U.S. FOOD & DRUG ADMINISTRATION

CENTER FOR DRUG EVALUATION AND RESEARCH

Advancing Health Through Innovation:

New Drug Therapy Approvals 2025

INNOVATION | PREDICTABILITY | ACCESS

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Contents

Acting Director's Message

Tracy Beth Høeg, M.D., Ph.D.

Acting Director, Center for Drug Evaluation and Research

Today, CDER releases its report, Advancing Health Through Innovation: New Drug Therapy Approvals 2025, the center's 15th annual report summarizing notable drug approvals.

The report highlights the year's 46 novel drug approvals. They are considered novel because they have not previously been approved or marketed in the U.S. Of these, 34 were new molecular entities (NMEs) and 12 were biologics. 70% (32/46) were approved in the U.S. before approval in other countries, and exactly half (23) received Orphan Drug Designation (intended to treat, diagnose or prevent rare diseases that affect fewer than 200,000 people in the U.S.). Notable approvals included treatments for two rare mitochondrial diseases (Kygevvi for thymidine kinase 2 deficiency and Forzinity for Barth syndrome), a first-in-class non-opioid pain medication (Journavx) and another first-in-class medication for dry eye disease (Tryptyr).

The number of novel drug and biologic approvals in 2025 was similar to the average for the last five years and above the historical average of 38 novel drugs per year since 2007. Combined with CBER, there were 58 novel approvals in 2025.

In total, CDER approved 123 products in 2025 (both novel drugs and non-novel drugs, including new dosage forms and formulations; this number excludes certain submission types, such as efficacy supplements). These drugs will be used in a wide variety of medical areas, including infectious diseases, neurology, pain management, mental health, heart, blood, kidney and endocrinediseases, inflammation, lung diseases, allergies, cancer, eye conditions, and women's health.

CDER also approved 18 biosimilars in 2025, 4 of which were for reference products (existing FDA-approved biologics to which biosimilars are compared) that previously had no approved biosimilars. These include Merilog and Kirsty (a rapid-acting insulin for diabetes); Omlyclo (a treatment for asthma, chronic rhinosinusitis, food allergies, and chronic hives); and Poherdy (a treatment for certain breast cancers). Since 2015, CDER has approved 81 biosimilars for 20 reference products.

Throughout the course of 2025, CDER continued to demonstrate its ongoing commitment to ensuring safety and efficacy of all FDA approved products by issuing complete response (CR) letters for applications that did not meet FDA's statutory requirements for approval. In 2025, CDER issued 19 CR letters for 18 novel drugs. As of September 2025, the FDA began making CR letters to companies available to the public. These documents provide critical insight into the reasons behind the rejections of applications and reflect our thoughtful, careful and collaborative review process. This move towards transparency will provide important clarity to both industry and the public about our decision-making and hopefully will increase confidence in the FDA.

It is worth noting that the work at CDER is not limited to the review of marketing applications but also includes extensive engagement with companies throughout drug development, including providing advice on protocols and holding formal meetings with sponsors. In 2025, CDER received over 3,000 INDs, comparable with recent years, approximately 12,300 protocols (over 600 more than in 2024), and over 4,500 meeting requests, continuing a steady increase in requests.

I would like to thank my CDER colleagues for their impressive work and their public service over the past year. Their commitment to the scientific method, critical thinking and communication with companies is commendable. Above all, their dedication to improving and protecting the lives of Americans is something they should be proud of. I look forward to seeing what we can accomplish together in 2026.

Tracy Beth Høeg, M.D., Ph.D.
Acting Director, Center for Drug Evaluation and Research

Executive Summary

CDER approved many drug therapies in 2025. These approvals, spanning a wide array of diseases and conditions, aim to help people live better and potentially longer lives.

Innovation Across Medical Conditions

In 2025, we approved 46 new drugs never before approved or marketed in the U.S., known as "novel" drugs. We also approved previously approved drugs for new conditions, patient populations, or in new doses or formulations.

The 2025 actions, both novel and other important drug approvals, focus on prevention, diagnosis, treatment and cure in many different areas, including infectious disease; neurology; pain management; mental health; heart, blood, kidney and endocrine diseases; inflammation; lung diseases; allergies; immunology; cancer; eye conditions; and women's health.

New Drugs for Patients with Rare Diseases

Patients with rare diseases are often in critical need of new therapies, as these individuals generally have few or no existing treatment options. In 2025, 23 of 46, or half, of our novel drug approvals received orphan drug designation because they target rare diseases, including:*

- Barth syndrome, a serious mitochondrial disease that affects the heart, muscles, immune system, and growth
- Acromegaly, an endocrine disorder that causes bones, organs, and other tissue to grow abnormally bigger
- Generalized myasthenia gravis, a chronic autoimmune disorder that leads to muscle weakness throughout the body
- Idiopathic pulmonary fibrosis, a serious and progressive disease characterized by scarring and thickening of the lung tissue
- Hemophilia, a serious bleeding disorder that occurs when blood does not clot normally

In 2025, CDER also approved many therapies for rare cancers or tumors, including:

- Low-grade serous ovarian cancer
- Diffuse midline glioma, an aggressive brain tumor
- Acute myeloid leukemia
- Non-small cell lung cancer with HER2 (ERBB2) activating mutations

**Not all drugs for rare diseases receive orphan drug designation.*

Efficiencies in Bringing Therapies to Market

Our 2025 approvals demonstrate efficiencies in our review process, as shown by the following:

- **Commissioner's National Priority Voucher (CNPV):** The agency took its first action in this new program that aims to shorten review times from 10-12 months to 1-2 months. The CNPV uses a collaborative review process to accelerate approvals for companies aligned with critical U.S. national health priorities.
- **User Fee Goals Performance:** Of the 46 new drugs approved in 2025, CDER met or exceeded its Prescription Drug User Fee Act goal dates for 44 of these approvals (96%).
- **First Cycle Approvals:** In 2025, CDER approved 39 of the 46 novel approvals (85%) on the first cycle. This differs from when CDER initially is unable to approve a drug because information in the application does not support approval. Subsequently, the sponsor resubmits the application with additional information, starting another review cycle that may lead to drug approval.
- **Approvals in U.S. Before Other Countries:** 32 of the 46 novel drugs approved in 2025 (70%) were first approved in the U.S.
- **Expedited Programs for Serious Conditions:** CDER has four broadly applicable programs to facilitate and expedite development and review of drugs for serious or life-threatening conditions: fast track, breakthrough therapy, priority review and accelerated approval. In 2025, 33 of the 46 of CDER's novel drug approvals (72%) used one or more of these expedited programs, which helped bring new therapies to the market sooner.

CDER's Novel Drug Approvals of 2025

In 2025, CDER approved 46 novel drugs, either as new molecular entities (NMEs) under New Drug Applications (NDAs), or as new therapeutic biologics under Biologics License Applications (BLAs). The active ingredient(s) in a novel drug have not been approved in the U.S.

CDER's novel drug approvals for 2025 are listed alphabetically below by trade name.*

See Appendix B for a summary chart of designations for CDER's novel approvals.

Trade Name	Active Ingredient(s)
Andembry	garadacimab-gxii
Anzupgo	delgocitinib
Avmapki Fakzynja (co-packaged)	avutometinib, defactinib
Blujepa	gepotidacin
Brinsupri	brensocatib
Cardamyst	etripamil
Datroway	datopotamab deruxtecan-dlnk
Dawnzera	donidalorsen
Ekterly	sebetralstat
Emrelis	telisotuzumab vedotin-tllv
Enflonsia	clesrovimab-cfor
Exdensur	depemokimab-ulaa
Forzinity	elamipretide
Gomekli	mirdametinib
Grafapex	treosulfan
Hernexeos	zongertinib
Hyrnuo	sevabertinib
Ibtrozi	taletrectinib
Imaavy	nipocalimab-aahu
Inluriyo	imlunestrant
Jascayd	nerandomilast
Journavx	suzetrigine
Keytruda Qlex	pembrolizumab, berahyaluronidase alfa-pmph
Komzifti	ziftomenib
Kygevvi	doxecitine, doxribtimine
Lerochol	lerodalcibep-liga
Lynkuet	elinzanetant
Lynozyfic	linvoseltamab-gcpt
Modeyso	dordaviprone
Myqorzo	aficamten
Nereus	tradipitant
Nuzolvence	zoliflodacin
Palsonify	paltusotine
penpulimab-kcqx**	penpulimab-kcqx
Qfitlia	fitusiran
Redemplo	plozasiran
Rhapsido	remibrutinib
Romvimza	vimseltinib
Sephience	sepiapterin
Tryptyr	acoltremon
Vanrafia	atrasentan
Vizz	aceclidine
Voyxact	sibeprenlimab-szsi
Wayrilz	rilzabrutinib
Yartemlea	narsoplimab-wuug
Zegfrovy	sunvozertinib

**This information is accurate as of December 31, 2025. In rare instances, CDER may need to change a drug's NME designation or the status of its application as a novel BLA. For instance, new information may become available that could lead to a reconsideration of the original designation or status. If CDER makes these types of changes, the agency intends to communicate the nature of, and the reason for, any revisions as appropriate.*

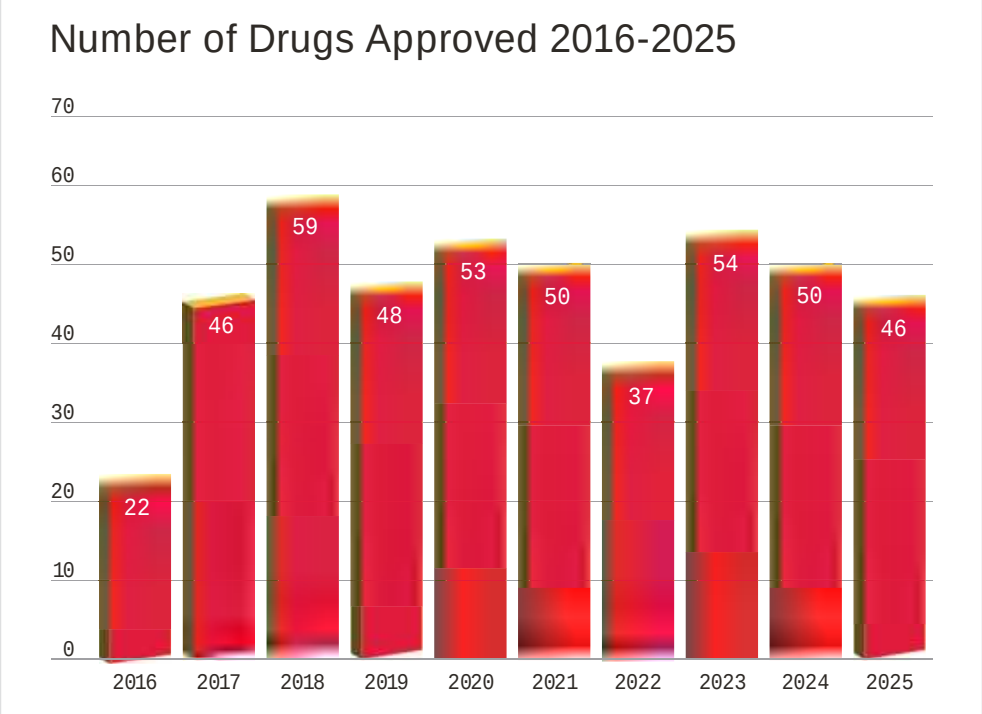
***Approved without a trade name*

Commissioner's National Priority Voucher (CNPV) Pilot Program

FDA completed its first action through the new Commissioner's National Priority Voucher (CNPV) program. This approval facilitated the relaunch of Augmentin XR (amoxicillin-clavulanate potassium) extended-release tablet, which can treat community-acquired pneumonia and acute bacterial sinusitis, strengthening the drug supply chain while helping address ongoing antibiotic shortages.

CDER's Annual Novel Drug Approvals: 2016 – 2025

The 10-year graph below shows that from 2016 through 2025, CDER has averaged approximately 47 novel drug approvals per year.



First-in-Class Drugs

CDER identified 20 of the 46 novel drugs approved (43%) in 2025 as first-in-class. These drugs have mechanisms of action different from those of existing therapies.

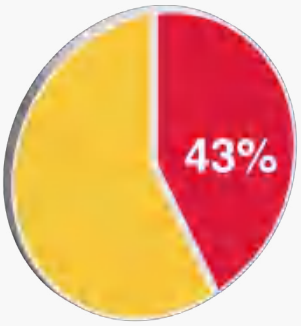
Novel drugs approved in 2025 that CDER identified as first-in-class were:

Andembry; Avmapki Fakzynja; Blujepa; Brinsupri; Dawnzera; Emrelis; Forzinity; Jascayd; Journavx; Kygevvi; Lynkuet; Modeyso; Nuzolvence; Qfitlia; Redemplo; Rhapsido; Tryptyr; Voyxact; Wayrilz; Yartemlea

Notable examples of novel first-in-class approvals include:

- **Blujepa (gepotidacin)** tablets to treat females 12 years and older weighing at least 40 kg with uncomplicated urinary tract infections caused by certain microorganisms. This drug was later approved to treat uncomplicated urogenital gonorrhea in patients 12 years and older with limited or no alternative treatment options.

First-in-Class Drugs



CDER identified 20 of the 46 novel drugs approved (43%) in 2025 as first-in-class.

Last year, FDA approved two treatments for gonorrhea, a sexually transmitted infection.

- **Brinsupri (brensocatib)** tablets to treat non-cystic fibrosis bronchiectasis, a chronic lung condition, in patients 12 years and older.
- **Dawnzera (donidalorsen)** injection to prevent attacks of hereditary angioedema, a genetic disorder that causes recurrent episodes of swelling in parts of the body, including the face, throat, limbs, and internal organs.
- **Emrelis (telisotuzumab vedotin-tllv)** injection to treat types of non-squamous non-small cell lung cancer with high c-Met protein overexpression in patients who received systemic therapy.
- **Journavx (suzetrigine)** tablets to treat moderate-to-severe pain as a non-opioid analgesic.
- **Nuzolvence (zoliflodacin)** oral suspension to treat patients 12 years and older weighing at least 35 kg with uncomplicated urogenital gonorrhea.
- **Voyxact (sibeprenlimab-szsi)** injection to treat IgA nephropathy (IgAN) in adults at risk of disease progression. IgAN is caused by a build-up of IgA deposits, causing inflammation that damages the kidneys.

FDA approved an opioid alternative for pain management as part of our multipronged efforts to combat the opioid overdose crisis.

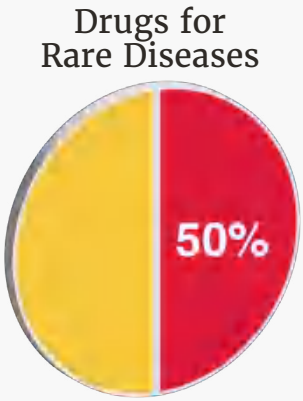
Drugs for Rare Diseases

In 2025, 23 of CDER's 46 novel drug approvals (50%) received orphan drug designation because they target rare diseases (diseases that affect fewer than 200,000 people in the U.S.).* Patients with rare diseases often have few or no drugs available to treat their conditions.

Novel drugs approved in 2025 with orphan drug designation were:

Andembry; Avmapki Fakzynja; Dawnzera; Ekterly; Forzinity; Gomekli; Grafapex; Hyrnuo; Ibtrozi; Imaavy; Jascayd; Komzifti; Kygevvi; Lynozyfic; Modeyso; Myqorzo; Palsonify; penpulimab-kcqx* Qfitlia; Redemplo; Sephience; Wayrilz; Yartemlea

**Approved without a trade name*



Half of novel drug approved received orphan drug designation.

Examples of novel approvals of 2025 for rare diseases include:

- **Avmapki Fakzynja (avutometinib and defactinib)** capsules and tablets to treat KRAS-mutated recurrent, low-grade serous ovarian cancer in patients who received systemic therapy.
- **Ekterly (sebetralstat)** tablets to treat acute attacks of hereditary angioedema.
- **Forzinity (elamipretide)** injection to treat Barth syndrome in patients weighing at least 30 kg. Barth syndrome is a serious and life-threatening mitochondrial disease that affects the heart, muscles, immune system, and growth. It was approved through the accelerated approval pathway.
- **Grafapex (treosulfan)** injection, in combination with fludarabine, as a preparative regimen for allogeneic (i.e., from a donor) hematopoietic stem cell transplantation in adult and pediatric patients with acute myeloid leukemia or myelodysplastic syndrome.

FDA approved the first treatment for Barth syndrome, a serious and life-threatening disease, in 2025.

- **Gomekli (mirdametinib)** tablets to treat patients two years and older with neurofibromatosis type 1 (a condition characterized by skin coloring changes and tumor growth) who have non-cancerous tumors that cannot be completely removed.
- **Komzifti (ziftomenib)** capsules to treat relapsed or refractory acute myeloid leukemia with a susceptible NPM1 mutations.
- **Kygevvi (doxecitine, doxribtimine)** infusion to treat thymidine kinase 2 deficiency, a rare disorder that affects the muscles in patients whose symptoms begin before age 12 years.
- **Lynozyfic (linvoseltamab-gcpt)** injection to treat relapsed or refractory multiple myeloma in patients who have received at least four lines of therapy.
- **Ibtrozi (taletrectinib)** capsules to treat locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC).
- **Imaavy (nipocalimab-aahu)** injection to treat generalized myasthenia gravis (gMG) in patients 12 years and older with certain autoantibody profiles. gMG is a chronic autoimmune disorder that leads to muscle weakness throughout the body.
- **Hyrnuo (sevabertinib)** tablets to treat non-small cell lung cancer with HER2 (ERBB2) activating mutations. It was approved through the accelerated approval pathway.
- **Jascayd (nerandomilast)** tablets to treat idiopathic pulmonary fibrosis, a serious and progressive disease characterized by lung tissue scarring and thickening. Jascayd was later approved in 2025 for progressive pulmonary fibrosis, another serious lung disease.
- **Modeyso (dordaviprone)** capsules to treat patients one year and older with diffuse midline glioma (an aggressive brain tumor) with the H3K27M mutation and progressive disease following therapy.
- **Palsonify (paltusotine)** tablets to treat acromegaly in patients who have had an inadequate response to surgery and/or for whom surgery is not an option. Acromegaly is an endocrine disorder that causes bones, organs, and other tissue to abnormally grow bigger.
- **Penpulimab-kcqx*** injection, in combination with cisplatin or carboplatin and gemcitabin or as a single agent, to treat adults with types of nasopharyngeal carcinoma, a cancer that starts in the back of the nasal cavity.
- **Redemplo (plozasiran)** injection to treat familial chylomicronemia syndrome, a disease that prevents the body from breaking down fats consumed through the diet.
- **Qfitlia (fitusiran)** injection to prevent or reduce the frequency of bleeding episodes in patients 12 years and older with hemophilia A or B with or without factor VIII or IX inhibitors. Hemophilia is a serious bleeding disorder that occurs when blood does not clot normally.

Approved without a trade name.

In 2025, FDA approved a new drug to treat hemophilia, a condition in which the blood does not clot in a typical way.

- **Sephience (sepiapterin)** oral powder to treat a certain type of phenylketonuria, an inherited disease that prevents the body from breaking down an amino acid called phenylalanine (Phe), in addition to a Phe-restricted diet.
- **Wayrilz (rilzabrutinib)** tablets to treat patients with persistent or chronic immune thrombocytopenia who have had an insufficient response to immunoglobulins, anti-D therapy, or corticosteroids. Patients with immune thrombocytopenia have low platelet counts, which affect blood clotting and can increase the risk of bleeding.
- **Yartemlea (narsoplimab-wuug)** infusion to treat hematopoietic stem cell transplant-related thrombotic microangiopathy, a serious transplant complication that can lead to blood clots and organ injury.

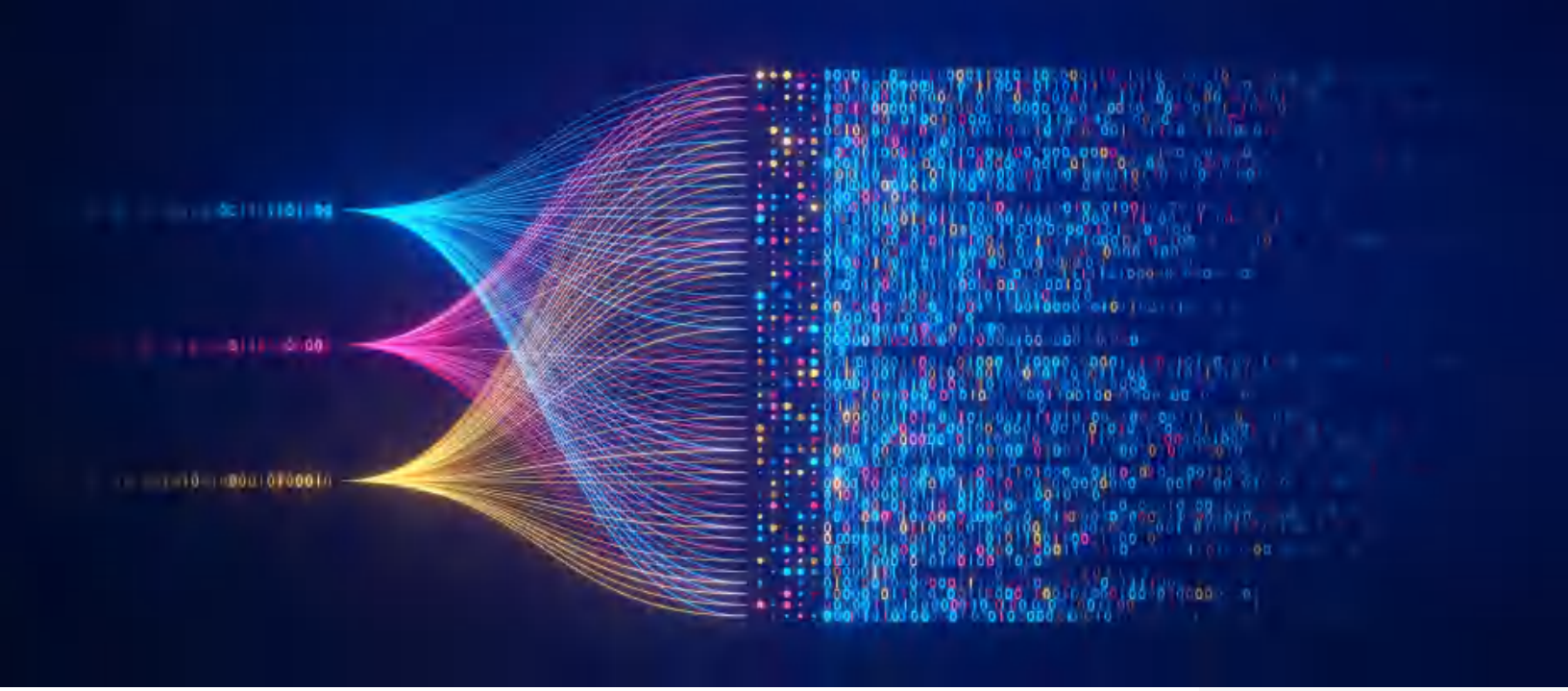
Other Novel Drug Approvals

In addition to the first-in-class drugs and drugs that received orphan drug designation, CDER had these notable approvals in 2025:

- **Anzupgo (delgocitinib)** cream to treat moderate-to-severe chronic hand eczema in patients who have had an inadequate response to topical corticosteroids, or in whom topical corticosteroids are not advisable.
- **Cardamyst (etrapamil)** nasal spray to treat episodes for paroxysmal supraventricular tachycardia, a heart rhythm disorder where the heart beats rapidly and irregularly.
- **Datroway (datopotamab deruxtecan-dlnk)** injection to treat HR-positive, HER2-negative, unresectable or metastatic breast cancer in patients who received endocrine-based therapy and chemotherapy.
- **Enflonsia (clesrovimab-cfor)** injection to prevent respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and infants who are born during or entering their first RSV season.
- **Hernexeos (zongertinib)** tablets to treat types of unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC) with HER2 TKD activating mutations after systemic therapy.
- **Inluriyo (imlunestrant)** tablets to treat estrogen-receptor-positive, HER2-negative, estrogen receptor-1-mutated breast cancer in patients whose disease has progressed after at least one endocrine therapy.
- **Lerochol (lerodalcibep-liga)** injection to reduce low-density lipoprotein cholesterol in several high-risk patient populations.
- **Lynkuet (elinzanetant)** capsules to treat moderate-to-severe vasomotor symptoms due to menopause.
- **Rhapsido (remibrutibinib)** tablets to treat chronic spontaneous urticaria (hives).
- **Romvimza (vimseltinib)** capsules to treat symptomatic tenosynovial giant cell tumors (TGCTs) in patients for whom surgery may cause significant side effects. TGCTs are noncancerous growths that form in the soft tissue around the joints.
- **Tryptyr (acoltremon)** ophthalmic solution to treat signs and symptoms of dry eye disease.

In 2025, CDER approved a new drug to treat signs and symptoms of dry eye disease.

- **Vanrafia (atrasentan)** tablets to reduce proteinuria (protein in the urine) in patients with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression. Vanrafia was approved through the accelerated approval pathway.
- **Zegfrovy (sunvozertinib)** tablets to treat locally advanced or metastatic NSCLC in patients with EGFR exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy. This drug was approved through the accelerated approval pathway.



Innovation: Use of Expedited Development and Review Pathways

Fast Track

CDER used many approaches to enhance and expedite drug review in 2025. These approaches enable increased flexibility, efficiency, and interactions between CDER staff and drug developers. They often also allow shorter review times to speed the availability of new therapies to patients with serious conditions, especially in cases where there are no satisfactory alternatives, while preserving FDA's rigorous standards for safety and effectiveness.

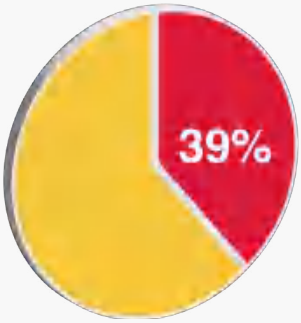
CDER granted fast track status to 18 of the 46 novel drugs (39%) that were approved in 2025. Fast track speeds development and review of new drug and biologics by increasing the level of communication between FDA and drug developers and by enabling CDER to review portions of a drug application on a rolling basis.

Drugs granted fast track status were:

Andembry; Anzupgo; Ekterly; Enflonsia; Forzinity; Gomekli; Hernexeos; Imaavy; Inluriyo; Journavx; Komzifti; Lynozyfic; Nuzolvence; penpulimab-kcqx *; Qfitlia; Redemplo; Romvimza; Wayrilz

**Approved without a trade name*

Fast Track



39% of novel drug approvals received fast track designation.

Breakthrough Therapy

CDER designated 15 of the 46 novel drugs (33%) approved in 2025 as breakthrough therapies. A breakthrough therapy designation includes all the fast track program features and offers intensive FDA guidance during drug development, including involvement from senior managers.

Drugs designated with breakthrough therapy status were:

Avmapki Fakzynja; Emrelis; Hernexeos; Hyrnuo; Ibtrozi; Jascayd; Journavx; Komzifti; Kygevvi; Myqorzo; penpulimab-kcqx*; Redemplo; Voyxact; Yartemlea; Zegfrovy

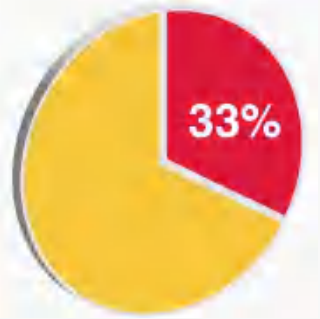
** Approved without a trade name.*

Priority Review

In 2025, 21 of the 46 novel drugs approved (46%) were designated priority review. A drug receives a priority review if CDER determines that the drug treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. Generally speaking, a priority review application is one in which CDER aims to take action within six months of filing (compared to a target date of 10 months under standard review).

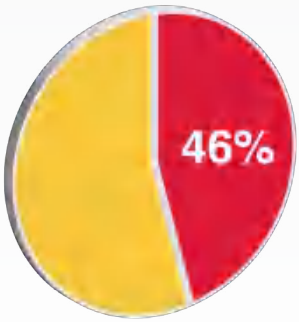
(Priority review for new drugs and biologics may be granted in other circumstances, such as when sponsors redeem a priority review voucher under CDER's priority review voucher program. Such drugs are not included in the list below, and do not meet priority review criteria.)

Breakthrough Therapy



33% of novel drugs approved received breakthrough therapy designation.

Priority Review



21 of the 46 novel drugs approved (46%) in 2025 received priority review.

Drugs designated priority review were:

Avmapki Fakzynja; Blujepa; Brinsupri; Emrelis; Forzinity; Gomekli; Hernexeos; Hyrnuo; Ibtrozi; Imaavy; Jascayd; Journavx; Komzifti; Kygevvi; Lynozyfic; Modeyso; Nuzolvence; Romvimza; Voyxact; Yartemlea; Zegfrovy

Accelerated Approval

CDER approved 11 of the 46 novel drugs (24%) in 2025 under the accelerated approval pathway. This program aims to bring drugs to market that can provide treatment for unmet medical needs on a faster timeline (due to the use of surrogate or intermediate clinical endpoints) than would be possible following a traditional approval pathway (which generally uses endpoints directly measuring clinical benefit). Accelerated approval may be an option for a new drug intended to treat a serious condition that offers a meaningful advantage over available therapies.

For drugs reviewed under the accelerated approval pathway, a determination of safety and effectiveness may be made based not on measures of direct clinical benefit, but rather on one of two alternative endpoints: (1) a surrogate endpoint that is reasonably likely to predict clinical benefit; or (2) an intermediate clinical endpoint that is reasonably likely to predict clinical benefit. Importantly, however, for products approved under the accelerated approval pathway, FDA requires post-approval studies designed to confirm clinical benefit, and, among other things, may withdraw approval of a drug that has received accelerated approval for failure to confirm clinical benefit.

The novel drugs approved via accelerated approval were:

Avmapki Fakzynja; Emrelis; Forzinity; Hernexeos; Hyrnuo; Keytruda Qlex; Lynozyfic; Modeyso; Vanrafia; Voyxact; Zegfrovy

Overall Use of Expedited Development and Review Methods

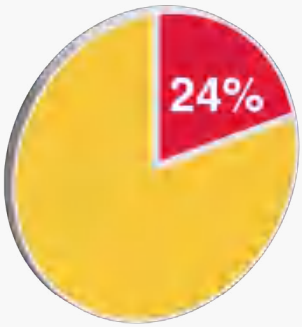
33 of the 50 novel drug approvals of 2024 (72%) used one or more expedited programs, specifically fast track designation, breakthrough therapy designation, priority review designation, or accelerated approval.

Novel drugs approved in 2025 that used at least one expedited program were:

Andembry; Anzupgo; Avmapki Fakzynja; Blujepa; Brinsupri; Ekterly; Emrelis; Enflonsia; Forzinity; Gomekli; Hernexeos; Hyrnuo; Ibtrozi; Imaavy; Inluriyo; Jascayd; Journavx; Keytruda Qlex; Komzifti; Kygevvi; Lynozyfic; Modeyso; Myqorzo; penpulimab-kcqx*; Nuzolvence; Qfitlia; Redemplo; Romvimza; Vanrafia;; Voyxact; Wayrilz; Yartemlea; Zegfrovy

**Approved without a trade name.*

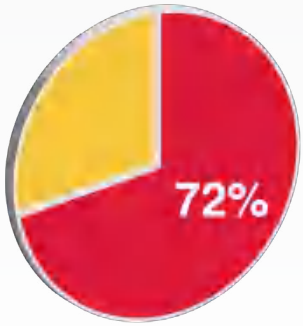
Accelerated Approval



24% of drugs approved in 2025 received accelerated approval.

CDER used at least one expedited program to speed approval of 72% of all novel drugs approved in 2025.

Overall Use of Expedited Development and Review Methods



72% of drugs approved used at least one expedited program.

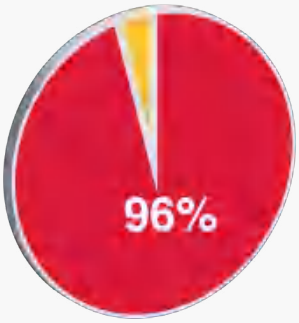
Predictability: Meeting PDUFA Goals

Under PDUFA, industry is assessed user fees that provide resources to CDER to expand capabilities for review activities. With PDUFA, applications are reviewed targeting specific timeframes. Throughout 2025, CDER met or exceeded the PDUFA goal date for taking action on 96% (44 of 46) of the novel drugs approved.

Novel drugs approved in 2025 on or before their PDUFA goal dates were:

Andembry; Anzupgo; Avmapki Fakzynja; Blujepa; Brinsupri; Cardamyst; Datroway; Dawnzera; Emrelis; Enflonsia; Exdensur; Forzinity; Gomekli; Grafapex; Hernexeos; Hyrnuo; Ibtrozi; Imaavy; Inluriyo; Jascayd; Journavx; Keytruda Qlex; Komzifti; Kygevvi; Lerochol; Lynkuet; Lynozyfic; Modeyso; Myqorzo; Nereus; Nuzolvence; Palsonify; Qfitlia; Redemplo; Rhapsido; Romvimza; Sephience; Tryptyr; Vanrafia; Vizz; Voyxact; Wayrilz; Yartemlea; Zegfrovy

Meeting PDUFA Goals



44 drugs (96%) met their PDUFA goals.

Access: First Cycle Approvals and First in U.S. Approvals

First Cycle Approvals

CDER approved 39 of the 46 novel drugs of 2025 (85%) on the "first cycle" of review. This high percentage in part reflects the extent to which CDER staff provide clarity to drug developers on the necessary study design elements and other data needed in the drug application to support a full and comprehensive drug assessment.

Novel drugs approved in 2025 on the first cycle were:

Anzupgo; Avmapki Fakzynja; Blujepa; Brinsupri; Datroway; Dawnzera; Ekterly; Emrelis; Enflonsia; Exdensur; Gomekli; Hernexeos; Hyrnuo; Ibtrozi; Imaavy; Inluriyo; Jascayd; Journavx; Keytruda Qlex; Komzifti; Kygevvi; Lerochol; Lynkuet; Modeyso; Myqorzo; Nereus; Nuzolvence; Palsonify; Qfitlia; Redemplo; Rhapsido; Romvimza; Sephience; Tryptyr; Vanrafia; Vizz; Voyxact; Wayrilz; Zegfrovy

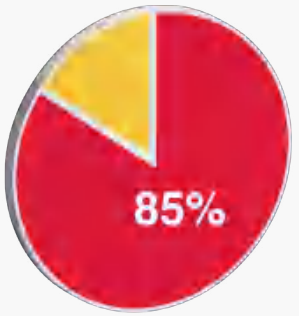
Approval in the U.S. Before other Countries

32 of the 46 novel drugs approved in 2025 (70%) were approved in the U.S. before any other country.

Novel drugs of 2025 approved first in the U.S. were:

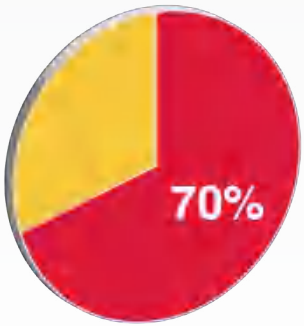
Avmapki Fakzynja; Blujepa; Brinsupri; Cardamyst; Dawnzera; Ekterly; Emrelis; Enflonsia; Forzinity; Gomekli; Hernexeos; Hyrnuo; Imaavy; Inluriyo; Jascayd; Journavx; Keytruda Qlex; Komzifti; Kygevvi; Lerochol; Modeyso; Nereus; Nuzolvence; Palsonify; Qfitlia; Redemplo; Rhapsido; Romvimza; Tryptyr; Vanrafia; Voyxact; Yartemlea

First Cycle Approvals



85% of novel drugs were approved on the first cycle.

Approval in the U.S. Before Other Countries



70% of novel drugs were first approved in the U.S.

New Uses of Approved Drugs

After CDER approves a new treatment, a drug sponsor may generate new data about the product that suggests an additional use. The drug sponsor may then submit an application to modify or expand the use of an approved drug based on this new data.

The products below are some 2025 CDER approvals for new uses or indications of an approved drug:

- **Amvuttra (vutrisiran)** injection was approved to treat cardiomyopathy (a heart muscle disease) caused by wild-type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality, cardiovascular hospitalizations, and urgent heart failure visits. Patients with this disorder have accumulation of abnormal proteins called amyloid fibrils, which affects how the heart pumps blood.
- **Aqvesme (mitapivat)** tablets to treat anemia in patients with thalassemia, a blood disorder that causes the body to have less hemoglobin, the protein in red blood cells that carries oxygen.
- **Cabometyx (cabozantinib)** tablets were approved to treat patients 12 years and older with previously treated, unresectable, locally advanced or metastatic, well-differentiated pancreatic neuroendocrine tumors.
- **Calquence (acalabrutinib)** capsules were approved in combination with bendamustine and rituximab to treat patients with untreated mantle cell lymphoma (a rare type of non-Hodgkin's lymphoma) who are ineligible for autologous (i.e., from the patient's body) hematopoietic stem cell transplantation.

FDA approved a previously approved drug to treat anemia in patients with thalassemia, a blood disorder.

- **Ctexli (chenodiol)** tablets were approved to treat cerebrotendinous xanthomatosis, a rare genetic condition that causes abnormal fat buildup in parts of the body.
- **Enhertu (fam-trastuzumab deruxtecan-nxki)** infusion was approved to treat unresectable or metastatic hormone receptor-positive/HER2-low or ultralow breast cancer that has progressed on one or more endocrine therapies in the metastatic setting. It was also approved in combination with pertuzumab for the first-line treatment of ads with unresectable or metastatic HER2-positive (IHC 3+ or ISH+) breast cancer
- **Empaveli (pegcetacoplan)** injection was approved to treat patients 12 years and older with C3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis, two rare diseases that can cause kidney failure.
- **Fabhalta (iptacopan)** capsules were approved as the first treatment for adults with C3G to reduce proteinuria (protein in the urine).
- **Gamifant (emapalumab-lzsg)** injection was approved as the first therapy for hemophagocytic lymphohistiocytosis/macrophage activation syndrome in Still's disease, a hyperinflammatory, life-threatening condition.
- **Imfinzi (durvalumab)** injection was approved to treat muscle-invasive bladder cancer in patients undergoing radical cystectomy (bladder removal). Imfinzi was also approved as neoadjuvant and adjuvant treatment in combination with fluorouracil, leucovorin, oxaliplatin, and docetaxel chemotherapy (followed by single agent Imfinzi) to treat patients with resectable gastric or gastroesophageal junction adenocarcinoma.
- **Kerendia (finerenone)** tablets were approved to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in patients with heart failure with left ventricular ejection fraction of 40% or more.
- **Keytruda (pembrolizumab)** injection was approved for adults with resectable, locally advanced head and neck squamous cell carcinoma (HNSCC) whose tumors express PD-L1 (CPS ≥1), as a single agent as neoadjuvant treatment, continued as adjuvant treatment in combination with radiotherapy with or without cisplatin after surgery, and then as a single agent.
- **Libtayo (cemiplimab-rwlc)** injection was approved for the adjuvant treatment of patients with cutaneous squamous cell carcinoma at high risk of recurrence after curative surgery and radiation.
- **Lumakras (sotorasib)** tablets were approved in combination with panitumumab to treat patients with a type of metastatic colorectal cancer who received chemotherapy.
- **Mavyret (glecaprevir and pibrentasvir)** tablets and oral pellets were approved to treat acute hepatitis C virus (HCV) infection in patients three years and older. Mavyret was previously approved to treat chronic HCV.

A previously approved drug was approved to treat acute hepatitis C virus in patients aged 3 years and older.

- **Monjuvi (tafasitamab-cxix)** injection was approved in combination with lenalidomide and rituximab to treat relapsed or refractory follicular lymphoma, providing a chemotherapy alternative.
- **Nityr (nitisinone) and Harliku (nitisinone)** tablets were approved to treat urine homogentisic acid in patients with alkaptonuria, a condition that causes arthritis, kidney stones, dark pigmentation spots, and dark urine.
- **Omvoh (mirikizumab-mrkz)** infusion and injection to treat moderately-to-severely active Crohn's disease, a type of inflammatory bowel disease.
- **Ozempic (semaglutide)** injection was approved to reduce the risk of sustained estimated glomerular filtration rate decline, end-stage kidney disease, or cardiovascular death in patients with type 2 diabetes and chronic kidney disease.
- **Padcev (enfortumab vedotin-ejfv)** injection in combination with Keytruda (pembrolizumab) was approved to treat patients with muscle-invasive bladder cancer who are undergoing radical cystectomy (bladder removal) and who cannot receive cisplatin-based chemotherapy.
- **Pluvicto (lutetium Lu 177 vipivotide tetraxetan)** injection was approved to treat patients with prostate-specific membrane antigen metastatic castration-resistant prostate cancer that has progressed after an androgen receptor pathway inhibitor (a type of hormone therapy).
- **Rinvoq (upadacitinib)** tablets to treat patients with giant cell arteritis, an inflammatory condition of large arteries that reduces blood flow.
- **Spravato (esketamine)** nasal spray was approved for treatment-resistant depression (TRD) as a single therapy. The original approval was for TRD with an oral antidepressant.
- **Susvimo (ranibizumab)** injection was approved to treat patients with diabetic macular edema (a diabetes complication that occurs when fluid accumulates in the eyes and can cause vision problems) and diabetic retinopathy who have responded to other medications.
- **TNKase (tenecteplase)** infusion was approved to treat acute ischemic stroke (when a blood clot blocks an artery leading to the brain) up to three hours after stroke onset.
- **Tremfya (guselkumab)** infusion and injection was approved to treat moderately-to-severely active Crohn's disease. It was also approved in a new subcutaneous (under the skin) dosage form for moderately-to-severely active ulcerative colitis, another inflammatory bowel disease.
- **Uplizna (inebilizumab-cdon)** infusion was approved as the first treatment for immunoglobulin G4-related disease, a chronic inflammatory condition that can lead to organ damage. Uplizna was also approved for generalized myasthenia gravis.

In 2025, a previously approved drug was approved to treat giant cell arteritis, an inflammatory condition of the large arteries.

- **Wegovy (semaglutide)** injection to treat metabolic-associated steatohepatitis (MASH) in adults with moderate-to-advanced fibrosis (excessive scar tissue in the liver). MASH, also known as nonalcoholic steatohepatitis, is a serious liver disease.
- **Welireg (belsutifan)** tablets was approved to treat patients 12 years and older with locally advanced, unresectable, or metastatic pheochromocytoma or paraganglioma, rare tumors that arise from a type of endocrine cell.
- **Yervoy (ipilimumab)** infusion in combination with Opdivo (nivolumab) was approved to treat patients 12 years and older with unresectable or metastatic microsatellite instability-high or mismatch repair deficient colorectal cancer.
- **Yeztugo (lenacapavir)** injection was approved as the first every six-month subcutaneous injection dosing for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV in patients weighing at least 35 kg.
- **Zynyz (retifanlimab-dlwr)** injection was approved in combination with carboplatin and paclitaxel or as a single agent to treat types of squamous cell carcinoma of the anal canal.

FDA approved a previously approved treatment for MASH, a serious liver disease, in adults with moderate-to-advanced fibrosis.

Approved Drugs Expanded for New Pediatric Populations

FDA approved an episodic migraine drug for certain pediatric patients.

Section 505B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (often referred to by the legislation that originally created it, the Pediatric Research Equity Act, or PREA) and section 505A of the FD&C Act (often referred to by the legislation that originally created it, the Best Pharmaceuticals for Children Act, or BPCA) give CDER the authority to require (PREA) or request (BPCA) pediatric studies under certain circumstances. These two laws have been largely responsible for the inclusion of pediatric information in the labeling for many drugs.

If pediatric studies are required under PREA, sponsors must, among other things, conduct a pediatric assessment to study safety and effectiveness of the drug in the pediatric population. Under BPCA, the Agency may issue Written Requests if it determines that information relating to the use of a new drug in the pediatric population may produce health benefits in that population. Sponsors may obtain additional marketing exclusivity if they "fairly respond" to FDA's Written Request for pediatric studies.

The products below are examples of 2025 approvals under PREA or BPCA for drugs expanded to include new pediatric populations:

Note: *Some drugs are approved for new pediatric populations through other regulatory pathways. Those actions are not listed in this section*

- **Ajovy (fremanezumab-vrfm)** injection was approved to treat episodic migraine in patients six to 17 years who weigh more than 45 kg.

- **Baqsimi (glucagon)** powder was approved to treat hypoglycemia (low blood sugar) in patients one to four years with type 1 diabetes. Baqsimi was originally approved in 2019 for patients four years and older with type 1 diabetes.
- **Descovy (emtricitabine and tenofovir alafenamide)** tablets were approved in combination with other antiretroviral agents to treat HIV-1 infection in pediatric patients weighing 14 kg to less than 35 kg.
- **Dextenza (dexamethasone)** ophthalmic insert was approved to treat pediatric patients two years and older with ocular (eye) pain and inflammation following ophthalmic surgery and itching associated with allergic conjunctivitis (pink eye).
- **Dupixent (dupilumab)** injection was approved to treat patients 12 years and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment. CSU is a skin condition characterized by hives and deep tissue swelling without a clear external trigger.
- **Eliquis Sprinkle (apixaban)** oral suspension was approved to treat venous thromboembolism (VTE) and reduce the risk of recurrent VTE in patients from birth and older after at least five days of initial anticoagulant treatment. VTE occurs when a blood clot forms in a vein. A new oral suspension dosage form was also approved.
- **Linzess (linaclotide)** capsules were approved for pediatric patients seven years and older with irritable bowel syndrome with constipation.
- **Kalydeco (ivacaftor)** tablets and granules to treat cystic fibrosis in patients one month and older who have at least one mutation in the CFTR gene that responds to ivacaftor.
- **Neffy (epinephrine)** nasal spray was approved as the first non-injection epinephrine to treat anaphylaxis (a severe allergic reaction) for patients four years and older weighing 15 kg to less than 30 kg.
- **Opzelura (ruxolitinib)** cream was approved for short-term and non-continuous chronic treatment of mild-to-moderate atopic dermatitis in non-immunocompromised children two years and older whose disease is not well controlled with topical prescription therapies, or when those therapies are not recommended.
- **Prezcobix (cobicistat and darunavir)** tablets were approved to treat HIV-1 infection in patients six years and older weighing at least 25 kg to less than 40 kg.
- **Odefsey (emtricitabine, rilpivirine, and tenofovir alafenamide)** tablets were approved to treat pediatric patients six years and older weighing at least 25 kg to treat HIV-1 infection as initial therapy in patients with no antiretroviral treatment or to replace a stable antiretroviral regimen in patients who are virologically suppressed.
- **Simponi (golimumab)** injection was approved to treat moderately-to-severely active pediatric ulcerative colitis.

In 2025, FDA approved the first treatment for irritable bowel syndrome with constipation for pediatric patients aged 7 years and older.

- **Sivextro (tedizolid phosphate)** infusion and tablets were approved for patients from birth (who were at least 26 weeks gestational age at birth and weigh at least 1 kg) to younger than 12 years to treat acute bacterial skin and skin structure infections, a group of infections that affect the skin and underlying tissues.
- **Soliris (eculizumab)** injection was approved to treat patients six years and older with generalized myasthenia gravis.
- **Tybost (cobicistat)** tablets were approved in combination with certain other antiretroviral agents to treat HIV-1 infection in certain pediatric patients.
- **Tremfya (guselkumab)** injection was approved to treat patients six years and older who weigh at least 40 kg with moderate-to-severe plaque psoriasis, who are candidates for systemic therapy or phototherapy, or active psoriatic arthritis.
- **Xenoview (xenon Xe 129 hyperpolarized)** oral inhalation was approved for patients six years to younger than 12 years to evaluate lung ventilation with an MRI. It was originally approved in 2022 for patients 12 years and older.

Biosimilar Approvals

The biosimilar pathway is an abbreviated approval pathway for biologics that are highly similar to and have no clinically meaningful differences in terms of safety, purity, and potency (safety and effectiveness) from an FDA-approved biologic, called a reference product. This pathway helps provide more treatment options, increase patient access, and potentially reduce the cost of therapies through competition.

In 2025, CDER approved 18 new biosimilars for 10 reference products, including four for three new reference products. Several of these biosimilars were approved as interchangeable biosimilars, which are biosimilars that may be substituted for the reference product at the pharmacy without the intervention of the prescriber, subject to state law.

The biosimilars approved for new reference products in 2025 are:

- **Merilog (insulin aspart-szjj)** injection to improve glycemic control in patients with diabetes (Reference product: Novolog). Merilog was approved as the first biosimilar to Novolog. **Kirsty (insulin aspart-xjhz)** injection to improve glycemic control in patients with diabetes (Reference product: Novolog). Kirsty was approved as the first interchangeable biosimilar to Novolog.
- **Omlyclo (omalizumab-igec)** injection to treat moderate-to-severe persistent asthma, chronic rhinosinusitis with nasal polyps as an add-on treatment, immunoglobulin E-mediated food allergy, and chronic spontaneous urticaria (hives) after HI antihistamine treatment (Reference product: Xolair). Omlyclo was approved as an interchangeable biosimilar.
- **Poherdy (pertuzumab-dpzb)** infusion to treat HER2-positive metastatic, locally advanced, inflammatory, and early-stage breast cancer. Poherdy is used in combination with trastuzumab and docetaxel or chemotherapy, depending on the indication (Reference product: Perjeta). Poherdy was approved as an interchangeable biosimilar.

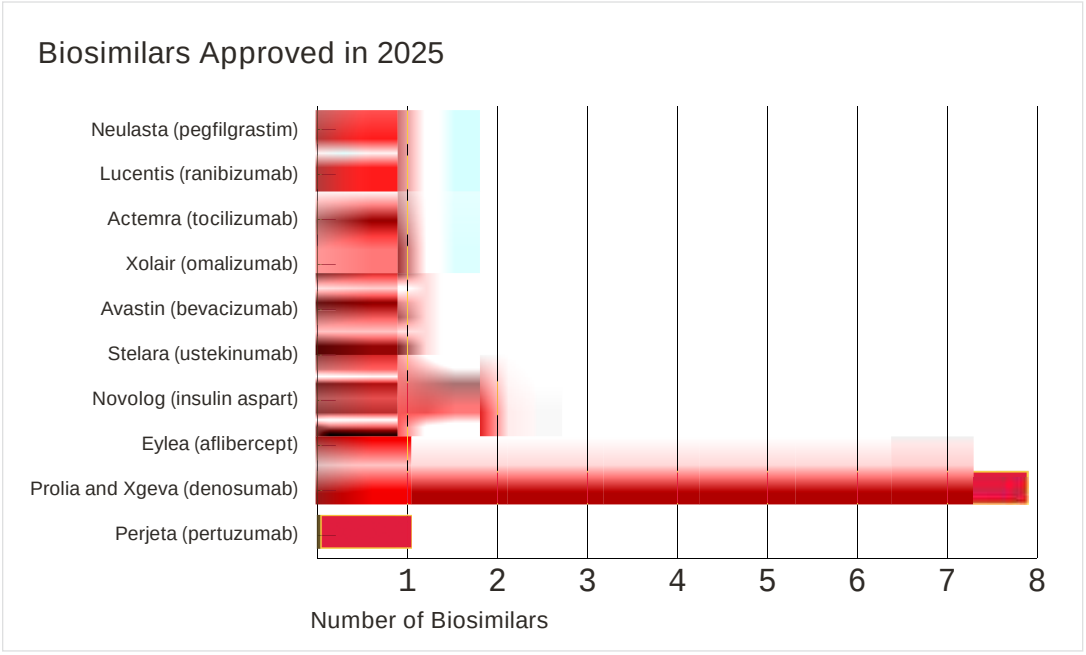
In 2025, CDER also approved many previously approved biosimilars as interchangeable biosimilars, including:

- 2 previously approved biosimilars to **Humira (adalimumab)** injection were approved as interchangeable products. Humira is approved to treat different types of inflammation, including kinds of arthritis, active ankylosing spondylitis, inflammatory bowel disease, and plaque psoriasis.
- 5 previously approved biosimilars to **Stelara (ustekinumab)** injection were approved as interchangeable products. Stelara is approved to treat plaque psoriasis, active psoriatic arthritis, and inflammatory bowel disease.
- 1 previously approved biosimilar to **Soliris (eculizumab)** injection was approved as an interchangeable product. It is approved for paroxysmal nocturnal hemoglobinuria to reduce hemolysis and for atypical hemolytic uremic syndrome to inhibit complement-mediated thrombotic microangiopathy.

In 2025, CDER approved 18 biosimilars for 10 reference products.

Also of note:

- 8 biosimilars to **Prolia/Xgeva (denosumab)** injection were approved last year as interchangeable biosimilars (6 of these were approved as biosimilar and later approved as interchangeable). Prolia/Xgeva is approved to treat osteoporosis in patients at high risk for fracture. It is also used to increase bone mass in patients with osteoporosis caused by medicine or cancer.
- **Pyzchiva (ustekinumab-ttwe**) injection autoinjector was approved as an interchangeable biosimilar to **Stelara's** prefilled syringe. It was approved as an autoinjector when there is no reference product available in an autoinjector. The approval was based, in part, on data from a comparative use human factors study that demonstrated that experienced users of the reference biologic could use the interchangeable biosimilar without additional training.
- 6 previously approved biosimilars to **Humira (adalimumab)** injection were approved for two new pediatric indications: hidradenitis suppurativa in patients 12 years and older and non-infectious intermediate, posterior, and panuveitis in patients two years and older.



CDER has approved 81 biosimilars for 20 different reference products since 2015.

CDER has approved 81 biosimilars for 20 different reference products since 2015. This includes at least one biosimilar for each of these top selling biologics in the U.S.:10 biosimilars to Humira; 9 biosimilars to Prolia and Xgeva; 8 biosimilars to Stelara; 7 biosimilars to Neulasta; 6 biosimilars to Avastin; 6 biosimilars to Eylea; 6 biosimilars to Herceptin; 4 biosimilars to Neupogen; 4 biosimilars to Remicade; 3 biosimilars to Actemra; 3 biosimilars to Lucentis; 3 biosimilars to Rituxan; 2 biosimilars to Enbrel; 2 biosimilars to Lantus; 2 biosimilars to Novolog; 2 biosimilars to Soliris; 1 biosimilar to Epogen/Procrit; 1 biosimilar to Perjeta; 1 biosimilar to Tysabri; and 1 biosimilar to Xolair.

Multiple biosimilars for an approved reference product can enhance competition, which increases patient access and may lead to reduced costs for both patients and our health care system.

Other Important Approvals

New formulations of approved drugs can offer significant therapeutic advances. Similarly, new dosage forms (such as from a capsule to a chewable tablet for those unable to swallow pills, or a needle to an oral solution for patients who are afraid of needles) can help increase adherence, make sure patients take the proper dose, and improve quality of life for patients who must use the medication on a prolonged basis. Below are examples of new formulations, drug-device combinations, new dosage forms and other notable approval actions of 2025:

- **Arbli (losartan potassium)** was approved in a new oral solution dosage form to lower blood pressure in patients older than six years.
- **Benlysta (belimumab)** was approved in a new subcutaneous injection dosage form for patients five years and older with active lupus nephritis who are receiving standard therapy.
- **Brynovin (sitagliptin)** was approved in a new oral solution dosage form to lower blood sugar in patients with type 2 diabetes.
- **Arynta (lisdexamfetamine dimesylate)** was approved in a new oral solution dosage form to treat attention deficit hyperactivity disorder and binge eating disorder.
- **Emblaveo (aztreonam and avibactam)** injection was approved in a new combination to treat complicated intra-abdominal infections.
- **Evrysdi (risdiplam)** was approved in a new tablet dosage for people with spinal muscular atrophy. The tablet can either be swallowed whole or dispersed in water.
- **Inlexzo (gemcitabine)** releasing system was approved as a drug-device combination that slowly releases a chemotherapy (gemcitabine) into the bladder to treat a type of non-muscle invasive bladder cancer.

Last year, FDA approved a new oral dosage form of a drug to treat attention deficit hyperactivity disorder and binge eating disorder.

- **Inzirqo (hydrochlorothiazide)** was approved in a new oral suspension dosage form to lower blood pressure in patients alone or in combination with other antihypertensive agents.
- **Leqembi Iqlik (lecanemab-irmb)** was approved as a subcutaneous (under-the-skin) injection dosage form for maintenance treatment of adults with Alzheimer's disease who have completed at least 18 months of treatment with intravenous (administered into the vein) Leqembi, allowing for home administration by a patient or caregiver.
- **Miudella (copper-releasing)** intrauterine system (IUS) was approved to prevent pregnancy for up to three years. Miudella is a drug-device combination and the second copper-containing IUS.
- **Soliris (eculizumab)** injection was approved to treat patients six years and older with generalized myasthenia gravis, a chronic autoimmune disorder that causes muscle weakness.
- **Sublocade (buprenorphine extended-release)** injection was approved in a new dosing regimen to treat opioid use disorder. Patients previously received seven days of sublingual (under the tongue) buprenorphine treatment before starting Sublocade, but now patients receive only one sublingual buprenorphine dose beforehand.
- **Vykat XR (diazoxide choline)** tablets were approved in a new formulation to treat hyperphagia (excessive and insatiable appetite) in patients four years and older with Prader-Willi syndrome, a condition where patients do not feel full after eating.
- **Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)** was approved in a new prefilled syringe dosage form for patients with generalized myasthenia gravis with certain antibodies and patients with chronic inflammatory demyelinating polyneuropathy, a rare autoimmune disorder.
- **Wegovy (semaglutide)** was approved in a new tablet dosage form to reduce the risk of major adverse cardiovascular events and for weight reduction in adults at high risk.
- **Zusduri (mitomycin)** was approved in a new formulation to treat recurrent low-grade, intermediate-risk, non-muscle invasive bladder cancer. The new formulation forms a semi-solid gel in the bladder for sustained drug release, providing a pharmacologic alternative to repeated surgical interventions.

Please note that all drugs carry risks and patients should review the drug labeling and consult with their health care professional to determine their preferred course of treatment.

In 2025, FDA approved a new dosing regimen for an opioid use disorder drug, aiming to improve treatment adherence.

Conclusion

Reviewing a drug application — whether for a novel drug or other notable approval — is a collaborative, well-coordinated process that involves scientific, regulatory, and policy experts from throughout CDER and sometimes other parts of the agency. For each application, we perform a very careful and diligent analysis of safety and effectiveness data, including a benefit-risk analysis that factors in the severity of the disease or condition, the available treatment options, and the intended patient population. If the therapy meets the standard for approval, we must reach agreement on the indication, labeling, safety issues, and other considerations.

We also listen to input from external parties. We often consult outside scientific experts, patients and patient advocates, industry representatives, academics, and other community members who are involved in drug development and review. Each of these parties has their unique expertise and perspective, and we consider their viewpoints. We take our regulatory decision-making seriously, because we know our decisions affect the health and well-being of patients and consumers nationwide.

Appendix A: CDER's Novel Approvals of 2025
(in alphabetical order)

For information about vaccines, allergenic products, blood and blood products, cellular and gene therapy products, go to the 2025 Biologics License Application Approvals.

Approval Date	Drug Name	Active Ingredient	FDA-approved Use on Approval Date	Dosage Form
6/16/2025	Andembry	garadacimab-gxii	To prevent attacks of hereditary angioedema	Injection
7/23/2025	Anzupgo	delgocitinib	To treat moderate-to-severe chronic hand eczema when topical corticosteroids are not advisable or produce an inadequate response	Cream
5/8/2025	Avmapki Fakzynja (co-packaged)	avutometinib and defactinib	To treat KRAS-mutated recurrent low-grade serous ovarian cancer (LGSOC) after prior systemic therapy	Capsule
3/25/2025	Blujepa	gepotidacin	To treat uncomplicated urinary tract infections	Tablet
8/12/2025	Brinsupri	brensocatib	To treat non-cystic fibrosis bronchiectasis	Tablet
12/12/2025	Cardamyst	etripamil	To treat episodes of paroxysmal supraventricular tachycardia	Nasal spray
1/17/2025	Datroway	datopotamab deruxtecan-dlnk	To treat patients with unresectable or metastatic, HR-positive, HER2-negative breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease	Injection
8/21/2025	Dawnzera	donidalorsen	To prevent attacks of hereditary angioedema	Injection
7/3/2025	Ekterly	sebetralstat	To treat acute attacks of hereditary angioedema	Tablet
5/14/2025	Emrelis	telisotuzumab vedotin-tllv	To treat locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC) with high c-Met protein overexpression after prior systemic therapy	Injection
6/9/2025	Enflonsia	clesrovimab-cfor	To prevent respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and infants who are born during or entering their first RSV season	Injection
12/16/2025	Exdensur	depemokimab-ulaa	To treat severe asthma characterized by an eosinophilic phenotype as an add-on maintenance therapy	Injection

Appendix A (continued)

Approval Date	Drug Name	Active Ingredient	FDA–approved Use on Approval Date	Dosage Form
9/19/2025	Forzinity	elamipretide	To improve muscle strength in patients with Barth syndrome weighing at least 30 kg	Injection
2/11/2025	Gomekli	mirdametinib	To treat neurofibromatosis type 1 who have symptomatic plexiform neurofibromas not amenable to complete resection	Tablet
1/21/2025	Grafapex	treosulfan	To use in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation for acute myeloid leukemia and myelodysplastic syndrome	Injection
8/8/2025	Hernexeos	zongertinib	To treat adults with unresectable or metastatic non-squamous non-small cell lung cancer whose tumors have HER2 tyrosine kinase domain activating mutations, as detected by an FDA-approved test, and who have received prior systemic therapy	Tablet
11/19/2025	Hyrnuo	sevabertinib	To treat locally advanced or metastatic non-squamous non-small cell lung cancer with tumors that have activating HER2 tyrosine kinase domain activating mutations in patients who received a systemic therapy	Tablet
6/11/2025	Ibtrozi	taletrectinib	To treat locally advanced or metastatic ROS1-positive non-small cell lung cancer	Capsule
4/29/2025	Imaavy	nipocalimab-aahu	To treat generalized myasthenia gravis	Injection
9/25/2025	Inluriyo	imlunestrant	To treat estrogen receptor-positive, human epidermal growth factor receptor 2-negative, estrogen receptor-1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy	Tablet
10/7/2025	Jascayd	nerandomilast	To treat idiopathic pulmonary fibrosis	Tablet
1/30/2025	Journavx	suzetrigine	To treat moderate-to-severe acute pain	Tablet
9/19/2025	Keytruda Qlex	pembrolizumab and berahyaluronidase alfa-pmph	To treat adult and pediatric (12 years and older) solid tumor indications approved for the intravenous formulation of pembrolizumab	Injection

Appendix A (continued)

Approval Date	Drug Name	Active Ingredient	FDA-approved Use on Approval Date	Dosage Form
11/13/2025	Komzifti	ziftomenib	To treat adults with relapsed or refractory acute myeloid leukemia with a susceptible nucleophosmin 1 mutation who have no satisfactory alternative treatment options	Capsule
11/3/2025	Kygevvi	doxecitine and doxribtimine	To treat thymidine kinase 2 deficiency in patients who start to show symptoms when they are 12 years old or younger	Powder
12/12/2025	Lerochol	lerodalcibep-liga	To reduce low-density lipoprotein cholesterol in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia, as an adjunct to diet and exercise	Injection
10/24/2025	Lynkuet	elinzanetant	To treat moderate-to-severe vasomotor symptoms due to menopause	Capsule
7/2/2025	Lynozyfic	linvoseltamab-gcpt	To treat relapsed or refractory multiple myeloma after at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti CD38 monoclonal antibody	Injection
8/6/2025	Modeyso	dordaviprone	To treat diffuse midline glioma harboring an H3 K27M mutation with progressive disease following prior therapy	Capsule
12/19/2025	Myqorzo	aficamten	To treat adults with symptomatic obstructive hypertrophic cardiomyopathy to improve functional capacity and symptoms	Tablet
12/30/2025	Nereus	tradipitant	To treat vomiting associated with motion	Capsule
12/12/2025	Nuzolvence	zoliflodacin	To treat uncomplicated urogenital gonorrhea due to Neisseria gonorrhoeae	Oral suspension
9/25/2025	Palsonify	paltusotine	To treat acromegaly in adults who had an inadequate response to surgery and/or for whom surgery is not an option	Tablet

Appendix A (continued)

Approval Date	Drug Name	Active Ingredient	FDA–approved Use on Approval Date	Dosage Form
4/23/2025	penpulimab-kcqx*	penpulimab-kcqx	In combination with either cisplatin or carboplatin and gemcitabine, to treat adults with recurrent or metastatic non-keratinizing nasopharyngeal carcinoma (NPC), or as a single agent while on or after platinum-based chemotherapy and at least one other prior line of therapy	Injection
3/28/2025	Qfitlia	fitusiran	To prevent or reduce the frequency of bleeding episodes in hemophilia A or B	Injection
11/18/2025	Redemplo	plozasiran	To reduce triglycerides in adults with familial chylomicronemia syndrome	Injection
9/30/2025	Rhapsido	remibrutinib	To treat chronic spontaneous urticaria in adults who remain symptomatic despite H1 antihistamine treatment	Tablet
2/14/2025	Romvimza	vimseltinib	To treat symptomatic tenosynovial giant cell tumor for which surgical resection will potentially cause worsening functional limitation or severe morbidity	Capsule
7/28/2025	Sephience	sepiapterin	To treat hyperphenylalaninemia in patients with sepiapterin-responsive phenylketonuria, in conjunction with a phenylalanine-restricted diet	Powder
5/28/2025	Tryptyr	acoltremon	To treat the signs and symptoms of dry eye disease	Ophthalmic solution
4/02/2025	Vanrafia	atrasentan	To reduce proteinuria in adults with primary immunoglobulin A nephropathy at risk of rapid disease progression	Tablet
7/31/2025	Vizz	aceclidine	To treat presbyopia	Ophthalmic solution
11/25/2025	Voyxact	sibeprenlimab-szsi	To reduce proteinuria in primary immunoglobulin A nephropathy in adults at risk for disease progression	Injection
12/23/2025	Yartemlea	narsoplimab-wuug	To treat hematopoietic stem cell transplant-associated thrombotic microangiopathy	Injection
7/2/2025	Zegfrovy	sunvozertinib	To treat locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor exon 20 insertion mutations, as detected by an FDA-approved test, with disease progression on or after platinum-based chemotherapy	Tablet

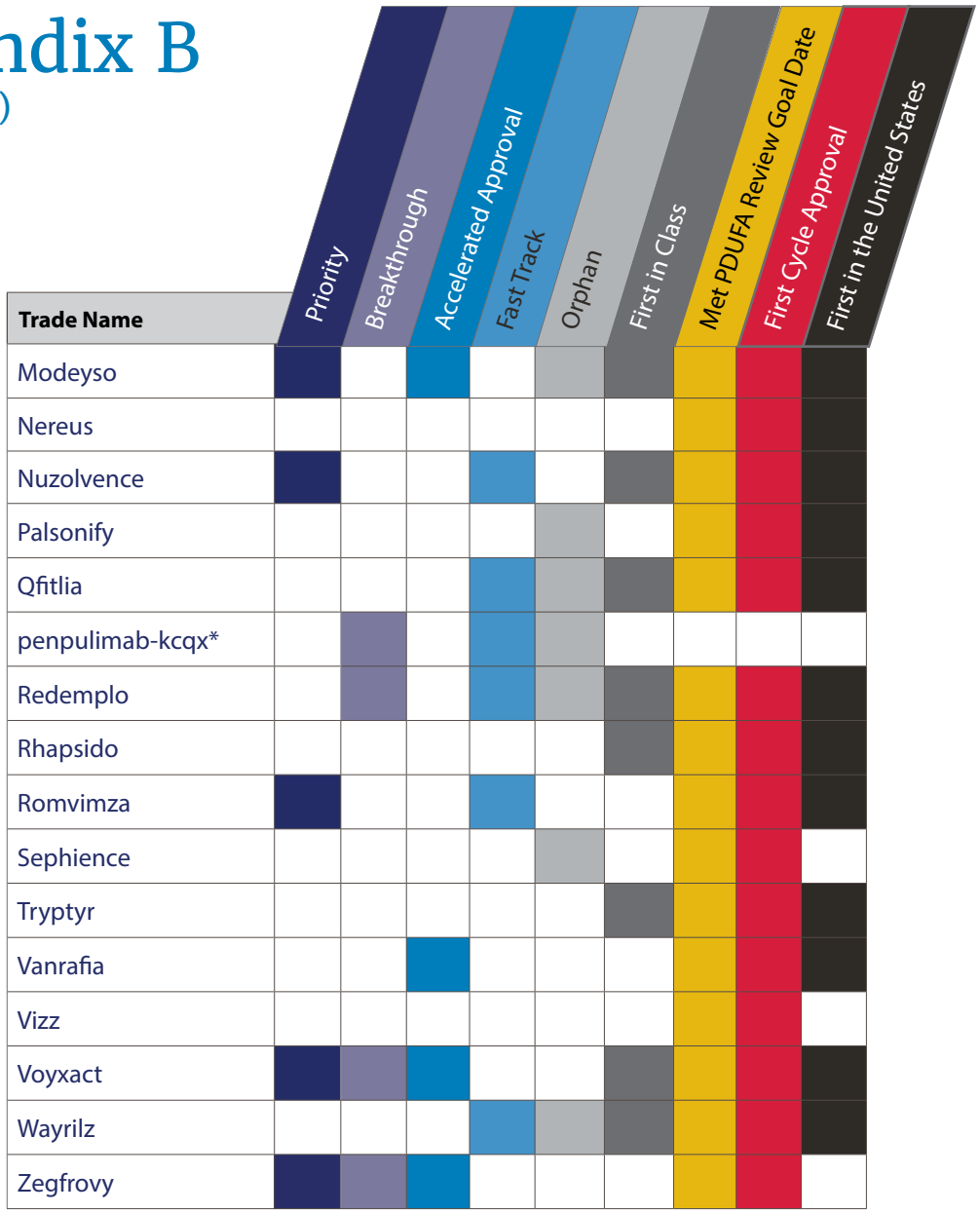
**Approved without a trade name*

Appendix B: Novel Drug Designations

(in alphabetical order)

Trade Name	Priority	Breakthrough	Accelerated Approval	Fast Track	Orphan	First in Class	Met PDUFA Review Goal Date	First Cycle Approval	First in the United States
Andembry				■	■	■	■		
Anzupgo				■			■	■	
Avmapki Fakzynja (co-packaged)	■	■	■		■	■	■	■	■
Blujepa	■					■	■	■	■
Brinsupri	■					■	■	■	■
Cardamyst							■	■	■
Datroway							■	■	
Dawnzera					■	■	■	■	■
Ekterly				■	■			■	■
Emrelis	■	■	■			■	■	■	■
Enflonsia				■			■	■	■
Forzinity	■		■	■	■	■	■	■	■
Gomekli	■			■	■		■	■	■
Grafapex					■		■		
Hernexeos	■	■	■	■			■	■	■
Hyrnuo	■	■	■		■		■	■	■
Ibtrozi	■	■			■		■	■	■
Imaavy	■			■	■		■	■	■
Inluriyo				■			■	■	■
Jascayd	■	■			■	■	■	■	■
Journavx	■	■		■		■	■	■	■
Keytruda Qlex			■				■	■	■
Komzifti	■	■		■	■	■	■	■	■
Kygevvi	■	■			■		■	■	■
Lerochol							■	■	■
Lynkuet							■	■	■
Lynozyfic	■		■	■	■		■		■

Appendix B
(continued)



Trade Name	Priority	Breakthrough	Accelerated Approval	Fast Track	Orphan	First in Class	Met PDUFA Review Goal Date	First Cycle Approval	First in the United States
Modeyso	■		■		■	■	■	■	■
Nereus							■	■	■
Nuzolvence	■			■		■	■	■	■
Palsonify					■		■	■	■
Qfitlia				■	■	■	■	■	■
penpulimab-kcqx*		■		■	■				
Redemplo		■		■	■	■	■	■	■
Rhapsido						■	■	■	■
Romvimza	■			■			■	■	■
Sephience					■		■	■	
Tryptyr						■	■	■	■
Vanrafia			■				■	■	■
Vizz							■	■	
Voyxact	■	■	■			■	■	■	■
Wayrilz				■	■	■	■	■	■
Zegfrovy	■	■	■				■	■	

*Approved without a trade name

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