# FDA Novel Drug Approvals 2026: Complete CDER Tracker

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## Executive Summary

The U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) had approved **29 novel drugs** in 2026 as of July 24, 2026, according to the agency's own running tracker, which showed "Showing 1 to 29 of 29 entries" (Source: www.fda.gov). That pace sits below the full-year totals of the prior three years: CDER approved **46 novel drugs in 2025** (Source: www.fda.gov), **50 in 2024**, and **55 in 2023**, per independent trade-press tabulation confirming that "FDA approved 55 novel drugs in 2023, 37 in 2022, and 50 in 2021" and that "in 2024, CDER approved 50 novel drugs" (Source: www.raps.org) (Source: www.raps.org), and it remains close to the agency's own long-run historical average of **38 novel drugs per year since 2007** (Source: www.fda.gov). This report draws its core approval counts, dates, indications, pathway statistics, and PDUFA measures from FDA and CDER publications. It also identifies when a claim relies on peer-reviewed research, a sponsor or company announcement, an SEC filing, or secondary news reporting; those sources are used for context or disclosed application-specific information rather than as substitutes for FDA's approval lists.

Expedited-pathway usage remains a dominant feature of CDER's approval mix. FDA defines four expedited programs—Fast Track, Breakthrough Therapy, Accelerated Approval, and Priority Review—while Orphan Drug designation is a separate rare-disease designation. In the most recently completed full year (2025), **72% of novel drug approvals used at least one of the four expedited programs**, with **46% (21 of 46) designated Priority Review** (Source: www.fda.gov). Orphan Drug designation is reported separately below. CDER also met or exceeded its PDUFA goal date for **96% (44 of 46) of its 2025 novel drug approvals**, consistent with the agency's finding that it "met or exceeded the 90-percent performance level for eight of the 10 review performance goals for FY 2023" (Source: www.fda.gov), though a separate industry analysis found on-time action rates dipped to **78% in the second half of 2025** (Source: endpoints.news), even as FDA reviewers largely held to review-timeline commitments amid 2025 staffing reductions (Source: endpoints.news).

On first-cycle approval, the picture has shifted markedly over the past two decades. A peer-reviewed 2026 analysis in *Drug Discovery Today* found that **87% of New Molecular Entities (NMEs) were approved during their first review cycle** across 2013 to 2023 (Source: doi.org), a substantial improvement over the roughly 50% first-cycle rate documented for 2000 to 2012 in JAMA (Source: jamanetwork.com) and the 54.1% rate found for NDAs from 2008 to 2017 (Source: pubmed.ncbi.nlm.nih.gov). No FDA-published aggregate first-cycle or Complete Response Letter (CRL) rate exists specifically for 2026 year-to-date; this report instead documents four named 2026 CRLs, at **Replimune** (Source: www.sec.gov), **Elevar Therapeutics** (Source: www.globenewswire.com), **Sobi** (Source: www.prnewswire.co.uk), and the **Pierre Fabre/Atara** partnership (Source: www.pierrefabrepharmaceuticals.com), each with FDA's stated rationale.

The report also profiles six named 2026 approvals in detail: **Avlayah** (Denali Therapeutics) for Hunter syndrome, which stacked Breakthrough Therapy, Fast Track, Priority Review, Orphan Drug designation, and Accelerated Approval into a single filing, detailed fully in the case studies section below; **LIPFENDRA** (Merck), described by the sponsor as "the first FDA-approved oral PCSK9 inhibitor shown to lower LDL-C" (Source: www.merck.com); **Fabhalta** (Novartis), which converted from accelerated to traditional approval on confirmatory kidney-outcomes data (Source: www.novartis.com); **REVTORPYK** (Celcuity), billed as "the first and only FDA-approved therapy that inhibits all class I PI3K isoforms" (Source: www.biospace.com); and **Loargys** (Immedica), an accelerated approval for an ultra-rare metabolic disease affecting an estimated 250 people in the United States (Source: www.immedica.com). Taken together, the data show an FDA that continues to lean heavily on expedited pathways to move novel therapies through review, a fact with direct implications for the regulatory-intelligence and AI-assisted submission strategies that life-sciences organizations are increasingly building (Source: intuitionlabs.ai).

## Introduction and Background

Tracking **FDA novel drug approvals** has become a standing exercise for regulatory affairs teams, investors, and life-sciences technology vendors alike, because CDER's annual and year-to-date tallies function as a leading indicator of innovation output, review-pathway strategy, and therapeutic-area momentum across the pharmaceutical industry. As of July 30, 2026, the question "how many new drugs has the FDA approved in 2026" has a precise, sourceable answer directly from the regulator, and this report builds its entire quantitative core from that primary source plus the agency's own annual reports, PDUFA performance data, and peer-reviewed regulatory-science studies.

FDA defines a **"novel" drug** as "a listing of new molecular entities and new therapeutic biological products approved by CDER and organized by calendar year" that excludes vaccines, allergenic products, blood and blood products, plasma derivatives, and cellular and gene therapy products, which fall under separate regulatory tracks(Source: www.fda.gov). This distinction matters for anyone benchmarking approval counts against outside figures: FDA itself cautions that classifying a drug as a **New Molecular Entity (NME)** for internal review purposes "is distinct from FDA's determination of whether a drug product is a 'new chemical entity' or 'NCE'" under separate statutory exclusivity provisions (Source: www.fda.gov).

The number of novel approvals each year is shaped heavily by how many applications qualify for FDA's four expedited programs—Breakthrough Therapy, Priority Review, Accelerated Approval, and Fast Track. This report also tracks Orphan Drug designation separately because it concerns rare diseases rather than being one of those expedited programs. Developing a single new prescription medicine that reaches the market remains, per the frequently cited Tufts Center for the Study of Drug Development analysis, an undertaking estimated at **$2,558 million** in research and development costs (Source: www.globenewswire.com), "a process often lasting longer than a decade" (Source: www.globenewswire.com), a figure the underlying peer-reviewed study derived from "a survey of 10 pharmaceutical firms" (Source: europepmc.org) covering "106 randomly selected new drugs" (Source: europepmc.org). Against that backdrop, every percentage point of first-cycle approval, every additional month shaved off PDUFA review clocks, and every expedited designation granted has outsized financial and strategic consequence for sponsors, which is why this tracker treats CDER's pathway statistics as core data rather than background color.

Regulatory affairs teams use this tracker in several distinct ways. Clinical development teams benchmark their own candidate's expected pathway against comparable recent approvals to calibrate submission timing. Investors and business-development teams watching a specific therapeutic area use the designation data to gauge how aggressively FDA is likely to expedite a pending application. Life-sciences technology vendors and consultancies building AI-assisted regulatory-intelligence tools increasingly treat CDER's published approval and designation data as a structured dataset worth monitoring continuously rather than reviewing only once a year when the annual innovation report appears. Each of these audiences needs slightly different granularity: a sponsor tracking a single competitor's application cares about exact PDUFA goal dates, while a portfolio-level analyst cares more about the aggregate designation percentages presented later in this report.

This report proceeds in four parts. It first lays out the methodology and scope FDA itself uses to define novel drug approvals, then presents the full 2026 tracker with month-by-month detail. It follows with a dedicated section on review pathways and expedited designations, a section on first-cycle approval and CRL rates, and an analysis of therapeutic-area and program-level segments. A dedicated data section, six named case studies, and a

discussion of implications for regulatory strategy (including the growing role of artificial intelligence in the review process) round out the analysis, closing with a frequently-asked-questions section addressing the specific queries regulatory professionals bring to this topic.

## Methodology and Scope of FDA Novel Drug Tracking

The report's core approval counts and pathway measures come from three FDA source types: CDER's year-by-year novel-drug approval lists; CDER's annual "Advancing Health Through Innovation" reports; and FDA's PDUFA performance reports. Other sections also cite peer-reviewed studies, sponsor or company disclosures, SEC filings, and clearly identified secondary reporting for claims those primary FDA sources do not publish. Because the 2026 annual innovation report will not be published until January 2027, this tracker's 2026 expedited-program figures (Breakthrough Therapy, Priority Review, Accelerated Approval, and Fast Track) and its separate Orphan Drug designation count are not yet available from FDA; this report is explicit about that gap rather than estimating figures FDA has not itself published.

CDER's own year-to-date list is the authoritative source for the raw 2026 count, updated continuously as the agency takes action on pending applications. Each entry on FDA's list carries the drug's brand name, active ingredient, approval date, and a short description of the approved indication, which this report uses to build the tracker table below. For historical comparison, this report also draws on FDA's archived annual lists back to 2015, several of which are only available via the Internet Archive's Wayback Machine because FDA does not permanently host every prior year's list at a stable current URL (Source: web.archive.org); those archived snapshots are cited explicitly as archive.org captures of the original FDA pages, not as independent secondary sources. One such capture confirms that CDER's 2019 cohort alone comprised 48 novel drugs (Source: web.archive.org), illustrating how far back a consistent methodology extends.

For pathway definitions, this report relies on FDA's own patient-facing explanatory pages, cited in full in the Review Pathways section below rather than paraphrased here. For first-cycle approval and CRL analysis, this report combines FDA's own regulatory text at 21 CFR 314.110 (Source: www.law.cornell.edu) and FDA's openFDA transparency database (Source: open.fda.gov) with peer-reviewed studies published in JAMA (Source: jamanetwork.com), a pharmacoepidemiology journal indexed on PubMed (Source: pubmed.ncbi.nlm.nih.gov), *Drug Discovery Today* (Source: doi.org), and *Therapeutic Innovation & Regulatory Science* (Source: link.springer.com), because no FDA-published aggregate first-cycle result is available for 2026 year-to-date. FDA's annual reports do publish annual first-cycle results, including 39 of 46 novel drugs (85%) in 2025 and 37 of 50 (74%) in 2024. Its PDUFA performance reports measure time-to-action against statutory goal dates, not first-submission approval outcomes, a distinction this report treats carefully rather than conflating the two metrics.

## Selected 2026 CDER Novel Drug Approval Profiles

CDER's 2026 novel drug approval count stood at **29** as of the agency's July 24, 2026 update, spanning therapeutic areas from rare pediatric metabolic disease to oncology to cardiometabolic disease. *Table 1* profiles ten selected approvals with confirmed dates and indications drawn directly from FDA's tracker; it is not a complete itemization of all 29 approvals.

| BRAND NAME | ACTIVE INGREDIENT | APPROVAL DATE (2026) | INDICATION |
|---|---|---|---|
| **Zycubo** | copper histidinate | January 12 | Menkes disease |
| **Adquey** | difamilast | February 12 | Mild to moderate atopic dermatitis |
| **Awiqli** | insulin icodec-abae | March 26 | Glycemic control in adults with type 2 diabetes |
| **Foundayo** | orforglipron | April 1 | Chronic weight management in adults with obesity |
| **Baxfendy** | baxdrostat | May 15 | Hypertension, combination therapy |
| **Xocova** | ensitrelvir | May 29 | Post-exposure prophylaxis of COVID-19 |
| **Ambelvist** | gadoquatrane | June 12 | MRI contrast agent for vascular lesions |
| **Trutakna** | atacicept-vymj | July 7 | Primary immunoglobulin A (IgA) nephropathy |
| **Jideytro** | zidesamtinib | July 22 | ROS1-positive non-small cell lung cancer |
| **Simtriyo** | centanafadine | July 24 | Attention-deficit hyperactivity disorder (ADHD) |

*Table 1* is compiled from FDA's own tracker (Source: www.fda.gov) and shows a deliberately broad therapeutic footprint for 2026's approvals: a rare genetic copper-metabolism disorder (Zycubo), a novel once-weekly basal insulin (Awiqli), an oral GLP-1 receptor agonist for obesity (Foundayo), and a targeted kinase inhibitor for a genomically defined lung cancer subtype (Jideytro) all cleared review within the same seven-month window. That spread is broadly consistent with CDER's own annual reporting, which in recent years has emphasized that novel approvals span a wide range of therapeutic areas rather than concentrating in one or two dominant categories. The July cluster is notable on its own: three of the ten profiled approvals, including the first-in-class ROS1 inhibitor Jideytro, landed within a three-week span, illustrating how CDER's review output can bunch even though PDUFA goal dates are set on a rolling basis rather than a fixed calendar.

## Review Pathways and Expedited Designations

FDA has four expedited programs that can facilitate development or review of drugs for serious conditions: Fast Track, Breakthrough Therapy, Accelerated Approval, and Priority Review. Orphan Drug designation is a separate designation for drugs and biologics intended for rare diseases. **Fast Track** designation "is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need" (Source: www.fda.gov). **Breakthrough Therapy** designation is "a process designed to expedite the development and review of drugs" that show substantial improvement over available therapy on a clinically significant endpoint (Source: www.fda.gov). **Priority Review** shortens FDA's statutory review clock: "FDA's goal is to take action on an application within 6 months (compared to 10 months under standard review)," a two-tiered system created in 1992 under PDUFA (Source: www.fda.gov). **Accelerated Approval**, instituted the same year, "allowed drugs for serious conditions that filled an unmet medical need to be approved based on a surrogate endpoint," where a surrogate endpoint is "a marker, a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit" without itself being a direct measure of that benefit (Source: www.fda.gov). Finally, **Orphan Drug** designation gives FDA "authority to grant orphan drug designation to a drug or biological product to prevent, diagnose or treat a rare disease" (Source: www.fda.gov) for a rare disease, defined for these purposes as one affecting fewer than 200,000 people in the United States.

*Table 2* below shows how heavily CDER's annual novel drug approvals leaned on these programs over the three most recently completed full years, with each figure drawn directly from CDER's own "Advancing Health Through Innovation" annual reports.

| YEAR | NOVEL DRUGS APPROVED | FAST TRACK | BREAKTHROUGH THERAPY | PRIORITY REVIEW | ACCELERATED APPROVAL | ORPHAN DRUG | USED ≥1 FDA EXPEDITED PROGRAM (EXCLUDES ORPHAN DRUG) |
|---|---|---|---|---|---|---|---|
| **2023** | 55 | 25 (45%) | 9 (16%) | 31 (56%) | 9 (16%) | 28 (51%) | 36 (65%) |
| **2024** | 50 | 22 (44%) | 18 (36%) | 28 (56%) | 7 (14%) | 26 (52%) | 33 (66%) |
| **2025** | 46 | 18 (39%) | 15 (33%) | 21 (46%) | 11 (24%) | 23 (50%) | 33 (72%) |

*Table 2* sources: 2023 figures, including that "CDER identified 9 of the 55 novel drugs (16%) approved in 2023 as Breakthrough Therapies" and that "Thirty-six of the 55 novel drug approvals of 2023 (65%) used one or more expedited pro[grams]" (Source: www.fda.gov); 2024 figures, including that "CDER granted fast track status to 22 of the 50 novel drugs (44%) in 2024," that 26 of 50 approvals (52%) received orphan drug designation, and that "33 of the 50 novel drug approvals of 2024 (66%) used one or more expedited programs" (Source: www.fda.gov); 2025 figures, including that "23 of CDER's 46 novel drug approvals (50%) received orphan drug designation" and that CDER "used at least one expedited program" for 72% of the year's approvals (Source: www.fda.gov).

The three-year trend in *Table 2* shows Fast Track use declining from 45% in 2023 to 39% in 2025, while Priority Review held just above half of all novel approvals in 2023 and 2024 before easing to 46% in 2025. Breakthrough Therapy usage climbed from 16% in 2023 to 33% in 2025, more than doubling in two years. Accelerated Approval usage has also risen, from 16% in 2023 to 24% in 2025, even as the total volume of novel approvals declined from 55 to 46. The share of approvals relying on at least one expedited program rose in parallel, from 65% in 2023 to 72% in 2025, indicating that a shrinking pool of novel approvals is increasingly composed of drugs sponsors and FDA jointly agreed merited some form of accelerated handling. No equivalent 2026 breakdown exists yet: CDER's annual innovation report covering 2026 will not be published until January 2027, so this report cannot state what share of the 29 drugs approved through July 24, 2026 carried each designation, a gap this report states explicitly rather than estimating.

Breakthrough Therapy designation requests themselves are tracked cumulatively by FDA regardless of ultimate approval outcome. Since the program's inception, FDA's cumulative cohort table, dated from "July 9, 2012" (Source: www.fda.gov), shows the program has processed over a thousand requests across its history, with the fiscal-year-2025 cohort table showing the program remains active. Not every granted designation results in an approval within the same calendar year, and not every approval with a designation is captured in that year's cohort table, which is why this report treats the annual innovation-report percentages in *Table 2* as the authoritative source for designation prevalence among actual approvals, rather than the separate cumulative request-tracking tables.

## First-Cycle Approval Rates and Complete Response Letters

A **first-cycle approval** occurs when FDA approves a New Drug Application (NDA) or Biologics License Application (BLA) on its initial review cycle, without the sponsor needing to resubmit after receiving a **Complete Response Letter (CRL)**. Under 21 CFR 314.110, "FDA will send the applicant a complete response letter if the agency determines that we will not approve the application" in its current form (Source: www.law.cornell.edu), after which the sponsor may "resubmit the application or abbreviated application, addressing all deficiencies identified in the complete response letter," withdraw it, or request a hearing (Source: www.law.cornell.edu). FDA's own openFDA transparency portal maintains a public CRL database and states plainly that "FDA will send the sponsor a CRL if the agency determines that it will not approve the application in its current form" (Source: open.fda.gov), and notes that "currently, the database includes CRLs issued to sponsors as recently as 2025" (Source: open.fda.gov).

FDA does not publish a 2026 year-to-date aggregate first-cycle approval rate. Its annual reports do publish annual results: 39 of 46 novel drugs (85%) in 2025 and 37 of 50 (74%) in 2024 were approved on the first cycle. This report also relies on peer-reviewed regulatory-science research for the longer historical trend. An analysis published in JAMA covering NME applications from 2000 to 2012 found that "of the 302 identified NME applications, 151 (50%) were approved when first submitted and 222 (73.5%) were ultimately approved" (Source: jamanetwork.com). A separate peer-reviewed study of NDAs from 2008 to 2017 found that "446 (54.1%) applications received first-cycle approvals without a review extension resulting from a major amendment" (Source: pubmed.ncbi.nlm.nih.gov). Most strikingly, a 2026 analysis in *Drug Discovery Today* covering NMEs from 2013 to 2023 found that fully **"87% of New Molecular Entities (NMEs) were approved during their first review cycle"** (Source: doi.org), a figure the same

study explicitly contrasts with the earlier era, noting that "only around 50% of NMEs were approved at the first attempt, while approximately 26% never achieved approval" during 2000 to 2012 (Source: doi.org). That gap, roughly 50% first-cycle success two decades ago versus 87% more recently, represents one of the more consequential structural shifts in FDA regulatory practice, though no FDA-published figure yet exists to confirm whether the 87% rate has held through 2026 specifically.

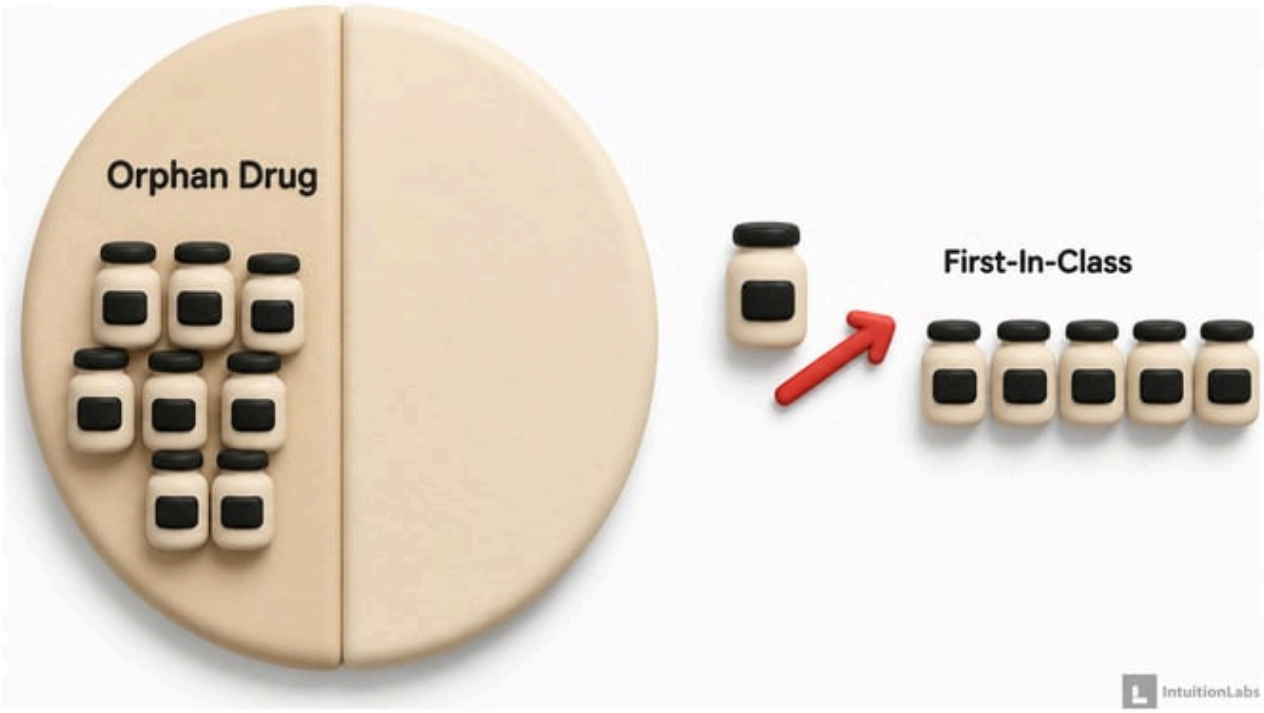
When CRLs do occur, a 2026 study in *Therapeutic Innovation & Regulatory Science* examined the underlying deficiencies for NMEs approved between 2020 and 2024 and found that "among 43 novel therapeutics with CRLs, manufacturing deficiencies were most common (65% facilities; 51% CMC)" (Source: link.springer.com). The same study found that recovery from a CRL is not fast: "median times from CRL receipt to resubmission and approval were 0.60 years (0.40 to 1.42) and 1.28 years (0.87 to 1.81)" respectively (Source: link.springer.com), meaning a rejected application typically costs a sponsor well over a year before reaching the market, if it reaches the market at all.

On review-time compliance specifically (a related but distinct metric from first-cycle approval), FDA's PDUFA performance reporting shows the agency generally hitting its self-imposed clocks. In FY2023, **Original Standard NMEs and BLAs achieved 100% on-time performance**, with "27 of 27 on time" against the 10-month standard goal (Source: www.fda.gov), while **Original Priority NMEs and BLAs hit 92% on-time performance**, with "35 of 38 on time" against the six-month priority goal (Source: www.fda.gov). As of the same report's preliminary FY2024 figures, FDA stated it was "currently meeting or exceeding the 90-percent performance level for all 10 performance goals" (Source: www.fda.gov). More recent independent analysis, however, has flagged some softening: Endpoints News, citing an RBC Capital Markets analysis, reported that in the second half of 2025, "78% of drug approvals (new and supplemental filings) got action on time," which the outlet characterized as "slightly down from the historical range of 85% to 90%" (Source: endpoints.news). The same analysis found that despite significant FDA staff reductions during 2025, "only two applications took more than a year for FDA to review, after the agency accepted them as reviewable" (Source: endpoints.news), suggesting review-timeline discipline has largely held even amid organizational disruption.

Four named CRLs from 2026 illustrate these dynamics directly. **Replimune** disclosed in an SEC filing that it "received a complete response letter (CRL) from the U.S. Food and Drug Administration (FDA) for the Company's Biologics License Application (BLA) for RP1" (Source: www.sec.gov) on April 10, 2026, the drug's second rejection; trade press reported that "Replimune's stock fell nearly 20% Friday after the FDA rejected its advanced melanoma drug for the second time" (Source: www.biospace.com). FDA's review team concluded that the data presented was "insufficient to conclude substantial evidence of effectiveness" of RP1 in unresectable advanced cutaneous melanoma (Source: www.biospace.com), and the agency's letter stated it "would not recommend" seeking approval based on results from a single-arm study (Source: www.biospace.com), despite RP1 being proposed in combination with Bristol Myers Squibb's Opdivo (Source: www.biospace.com). **Elevar Therapeutics** received a July 10, 2026 CRL for a hepatocellular carcinoma combination therapy where "the FDA's decision was related to deficiencies identified during a cGMP inspection of a manufacturing site listed on the Rivoceranib NDA" (Source: www.globenewswire.com), a manufacturing-site issue consistent with the peer-reviewed finding that facility deficiencies are the leading CRL cause. **Sobi** received a June 26, 2026 CRL for its gout therapy where the company reported that "the FDA identified no concerns regarding the clinical efficacy or safety of NASP that impact approvability" (Source: www.prnewswire.co.uk), again pointing to chemistry, manufacturing, and controls (CMC) issues rather than clinical shortfalls. Finally, **Pierre Fabre and Atara Biotherapeutics** received a second CRL in January 2026 for tabelecleucel after FDA reversed its own earlier position, stating "that it no longer considers the previously accepted single-arm ALLELE study to be adequate to support accelerated approval" (Source: www.pierrefabrepharmaceuticals.com), an unusually direct example of a regulator changing its assessment of trial-design adequacy between review cycles.

## Analysis of Key Segments

Beyond the raw approval count, CDER's 2025 annual report offers a useful lens for segmenting novel drug approvals by structural characteristics, and several of those segments carry directly into what can be observed in the 2026 tracker. **Orphan Drug designation** covered half of all 2025 novel approvals, a figure detailed in *Table 2* above. That rare-disease concentration is visible in the 2026 tracker as well: Zycubo, for Menkes disease, and Trutakna, for IgA nephropathy, both address conditions affecting small patient populations, continuing a multi-year pattern in which roughly half of all novel approvals serve rare or ultra-rare indications.




A second segment worth tracking is **first-in-class** status, meaning a drug works through a mechanism distinct from any previously approved therapy. CDER's 2025 report found that "CDER identified 20 of the 46 novel drugs approved (43%) in 2025 as first-in-class" (Source: www.fda.gov), meaning nearly half of all novel approvals introduced a genuinely new mechanism rather than an incremental improvement on existing therapy classes. Several of the case studies profiled later in this report carry first-in-class or first-and-only claims for 2026, including Merck's LIPFENDRA, described as "the first FDA-approved oral PCSK9 inhibitor shown to lower LDL-C" (Source: www.merck.com), Celcuity's REVTORPYK, described as inhibiting "all class I PI3K isoforms" simultaneously (Source: www.biospace.com), and Novartis's Fabhalta, itself considered a first-in-class complement inhibitor as detailed in the case studies section below, suggesting the trend has continued into the current year even without a confirmed percentage.

A third segment is **biosimilars**, which are tracked separately from novel drug approvals but form an increasingly important adjacent category for the same review divisions. CDER's 2025 report notes that "since 2015, CDER has approved 81 biosimilars for 20 reference products" (Source: www.fda.gov), a cumulative figure that continues to grow each year as more biologics lose exclusivity. Finally, FDA's 2025 report disclosed a new fast-lane mechanism worth watching through 2026: the **Commissioner's National Priority Voucher pilot**, under which "the agency took its first action in this new program that aims to shorten review times from 10-12 months to 1-2 months" (Source: www.fda.gov). If that pilot scales through 2026 and 2027, it could materially compress the review-time distribution this report has otherwise characterized using the decades-old Priority Review and Standard Review framework.

These segments interact with one another rather than operating independently. A drug that is both first-in-class and intended for a rare disease is statistically more likely to receive multiple simultaneous designations, since Orphan Drug status and Breakthrough Therapy designation are frequently sought together by sponsors developing therapies for small, well-defined patient populations where a strong unmet-need argument is easier to make. Conversely, drugs addressing larger, more common conditions, such as Awiqli's basal-insulin indication or Xocova's infectious-disease indication in this year's tracker, more often proceed through standard or priority review without the full designation stack that characterized Avlayah's Hunter syndrome approval. Recognizing which segment a candidate falls into early in development remains one of the more consequential judgment calls a regulatory affairs team makes, because it shapes which of FDA's four expedited programs may be relevant and whether a separate Orphan Drug designation may be appropriate.

## Data Analysis and Evidence

The clearest way to contextualize 2026's pace of novel drug approvals is against FDA's own year-by-year totals going back over a decade. *Table 3* compiles that series directly from CDER's published lists for each calendar year, with a secondary trade-press citation added for the years an independent source cross-confirmed the totals.

| YEAR | CDER NOVEL DRUG APPROVALS | SOURCE |
|---|---|---|
| **2015** | 45 | (Source: web.archive.org) |
| **2016** | 22 | (Source: web.archive.org) |
| **2017** | 46 | (Source: web.archive.org) |
| **2018** | 59 | (Source: web.archive.org) |
| **2019** | 48 | (Source: web.archive.org) |
| **2020** | 53 | (Source: web.archive.org) |
| **2021** | 50 | (Source: www.raps.org) |
| **2022** | 37 | (Source: www.raps.org) |
| **2023** | 55 | (Source: www.raps.org) |
| **2024** | 50 | (Source: www.raps.org) |
| **2025** | 46 | (Source: www.fda.gov) |
| **2026 (through July 24)** | 29 | (Source: www.fda.gov) |

*Table 3* makes clear that annual novel drug approval totals are volatile year to year rather than following a smooth trend line: the series swings from a low of 22 in 2016 (Source: web.archive.org) to a high of 59 in 2018 (Source: web.archive.org). Only four of the 10 adjacent year-pairs in the table are within five approvals of one another, reinforcing that annual totals vary materially. Averaging the full eleven complete years shown (2015 through 2025) yields roughly 46 approvals per year. Independent trade-press tabulation corroborates the FDA-sourced totals directly, confirming that "in 2024, CDER approved 50 novel drugs" (Source: www.raps.org) and that "FDA approved 55 novel drugs in 2023, 37 in 2022, and 50 in 2021" (Source: www.raps.org), figures that match FDA's own tables exactly. Annualizing the 2026 year-to-date figure is not straightforward given how unevenly approvals land within a calendar year, but a simple run-rate extrapolation from 29 approvals through the first seven months would put 2026 on pace for roughly the high 40s by year-end, a figure that would land near the middle of the eleven-year historical range rather than at either extreme, though this is this report's own extrapolation rather than an FDA projection. No discrepancies of substance were found between FDA's primary tables and the secondary trade-press confirmation, though this report treats the FDA tables themselves as authoritative in every case where the two sources might have diverged.

The volatility evident in *Table 3* has several plausible drivers beyond FDA's own operational capacity: a given year's total reflects how many sponsor applications happened to complete Phase 3 development and clear internal company review in that specific twelve-month window, a function of biotech funding cycles, clinical trial enrollment speed, and manufacturing readiness that FDA does not control. A low year like 2016's 22 approvals does not necessarily indicate a more conservative agency; it may simply reflect a thinner pipeline of applications reaching FDA's door that year. This distinction matters for anyone using annual approval counts as a proxy for regulatory stringency, since the same review standards can produce very different annual totals depending on factors entirely outside CDER's control.

## Case Studies and Real-World Examples

### Avlayah (Denali Therapeutics): Four Designations and Accelerated Approval

FDA approved **Avlayah** (tividenofusp alfa-eknm) on March 24, 2026, "to treat certain individuals with Hunter syndrome" (Source: www.fda.gov), a rare inherited disorder also known as Mucopolysaccharidosis Type II (MPS II). The approval is a rare example of a single application stacking nearly every expedited tool FDA offers: Avlayah "received breakthrough, fast track, priority review, and orphan drug designations and accelerated approval for this indication" (Source: www.fda.gov). The approval rested on a Phase 1/2 trial in pediatric patients, where "the 44 patients with measurements at Week 24 had a 91% average decrease from baseline in CSF HS" (cerebrospinal fluid heparan sulfate, a disease biomarker) (Source: www.fda.gov). Denali's own investor announcement noted that, in connection with the approval, "the FDA granted Denali Therapeutics a Rare Pediatric Disease Priority Review Voucher (PRV)" (Source: investors.denalitherapeutics.com), a transferable credit that can itself be sold or used to expedite a future, unrelated application, adding a secondary financial dimension to the approval beyond the drug's own commercial prospects.

### LIPFENDRA (Merck): The First Oral PCSK9 Inhibitor

FDA approved Merck's **LIPFENDRA** (enlicitide decanoate) on July 15, 2026, to reduce low-density lipoprotein cholesterol (Source: www.fda.gov). Merck announced that LIPFENDRA tablets 20 mg are an adjunct to diet and exercise for lowering LDL cholesterol in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (Source: www.merck.com). Merck describes the compound as "a novel macrocyclic peptide" and "the first FDA-approved oral PCSK9 inhibitor shown to lower LDL-C" (Source: www.merck.com), a distinction that matters commercially because every previously approved PCSK9 inhibitor required injection. The approval rested on "two Phase 3 trials from the CORALreef clinical program: CORALreef Lipids and CORALreef HeFH" (Source: www.merck.com). FDA states that Lipfendra received Priority Review and that the application was also reviewed under the Commissioner's National Priority Voucher pilot program.

## Fabhalta (Novartis): From Accelerated to Traditional Approval

**Fabhalta** (iptacopan) offers a case study in how CDER's expedited pathways are designed to resolve over time rather than remain permanent. On July 16, 2026, Novartis announced that FDA "has granted traditional approval for Fabhalta to slow kidney function decline in adults with primary immunoglobulin A nephropathy" (Source: www.novartis.com). Novartis describes Fabhalta, "a first-in-class complement inhibitor," as having "received approval under a priority review designation after an initial FDA accelerated approval in August 2024" (Source: www.novartis.com). In other words, the drug's original 2024 approval relied on a surrogate endpoint under Accelerated Approval, and its 2026 conversion to full, traditional approval was supported by confirmatory outcomes data showing that Fabhalta "slowed eGFR decline by 48% vs placebo over two years, demonstrating kidney function preservation" (Source: www.novartis.com). This is precisely the mechanism Accelerated Approval was designed to enable: faster initial access based on a surrogate marker, followed by verification against a clinical outcome that either confirms or withdraws that access.

## REVTORPYK (Celcuity): A First-in-Class Dual Pathway Inhibitor

FDA approved **REVTORPYK** (gedatolisib), sponsored by Celcuity, on July 14, 2026, with the company stating "today announced that the U.S. Food and Drug Administration (FDA) approved REVTORPYK (gedatolisib)" for HR-positive, HER2-negative, PIK3CA wild-type locally advanced or metastatic breast cancer (Source: www.biospace.com). Celcuity describes the drug as "the first and only FDA-approved therapy that inhibits all class I PI3K isoforms" and both mTOR complexes simultaneously (Source: www.biospace.com), a mechanism distinct from narrower PI3K-alpha-selective inhibitors already on the market. The approval was "based on positive clinical results from the PIK3CA wild-type cohort of the Phase 3 VIKTORIA-1 trial" (Source: www.biospace.com), an example of biomarker-defined cohort selection increasingly common in oncology approvals.

## Loargys (Immedica Pharma): Accelerated Approval for an Ultra-Rare Disease

FDA granted accelerated approval to **Loargys** (pegzilarginase-nbln) on February 23, 2026, with Immedica announcing "the U.S. Food and Drug Administration (FDA) has granted accelerated approval of Loargys, an arginine specific enzyme indicated for the treatment of hyperargininemia" in patients with Arginase 1 Deficiency (ARG1-D) (Source: www.immedica.com). The company describes ARG1-D as affecting "an estimated 250 people living in the U.S." (Source: www.immedica.com), making it one of the smallest patient populations addressed by any 2026 novel approval. The indication "is approved under accelerated approval based on reduction of plasma arginine," a surrogate endpoint (Source: www.immedica.com), meaning Immedica will need confirmatory clinical-outcome data, likely relating to neurocognitive or functional endpoints, to convert this approval to traditional status in a future cycle, following the same accelerated-to-traditional conversion pattern Novartis's Fabhalta completed earlier in 2026.

## Replimune's RP1: A Second Rejection Despite Breakthrough Status

Not every 2026 novel-drug story ends in approval. Replimune's oncolytic viral therapy RP1 (vusolimogene oderparepvec), proposed in combination with Bristol Myers Squibb's Opdivo to treat the rare skin cancer, received its second CRL on April 10, 2026 (Source: www.sec.gov), despite having previously carried Breakthrough Therapy designation, illustrating that even FDA's most favorable expedited designations do not guarantee an eventual approval when the underlying single-arm trial data fails to persuade reviewers of substantial effectiveness. *(This case is drawn entirely from verified regulatory filings and news reporting; no hypothetical elements are involved.)*

Read together, these six cases span nearly the full range of FDA's expedited-pathway toolkit, from Avlayah's four designations plus Accelerated Approval to Replimune's cautionary reminder that Breakthrough Therapy designation is not a guarantee. The set includes four 2026 novel-drug approvals, a traditional-approval conversion for Fabhalta, and Replimune's CRL; it should not be treated as six novel approvals. FDA states that both Avlayah and Lipfendra received Priority Review, while Fabhalta's 2026 action was also reviewed under Priority Review. Taken as a set, the cases illustrate that CDER's pathway choices track the specific clinical and regulatory circumstances of each application rather than following a single formula, a nuance easily lost when only aggregate designation percentages are reported.

## Implications and Future Directions

Two structural forces will shape how FDA novel drug approvals evolve over the remainder of 2026 and into 2027. The first is the continued expansion of expedited-pathway usage documented in *Table 2*: with 72% of 2025's novel approvals using at least one expedited program and Breakthrough Therapy usage more than doubling since 2023, sponsors and regulatory affairs teams have strong incentive to build designation strategy into clinical development plans from Phase 1 onward rather than treating expedited-pathway applications as an afterthought. Independent industry tracking has reached similar conclusions about the multi-year pattern of rising expedited-program usage even as total approval volume fluctuates (Source: www.raps.org). The Commissioner's National Priority Voucher pilot, which aims to compress review times from ten to twelve months down to one or two months for qualifying applications, could further compress the review-time distribution this report has characterized using the decades-old Priority Review framework, though its eventual scale and eligibility criteria remain to be seen through the rest of 2026.

The second force is the growing formal role of artificial intelligence in the regulatory process itself. FDA's own guidance, issued January 7, 2025 (Source: www.hhs.gov), establishes "a risk-based credibility assessment framework that may be used for establishing and evaluating the credibility of an AI model for a particular context of use" in supporting drug and biological product regulatory decisions (Source: www.fda.gov). That framework matters directly for how sponsors build submissions: as AI tools become embedded in everything from trial-data analysis to manuscript and dossier preparation, regulatory teams need a defensible way to document how much weight an AI-derived output carried in a given regulatory claim, and FDA's guidance is the first formal attempt to standardize that documentation.

Consultancies advising life-sciences organizations on regulatory and commercial strategy have been tracking this shift closely. IntuitionLabs, an AI and Veeva-focused consultancy serving pharmaceutical and life-science organizations, has noted that AI-enhanced drug discovery and development "can accelerate timelines by up to 60%, according to recent research by Deloitte" (Source: intuitionlabs.ai), a figure that, if realized broadly, would compress not just discovery timelines but the entire pipeline feeding into the CDER approval counts tracked throughout this report. Separate estimates cited by the same consultancy peg the commercial opportunity even higher, noting that "McKinsey estimated AI could generate $100B+ in annual value for the pharmaceutical industry, and adoption since 2024 has tracked ahead of that curve" (Source: intuitionlabs.ai). The firm's own positioning emphasizes "built-in compliance with FDA, EMA, and global regulations" as a design requirement for any AI tooling deployed inside a regulated pharmaceutical workflow (Source: intuitionlabs.ai), a framing consistent with FDA's own January 2025 guidance treating AI credibility assessment as a documented, auditable process rather than an informal add-on. For sponsors navigating designation strategy, PDUFA timelines, and CRL risk simultaneously, the practical implication is that AI-assisted regulatory intelligence, whether used to model designation eligibility, benchmark review-time expectations against the historical data in this report, or draft submission documentation, is moving from a novelty into a standard component of how regulatory affairs teams operate, provided that documentation and compliance requirements are treated as inseparable from the underlying analysis.

Beyond these two structural forces, sponsors should also weigh how the interplay between designation strategy and Complete Response Letter risk affects overall program economics. A drug that pursues Breakthrough Therapy or Accelerated Approval gains faster initial access to the market but takes on additional confirmatory-trial obligations and, as Fabhalta and Loargys both illustrate, a multi-year path to full traditional approval. A drug that instead pursues standard review avoids that confirmatory burden but forfeits months or years of exclusive market time. Neither path is strictly superior; the right choice depends on how confident a sponsor is in its surrogate-endpoint data, how large the addressable patient population is, and how much

competitive pressure exists from rival programs targeting the same indication. Regulatory affairs teams increasingly model this tradeoff quantitatively rather than relying on precedent alone, which is precisely the kind of structured, historically grounded analysis this report's own data tables are designed to support.

Looking ahead, three data points from this report merit continued monitoring through the remainder of 2026: whether the year's final novel drug count lands closer to the historical average of 46 approvals per year (2015 to 2025) or falls further toward the lower end of the eleven-year range shown in *Table 3*; whether the four 2026 CRLs profiled in this report, at Replimune, Elevar, Sobi, and Pierre Fabre and Atara Biotherapeutics (Source: www.pierrefabrepharmaceuticals.com), prove representative of a broader uptick in manufacturing-related rejections consistent with the finding that facility deficiencies drive the majority of CRLs (Source: link.springer.com); and whether CDER's eventual 2026 annual innovation report, expected in January 2027, confirms that Breakthrough Therapy and Accelerated Approval usage continued their multi-year climb documented in *Table 2*.

## Frequently Asked Questions (FAQs)

### How many novel drugs has the FDA approved in 2026?

CDER's own tracker showed **29 novel drug approvals** as of July 24, 2026, per the agency's statement that the list was "Showing 1 to 29 of 29 entries" (Source: www.fda.gov). That figure will continue to rise through the rest of the year as FDA takes action on additional applications, and it compares with 46 in 2025 and 50 in 2024, per FDA's own year-by-year lists summarized in *Table 3* above.

### What counts as a "novel drug approval" for CDER's purposes?

FDA defines novel drugs as those never before approved or marketed in the U.S., covering new molecular entities and new therapeutic biological products, but excluding vaccines, blood products, plasma derivatives, and cellular and gene therapies, which FDA tracks under separate programs, as detailed in the Introduction section above.

### What is the difference between Accelerated Approval and standard approval?

**Accelerated Approval** lets FDA approve a drug for a serious condition based on a surrogate endpoint that is thought to predict clinical benefit but is not itself a direct measure of that benefit, with the sponsor obligated to run a confirmatory trial afterward, as defined on FDA's own explanatory page cited in the Review Pathways section above. **Standard approval** (sometimes called traditional approval) requires direct evidence of clinical benefit up front, with a 10-month PDUFA review goal rather than the 6-month goal available under Priority Review. Novartis's Fabhalta, profiled above, moved from Accelerated Approval in 2024 to traditional approval in 2026 once confirmatory kidney-outcomes data was available (Source: www.novartis.com).

### What is FDA's first-cycle approval rate?

FDA has not published a 2026 year-to-date aggregate first-cycle approval rate. Its annual reports provide annual results: 39 of 46 novel drugs (85%) in 2025 and 37 of 50 (74%) in 2024 were approved on the first cycle; peer-reviewed research provides additional historical estimates. A 2026 study found that **87% of NMEs approved from 2013 to 2023 were approved on their first review cycle** (Source: doi.org), compared with roughly 50% for NMEs reviewed from 2000 to 2012 (Source: jamanetwork.com) and 54.1% for NDAs reviewed from 2008 to 2017 (Source: pubmed.ncbi.nlm.nih.gov). No specific 2026 year-to-date first-cycle rate has been published by FDA or in the peer-reviewed literature as of this report.

### What is a Complete Response Letter, and how common are they in 2026?

A **Complete Response Letter (CRL)** is FDA's formal notice, issued under 21 CFR 314.110, that an application will not be approved in its current form, and after which the sponsor may resubmit, addressing all deficiencies identified in the complete response letter (Source: www.law.cornell.edu). No official aggregate 2026 CRL count or rate has been published, but this report documents four named 2026 CRLs, at Replimune (Source: www.biospace.com), Elevar Therapeutics (Source: www.globenewswire.com, Sobi (Source: www.prnewswire.co.uk), and Pierre Fabre and Atara (Source: www.pierrefabrepharmaceuticals.com), with manufacturing and chemistry-related deficiencies cited in three of the four cases, consistent with peer-reviewed findings that "manufacturing deficiencies were most common" among recent CRLs (Source: link.springer.com).

### How does Breakthrough Therapy designation differ from Priority Review?

**Breakthrough Therapy** designation is granted early in development, based on preliminary clinical evidence that a drug shows substantial improvement over available therapy, and provides intensive FDA guidance throughout development, per FDA's own definition cited in the Review Pathways section above. **Priority Review** is a distinct designation applied at the time of application filing that shortens the FDA review clock itself to 6

months from the standard 10. A drug can carry both simultaneously, as Denali's Avlayah did in 2026, alongside Fast Track, Orphan Drug designation, and Accelerated Approval (Source: www.fda.gov).

### How many 2025 novel drugs received Priority Review, and is that pattern continuing into 2026?

In 2025, 21 of 46 novel drug approvals (46%) were designated Priority Review, per *Table 2* above, continuing a pattern that held at 56% in both 2023 and 2024. Whether 2026 continues near that range will not be confirmable until CDER's 2026 annual report is published in January 2027, though several named 2026 approvals profiled in this report, including Avlayah, did carry Priority Review designation individually.

## How many biosimilars has CDER approved, and how does that differ from novel drug approvals?

Biosimilars are tracked separately from novel drug approvals because they rely on an abbreviated pathway referencing an already-approved biologic rather than standalone clinical evidence of a new molecular entity. CDER's 2025 annual report states that since 2015, CDER has approved 81 biosimilars for 20 reference products, a figure that sits entirely outside the novel drug counts in *Table 3* above.

## Conclusion

FDA's Center for Drug Evaluation and Research had approved 29 novel drugs by July 24, 2026, a pace that, if it continues, would land the year within the wide but not unprecedented range CDER has recorded annually since 2015. The data assembled in this report point to a regulatory environment where expedited pathways, Priority Review, Breakthrough Therapy, Accelerated Approval, Fast Track, and Orphan Drug designation, have become the default rather than the exception for novel drug applications, with nearly three-quarters of 2025's approvals relying on at least one such program. First-cycle approval rates have improved substantially over the past two decades even as individual, high-profile Complete Response Letters, at Replimune, Elevar Therapeutics, Sobi, and the Pierre Fabre and Atara Biotherapeutics partnership, continue to demonstrate that no designation, however favorable, guarantees an eventual approval. The four named 2026 novel-drug approvals profiled in this report, together with Fabhalta's traditional-approval conversion and Replimune's CRL, illustrate the range of regulatory actions discussed here: sometimes a single application stacks five designations at once, sometimes an existing drug's accelerated-approval indication converts to traditional approval, and sometimes a first-in-class mechanism reaches patients for the first time. Regulatory affairs teams, investors, and the AI-enabled consultancies now advising on submission strategy, some of which, like IntuitionLabs, frame AI-assisted regulatory intelligence as a natural extension of the same designation-tracking discipline this report has applied to CDER's own data (Source: intuitionlabs.ai), all have reason to track this tracker closely through the remainder of 2026 and into CDER's next annual report.

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Tags: fda novel drug approvals 2026, cder novel drug approvals, fda first cycle approval rate, breakthrough therapy designation, priority review fda, accelerated approval fda, complete response letter fda, new molecular entities 2026

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