FDA Regulatory Review

HEALTH CARE NUTS AND BOLTS with CHBRP

The U.S. Food and Drug Administration (FDA) is the federal agency that evaluates whether drugs and medical devices are safe and effective before they reach consumers. Its review pathways and terminology vary by product type and risk.

DRUG OR DEVICE?

Federal law defines both as products intended to diagnoses, cure, mitigate, treat, or prevent disease. The distinction between the two is how the product works.

	Pharmaceutical drug	Medical device
How it works	Chemical action in the body, or by being metabolized	Physical, mechanical, or structural means
Includes	Small-molecule drugs and biologics	Instruments, implants, and certain software
Excludes	Dietary supplements and cosmetics	Specific digital health software
Reviewed by	FDA's Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research	Center for Devices and Radiological Health

Combination products, such as prefilled syringes and drug-eluting stents, contain both pharmaceuticals and medical drugs. The FDA assigns them to a lead review center based on the primary mode of action.

REVIEW REQUIREMENTS SCALE BASED ON RISK

Drugs

Over-the-counter drugs (low risk): Follow a set of conditions for an entire drug category, with no product-specific pre-approval. Examples include aspirin, antacids, and sunscreen.

Generic drugs (moderate risk): Submit an Abbreviated New Drug Application (ANDA) to show bioequivalence to an already-approved drug. Examples include amoxicillin and metformin.

New drugs (high risk): Submit a New Drug Application (NDA) or Biologics License Application (BLA) supported by full clinical trials. Examples include new cancer therapies and vaccines.

Devices

Class I (low risk): Register the facility and list the device. Examples include bandages and manual stethoscopes.

Class II (moderate risk): Submit a 510(k) showing substantial equivalence to a legally marketed device. Examples include infusion pumps and blood pressure monitors.

Class III (high risk): Complete a premarket approval (PMA) with clinical evidence. Examples include pacemakers and heart valves.

TYPICAL FDA REVIEW TIMING



FDA REVIEW PROCESS FOR NEW DRUGS

Before marketing a new drug, its sponsor completes laboratory and animal testing. The drug is then tested in humans through three clinical trials phases. If they succeed, the sponsor submits an NDA or BLA.

Phase 1: 20 - 80 volunteers; tests safety and side effects

Phase 2: 100+ patients; tests preliminary effectiveness

Phase 3: 1,000+ patients; tests dosages, drug combinations, and varried populations

About 10-12% of drugs that enter clinical trials receive FDA approval.

FY 2027 application fees range from $28,653 for a 510(k) to about $4.6 million for a drug application with clinical data.

$1-3 billion is the typical cost of preclinical and clinical development for a new drug.

FDA TERMINOLOGY

Term	Explanation	Used?
“FDA-granted”	Novel low-to-moderate risk devices classified via the De Novo pathway	✓
“FDA-approved”	Drugs and biologics reviewed through an NDA, ANDA, or BLA; Class III devices reviewed via PMA	✓
“FDA-authorized”	Products that reached the market under an Emergency Use Authorization	✓
“FDA-cleared”	Devices that showed substantial equivalence through the 510(k) pathway	✓
“Listed”	Class I devices with a registered facility and an FDA database listing	✓
“FDA-registered”	The FDA registers facilities; registration is not an evaluation of a product	✗
“FDA-certified”	The FDA does not certify medical devices	✗
“FDA registration certificate”	The FDA does not issue these to device establishments	✗

EXPEDITED PATHWAYS

Drugs

Fast Track: More frequent FDA communication for drugs that treat serious conditions with unmet need

Priority Review: Goal shortened from 10 months to 6

Accelerated Approval: Earlier approval based on a surrogate marker (e.g., biomarker or laboratory measurement) that reliably predicts a clinical benefit

Breakthrough Therapy: Expedited process for drugs showing a clear advantage over available therapy

Devices

Breakthrough Devices: Priority review for devices addressing life-threatening or irreversibly debilitating conditions

De Novo: Classification route for novel devices with no equivalent on the market

Humanitarian Device Exemption: Route for devices for conditions affecting no more than 8,000 people in the US per year

AFTER APPROVAL

MedWatch: FDA program for reporting adverse events and product problems

Recalls: Removal or correction of a product, with most as volunatry

WANT TO LEARN MORE?

Read the full explainer at chbrp.org!

Data sources linked in the explainer.

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