ABOUT FDA: Patient Q&A

What is the FDA and what does it do?

Protecting patient and consumer health is the Food and Drug Administration's (FDA) highest priority. The FDA protects public health by enforcing laws and regulations intended to assure the safety, efficacy and security of human and animal drugs, biologics, medical devices, products that give off radiation, cosmetics and foods.

What products does the FDA regulate?

FDA regulates products many people use in their daily lives including:

- Drugs for people, including prescription and non-prescription (over-the-counter)
- Drugs for animals
- Biologics (e.g., vaccines)
- Medical devices (e.g., blood glucose monitors)
- Electronic products that give off radiation such as X-Ray machines
- Cosmetics
- Veterinary products (e.g., pet foods)
- Tobacco products

See What does FDA regulate? for more information.

Does the FDA regulate medical services, availability of medical products, pricing and health insurance?

No. The FDA does not regulate the practice of medicine, medical services, the price or availability of medical products and whether they are reimbursed by health insurance or Medicare.

How does the FDA accomplish its work?

- Reviewing drugs, devices and biological products for safety, effectiveness and quality
- Inspecting manufacturing facilities to help ensure product quality
- Conducting surveillance of products currently available on the market to mitigate risks to patients
- Promoting compliance with federal laws and taking appropriate actions when violations occur to remove dangerous products from the market and protect patients from harm

What are biological products (biologics)?

- Vaccines
- Human or animal blood and blood components
- Allergy shots
- Human or animal cells
- Gene therapy
- Human or animal tissues

What are medical devices?

- Medical devices can range from simple to complex. *Examples include:*
  - Tongue depressors and hospital gowns
  - Contact lenses and wheelchairs
  - Programmable pacemakers and robotic surgical systems

The 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.

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- Some medical tests done on human body fluids (such as blood, saliva, urine or tissue samples) are also considered medical devices.
  Examples include:
  - Pregnancy tests
  - Blood glucose monitors
- Certain electronic products that give off radiation that have a medical use or make medical claims are also considered medical devices.
  Examples include:
  - Ultrasound machines
  - X-ray machines
  - Medical lasers
- Some digital health technologies are medical devices that may collect information on how your body is functioning.
  Examples include:
  - A smart watch that monitors your heart's rhythm
  - Mobile applications that provide therapy for mood disorders

What does "FDA approved" mean?

The FDA approval of a medical product (e.g., drug, device or biologic) means the product's safety and effectiveness have been reviewed by the FDA and the product's known and potential benefits outweigh the known and potential risks. If the FDA grants an approval, it means the agency has determined the product is safe and effective for its intended use.

What does "FDA cleared" mean?

"FDA cleared" means a new medical device has been shown to be substantially equivalent to devices that are already legally marketed for the same use. Medical device manufacturers are required to submit information if they intend to introduce a device commercially for the first time or reintroduce a device that will be significantly changed to the extent that its safety or effectiveness could be affected.

Does the FDA work internationally?

Yes. The FDA inspects facilities located in other countries that manufacture products for sale in the U.S. The agency also reviews imported products for entry into the United States including food and medical products (such as drugs and devices). The FDA collaborates with international regulators to help assure safe, effective and high-quality products are available and promote information sharing to reduce risks to patients.

Does the FDA approve companies that make medical products?

No. The FDA does not approve medical product companies, health care facilities, labs or manufacturers. FDA reviews and approves medical products for intended uses.

Does the FDA develop medical products?

No. The FDA does not develop medical products or choose which disease will be the target of medical product development.

Are the FDA's decisions influenced by politics?

No. The FDA is committed to ensuring the agency's decisions are guided by sound science. The FDA uses evidence-based scientific information, confirms the reliability of the information and makes scientific decisions in an unbiased manner.

How is FDA's role different from the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC)?

See above for what the FDA does. See About CDC, and NIH mission and goals for more information about each agency.

Additional Resources

About FDA

- What does FDA do?
- What does FDA regulate?

About other public health agencies

- About CDC
- NIH mission and goals

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