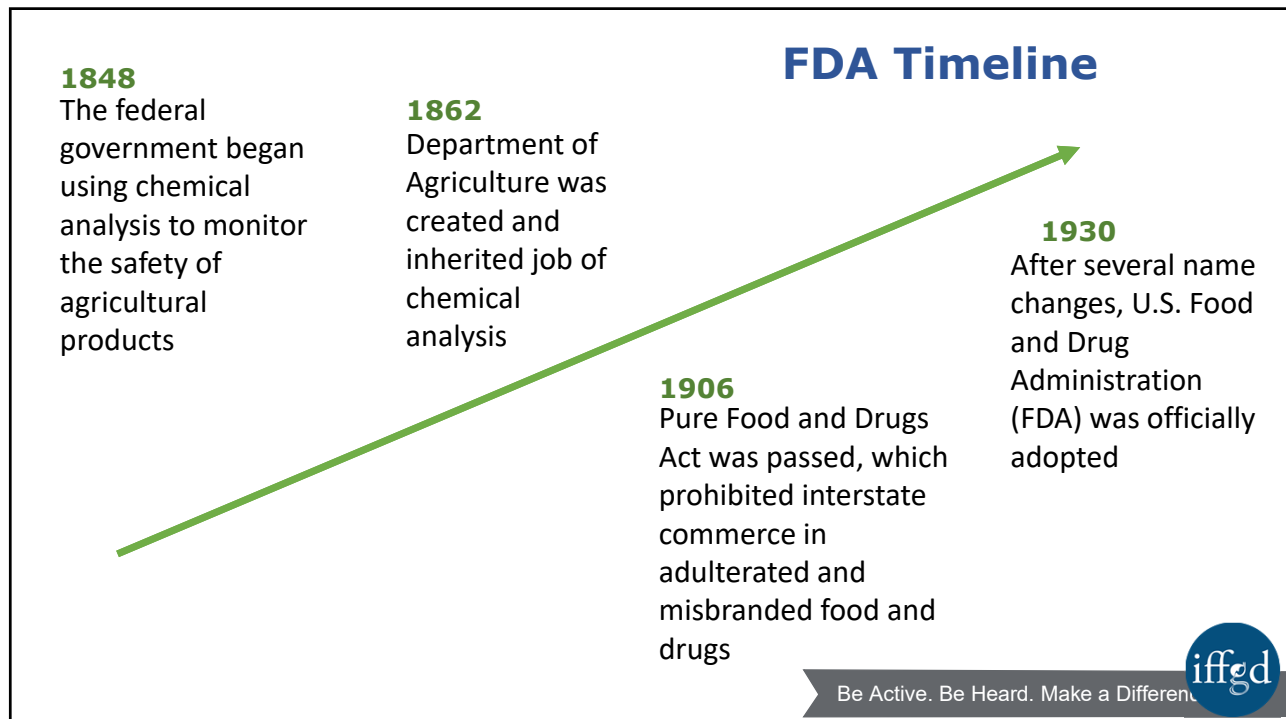
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U.S. FOOD & DRUG ADMINISTRATION

- The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.
- FDA is responsible for advancing the public health by helping to execute innovations that make medical products more effective, safer, and affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.

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What does FDA do?

- Protect the public health by assuring that foods are safe, wholesome, sanitary and properly labeled; ensuring that human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective
- Protect the public from electronic product radiation
- Assure cosmetics and dietary supplements are safe and properly labeled
- Regulate tobacco products
- Advance the public health by helping to speed product innovations

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FDA is an agency within the Department of Health and Human Services and consists of nine Center-level organizations and thirteen Headquarter (HQ) Offices.

- Center for Biologics Evaluation and Research
- Center for Devices and Radiological Health
- Center for Drug Evaluation and Research
- Center for Food Safety and Applied Nutrition
- Center for Tobacco Products
- Center for Veterinary Medicine
- National Center for Toxicological Research
- Office of Regulatory Affairs
- Office of Operations

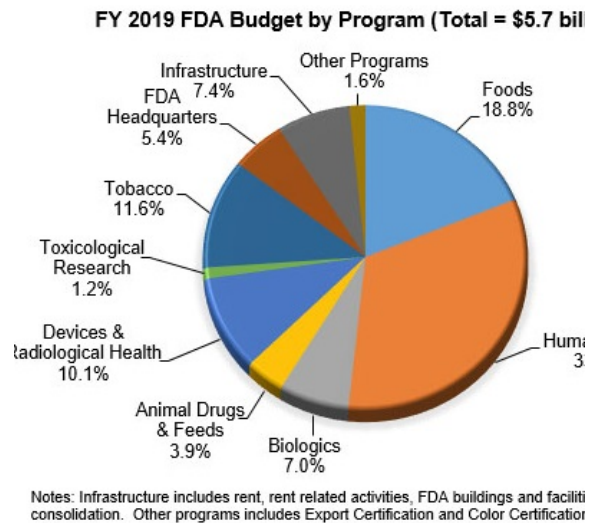
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FDA Funding

- About 55 percent, or \$3.1 billion, of FDA's budget is provided by federal budget authorization. The remaining 45 percent, or \$2.6 billion, is paid for by industry user fees.
- The Tobacco Control Act Program is paid for entirely by industry user fees.



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What does FDA regulate?



Foods, including:

- dietary supplements
- bottled water
- food additives
- infant formulas
- other food products



Drugs, including:

- prescription drugs (both brand-name and generic)
- non-prescription (over-the-counter) drugs

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FDA also regulates

Biologics, including:

- vaccines for humans
- blood and blood products
- cellular and gene therapy products
- tissue and tissue products
- allergenics



Medical Devices, including:

- simple items like tongue depressors and bedpans
- complex technologies such as heart pacemakers
- dental devices
- surgical implants and prosthetics



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And the FDA also regulates

Electronic Products that give off radiation, including:

- microwave ovens
- x-ray equipment
- laser products
- ultrasonic therapy equipment
- mercury vapor lamps
- sunlamps



Cosmetics, including:

- color additives found in makeup and other personal care products
- skin moisturizers and cleansers
- nail polish and perfume



Veterinary Products, including:

- livestock feeds
- pet foods
- veterinary drugs and devices

Tobacco Products, including:

- cigarettes
- cigarette tobacco
- roll-your-own tobacco
- smokeless tobacco



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However, it does not regulate

- Advertising
- Alcohol
- Consumer Products
- Drugs of Abuse
- Meat and Poultry
- Pesticides
- Vaccines for Animal Diseases
- Water

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FDA REGULATION AT A GLANCE: HUMAN PRODUCTS



More than
20,000
prescription
drug products



At least 6,500
medical
device
product
categories



More than
85,000
tobacco
products



Approximately
400 licensed
biologics



About
190,000
registered
facilities for
human foods

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FDA-REGULATED PRODUCTS ACCOUNT
FOR ABOUT **20 CENTS** OF EVERY DOLLAR
SPENT BY U.S. CONSUMERS.

40¢

60¢

80¢

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Frequent Misconceptions about the Drug Approval Process

- The FDA chooses what disease state a drug is used for
 - Actually the company that owns the drug decides this before it applies with the FDA to begin their research studies (see Lifecycle of a Drug – Part 1)
- The FDA is in charge of the research
 - The FDA oversees the process and ensures safety measures are being taken and the research is done well. They have no control on the actual research
- The FDA determines prices for drugs and insurance coverage
 - Drug pricing and insurance is handled outside of the FDA (see Lifecycle of a Drug – Part 2)
- If enrolled in a clinical trial that ends, the FDA will not allow me to continue getting the medication until the drug is approved
 - Participants can apply for Post Trial Access to medication with the help of their health care professional. The final decision to provide the medication; however, is left to the company providing it.

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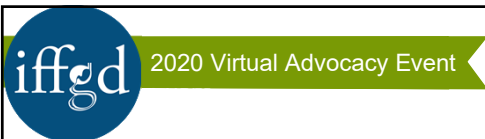
Frequent Misconceptions about the Drug Approval Process

- Doctors can only prescribe a drug for a medical indication that has been approved by FDA.
 - Actually, doctors can prescribe a drug for an individual patient for any medical problem as long as they believe it might help the patient. Unfortunately, insurance does not have to pay for the drug if it is written “off label”
- FDA seeks physician/researcher input but often they have conflicts of interest.
- The FDA’s decisions on research studies and approvals are influenced by Pharma money and size
 - The FDA looks at each application individually and looks to bring the best products to the market. The process for drug approval is the same for all companies.

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Did you know??

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Did you know??

*FDA is responsible for the oversight of more than **\$2.6 trillion** in consumption of food, medical products, and tobacco.*

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Did you know??

*FDA regulates about **77 percent** of the U.S. food supply.*

This includes everything we eat except for meat, poultry, and some egg products.

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Did you know??

*FDA regulations cover about **35,000** produce farms, **300,000** restaurant chain establishments, and **10,500** vending machine operators.*

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Did you know??

*FDA products are manufactured or handled at nearly **270,000 registered facilities**, more than half of which are overseas.*

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Did you know??

*In the US, about **53 percent** of fresh fruit, **29 percent** of vegetables, and **93 percent** of seafood consumption by volume are imports.*

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Did you know??

*The FDA budget is equivalent to **\$9.63** per American per year.*

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