U.S. FOOD & DRUG ADMINISTRATION

CENTER FOR DRUG EVALUATION AND RESEARCH

Advancing Health Through Innovation:

New Drug Therapy Approvals 2022

INNOVATION PREDICTABILITY ACCESS

January 2023

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Director's Message

Patrizia Cavazzoni, M.D.

Director, Center for Drug Evaluation and Research

Welcome to FDA's Center for Drug Evaluation and Research's (CDER) 12th iteration of the annual report, *Advancing Health Through Innovation: New Drug Therapy Approvals.* This report showcases our role in bringing drug therapies to patients that are safe and effective.

2022 marked the third consecutive year that COVID-19 has taken its toll on the global community. Mpox also emerged as a public health concern. Despite these hardships, we approved many therapies to prevent, diagnose, and treat a wide range of diseases and conditions.

Our report highlights CDER's novel approvals of 2022 that will make a difference in people's lives. The report also illustrates the ways we evaluated drug safety and efficacy, as well as the regulatory tools we used to review and approve drug applications. We approved almost all of these therapies on or before their goal dates, or congressionally authorized agreements with industry. More than half were approved in the U.S. before any other country.

The report also includes examples of previously approved drugs that CDER approved in new settings in 2022, such as for a different disease, a new patient population (e.g., children), or in a new dosage form or formulation. Regarding pediatrics, the report includes a section describing CDER's actions to expand the use of previously approved products to child or adolescent populations.

We approved many drugs in 2022 for patients with few or no treatment options. Other approvals offered improvements in efficacy, safety, or ease of use.

In 2022, we approved the 40th biosimilar, a milestone in biosimilar product development. CDER also approved two interchangeable biosimilar products, which are biosimilars that meet additional requirements and may be substituted for the reference product at the pharmacy without the intervention of a prescriber, subject to state law, similar to how generic drugs are substituted for brand name drugs.

In September 2022, Congress authorized the Prescription Drug User Fee Program Act (PDUFA) VII, the Biosimilar User Fee Act (BsUFA) III, and other FDA user fee programs. These programs provide essential funding for the review of medical products and ultimately help the agency fulfill its public health mission. For more information, please see the PDUFA VII and the BsUFA III commitment letters on the FDA website.

This report captures CDER's 2022 approvals and spotlights examples of notable treatments. FDA's Center for Biologics Evaluation and Research (CBER) also approves important therapies. Please visit CBER's webpage for 2022 Biological Product Approvals for information on these actions.

We hope this report helps demonstrate CDER's unrelenting commitment to improving patient care through the approval of safe and effective treatments.

Patrizia Cavazzoni, M.D.
Director, Center for Drug Evaluation and Research

This report captures CDER's 2022 approvals and spotlights examples of notable treatments.

Executive Summary

CDER approved many safe and effective drug therapies in 2022, even as we contended with the COVID-19 pandemic. These approvals, spanning a wide range of diseases and conditions, will help many people live better and potentially longer lives.

Innovation Across Medical Conditions

In 2022, we approved 37 new drugs never before approved or marketed in the U.S., known as "novel" drugs. We also approved previously approved drugs in new settings, such as for new indications and patient populations.

The 2022 actions, both novel drug approvals and drugs approved in new settings, target diseases and conditions such as:

- Infectious diseases, including COVID-19, HIV, smallpox, influenza, and *H. pylori* infection, a bacterial infection in the stomach.
- Neurological conditions, such as amyotrophic lateral sclerosis and spinal muscular atrophy.
- Heart, blood, kidney, and endocrine diseases, such as type 1 diabetes and type 2 diabetes, a type of anemia, types of kidney impairment, and chronic weight management.

- Autoimmune, inflammatory, and lung conditions, such as inflammatory bowel disease, nutritional deficiencies, lupus nephritis, arthritis, eosinophilic esophagitis (a chronic inflammatory disorder), and psoriasis.
- Different types of cancers, such as lung cancer, prostate cancer, types of breast cancer, a rare overgrowth syndrome known as PROS, and melanoma.

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 2022, 20 of 37, or 54% of our novel drug approvals, were for rare diseases, including:

- Acid sphingomyelinase deficiency (Niemann-Pick disease type A, B, A/B), an inherited disease that affects the body's ability to metabolize fat.
- Generalized pustular psoriasis, a rare, life-threatening skin disease.
- Obstructive hypertrophic cardiomyopathy, a disease in which the heart muscle thickens.
- Metastatic or unresectable uveal melanoma, a rare cancer that develops in a part of the eye called the uvea.
- Hepatorenal syndrome, a form of impaired kidney function in people with advanced liver disease.

Efficiencies in Bringing Therapies to Market

Our 2022 approvals demonstrate efficiencies in our review process, as shown by the following:

- **User Fee Goal Performance:** In 2022, CDER met or exceeded its PDUFA goal dates for 36 of 37 the novel drugs approved (97%).
- **First Cycle Approvals:** In 2022, CDER approved 28 of the 37 novel approvals (76%) on the first cycle. This differs from CDER not approving the drug when the sponsor first submits the application and possibly asking the sponsor for more information.
- **Approvals in U.S. Before Other Countries:** 25 of the 37 novel drugs approved in 2022 (68%) 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 2022, 24 of the 37 of CDER's novel drug approvals (65%) used one or more of these expedited programs.

CDER's Novel Drug Approvals of 2022

In 2022, CDER approved 37 novel drugs, either as new molecular entities (NMEs) under New Drug Applications (NDAs), or as new therapeutic biological products under Biologics License Applications (BLAs). The active ingredient(s) in a novel drug has never been approved in the U.S.

The number of drug applications CDER received in 2022 was similar to the past few years (and higher than historical norms), demonstrating that innovation remains strong in the drug development sector. CDER only approves drug and biologic applications that meet our high regulatory standards.

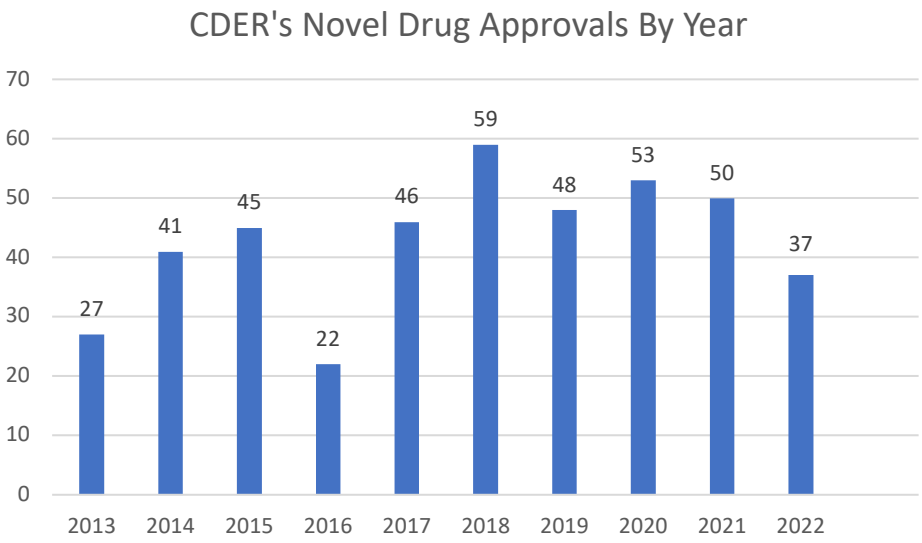
CDER's novel drug approvals for 2022 are listed alphabetically below by trade name.*

Trade Name	Active Ingredient(s)
Amvuttra	vutrisiran
Briumvi	ublituximab-xiiy
Camzyos	mavacamten
Cibinqo	abrocitinib
Daxxify	daxibotulinumtoxinA-lanm
Elahere	mirvetuximab soravtansine-gynx
Elucirem	gadopiclenol
Enjaymo	sutimlimab-jome
Imjudo	tremelimumab-actl
Kimmtrak	tebentafusp-tebn
Krazati	adagrasib
Lunsumio	mosunetuzumab-axgb
Lytgobi	futibatinib
Mounjaro	tirzepatide
NexoBrid	anacaulase-bcdb
Omlonti	omidenepag isopropyl
Opdualag	nivolumab and relatlimab-rmbw
Pluvicto	lutetium Lu 177 vipivotide tetraxetan
Pyrukynd	mitapivat
Quviviq	daridorexant
Relyvrio	sodium phenylbutyrate and taurursodiol
Rezlidhia	olutasidenib
Rolvedon	eflapegrastim-xnst
Sotyktu	deucravacitinib
Spevigo	spesolimab-sbzo
Sunlenca	lenacapavir
Tecvayli	teclistamab-cqyv
Terlivaz	terlipressin
Tzield	teplizumab-mzwv
Vabysmo	faricimab-svoa
Vivjoa	oteseconazole
Vonjo	pacritinib
Voquezna Triple Pak	vonoprazan, amoxicillin, and clarithromycin (co-packaged)
Vtama	tapinarof
Xenoview	hyperpolarized Xe-129
Xenpozyme	olipudase alfa-rpcp
Ztalmy	ganaxolone

** This information is accurate as of December 31, 2022. 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.*

CDER's Annual Novel Drug Approvals: 2013–2022

The 10-year graph below shows that from 2013 through 2022, CDER has averaged about 43 novel drug approvals per year.



CDER approved 20 first-in-class drugs in 2022.

First-in-Class Drugs

CDER identified 20 of the 37 novel drugs approved in 2022 (54%) as first-in-class. These drugs have mechanisms of action different from those of existing therapies.

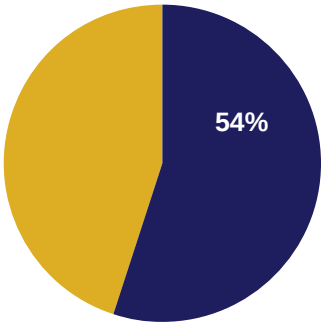
Novel drugs approved in 2022 that CDER identified as first-in-class were:

Camzyos, Elahere, Enjaymo, Kimmtrak, Lunsumio, Mounjaro, Opdualag, Pluvicto, Pyrukynd, Sotyktu, Spevigo, Sunlenca, Tecvayli, Terlivaz, Tzield, Voquezna Triple Pak, Vtama, Xenoview, Xenpozyme, Ztalmy

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

- **Camzyos (mavacamten)** capsules to improve functional capacity and symptoms in patients with a type of obstructive hypertrophic cardiomyopathy, in which the heart muscle thickens, making it harder to pump blood.
- **Mounjaro (tirzepatide)** injection to improve glycemic control in adults with type 2 diabetes, as an addition to diet and exercise. Mounjaro is a first-in-class medication that activates two hormone receptors, which leads to improved glycemic control.

First-in-Class Drugs



CDER identified 20 of the 37 (54%) novel drugs approved in 2022 as first-in-class.

- **Pluvicto (lutetium 177 Lu vipivotide tetraxetan)** injection to treat adults with prostate-specific, membrane-positive, metastatic, castration-resistant (cancer that grows despite reduced amounts of testosterone) prostate cancer who have received at least two prior therapies, including a chemotherapy [see also Locametz on page 17].
- **Sunlenca (lenacapavir)** tablets and injection for adults with HIV who have previously received many HIV therapies and whose disease cannot be treated with other available drugs due to resistance, intolerance, or safety concerns. After patients complete a starting dose of Sunlenca, they receive injections once every six months. Patients receive Sunlenca in combination with other antiretroviral(s).
- **Tzield (teplizumab-mzwv)** injection to delay the onset of Stage 3 type 1 diabetes in adults and pediatric patients aged 8 years and older with Stage 2 type 1 diabetes. Tzield is the first drug approved for this indication.
- **Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin)** and **Voquezna Dual Pak (vonoprazan and amoxicillin)** are co-packaged products containing combinations of tablets and capsules to treat adults with *H. pylori* infection, a bacterial infection in the stomach.

Drugs in brackets refer to other treatments for the same or similar disease.

Drugs for Rare Diseases

In 2022, 20 of CDER's 37 novel drug approvals (54%) were approved to treat rare or "orphan" 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 2022 with the orphan drug designation were:

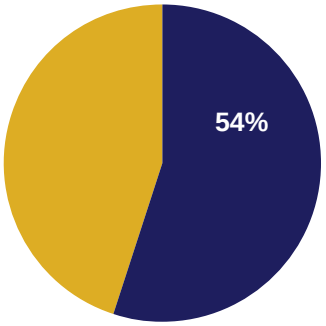
Amvuttra, Camzyos, Elahere, Enjaymo, Imjudo, Kimmtrak, Krazati, Lunsumio, Lytgobi, NexoBrid, Opdualag, Pyrukynd, Relyvrio, Rezlidhia, Spevigo, Tecvayli, Terlivaz, Vonjo, Xenpozyme, Ztalmy

Examples of novel approvals of 2022 for rare diseases include:

- **Amvuttra (vutrisiran)** injection to treat polyneuropathy (damage of multiple nerves throughout the body) in adults with hereditary transthyretin-mediated amyloidosis, a disease that leads to organ and tissue dysfunction.
- **Elahere (mirvetuximab soravtansine-gynx)** injection to treat patients with recurrent ovarian cancer that is resistant to platinum therapy.
- **Enjaymo (sutimlimab-jome)** injection to decrease the need for red blood cell transfusion due to hemolysis (red blood cell destruction) in adults with cold agglutinin disease, a rare type of anemia.

CDER approved the first therapy for a rare cancer that develops in a part of the eye called the uvea.

Orphan Drug Approvals



20 (54%) of CDER's 37 novel drug approvals were for rare or orphan diseases.

- **Imjudo (tremelimumab-actl)** injection to treat unresectable hepatocellular carcinoma, the most common type of liver cancer, in combination with Imfinzi [see page 17].
- **Kimmtrak (tebentafusp-tebn)** injection is the first therapy for metastatic or unresectable uveal melanoma, a rare cancer that develops in a part of the eye called the uvea.
- **Lunsumio (mosunetuzumab-axgb)** injection to treat adults with relapsed or refractory follicular lymphoma, a type of non-Hodgkin lymphoma. Lunsumio was approved through the Accelerated Approval program.
- **Opdualag (nivolumab and relatlimab-rmbw)** injection to treat patients aged 12 years or older with metastatic or unresectable melanoma.
- **Pyrukynd (mitapivat)** tablets to treat hemolytic anemia (a disorder in which red blood cells are destroyed faster than they can be made) in adults with pyruvate kinase deficiency, an inherited disorder that causes premature red blood cell destruction.
- **Relyvrio (taurusodiol and sodium phenylbutyrate)** powder for oral solution to treat amyotrophic lateral sclerosis (ALS), a progressive neurodegenerative disease that affects nerve cells in the brain and spinal cord.
- **Spevigo (spesolimab-sbzo)** injection to treat flares in patients with generalized pustular psoriasis, a life-threatening skin disease. Spevigo is the first approved treatment for this disease.
- **Tecvayli (teclistamab-cqyv)** injection to treat adults with relapsed and refractory multiple myeloma who have received at least four prior therapies. Tecyayli was approved through the Accelerated Approval program.
- **Terlivaz (terlipressin)** injection to improve kidney function in adults with hepatorenal syndrome, a rare form of impaired kidney function in people with advanced liver disease. Terlivaz is the first approved medication for this condition.
- **Vonjo (pacritinib)** capsules to treat adults with a rare bone marrow disorder known as intermediate or high-risk primary or secondary myelofibrosis and who have platelet (blood clotting cells) levels below 50,000/μL. Vonjo was approved through the Accelerated Approval program.
- **Xenpozyme (olipudase alfa-rpcp)** infusion to treat non-central nervous system manifestations of acid sphingomyelinase deficiency (Niemann-Pick disease type A, B, A/B). This is the first treatment for this inherited disease that affects the body's ability to metabolize fat and can impact the lung, liver, and spleen.

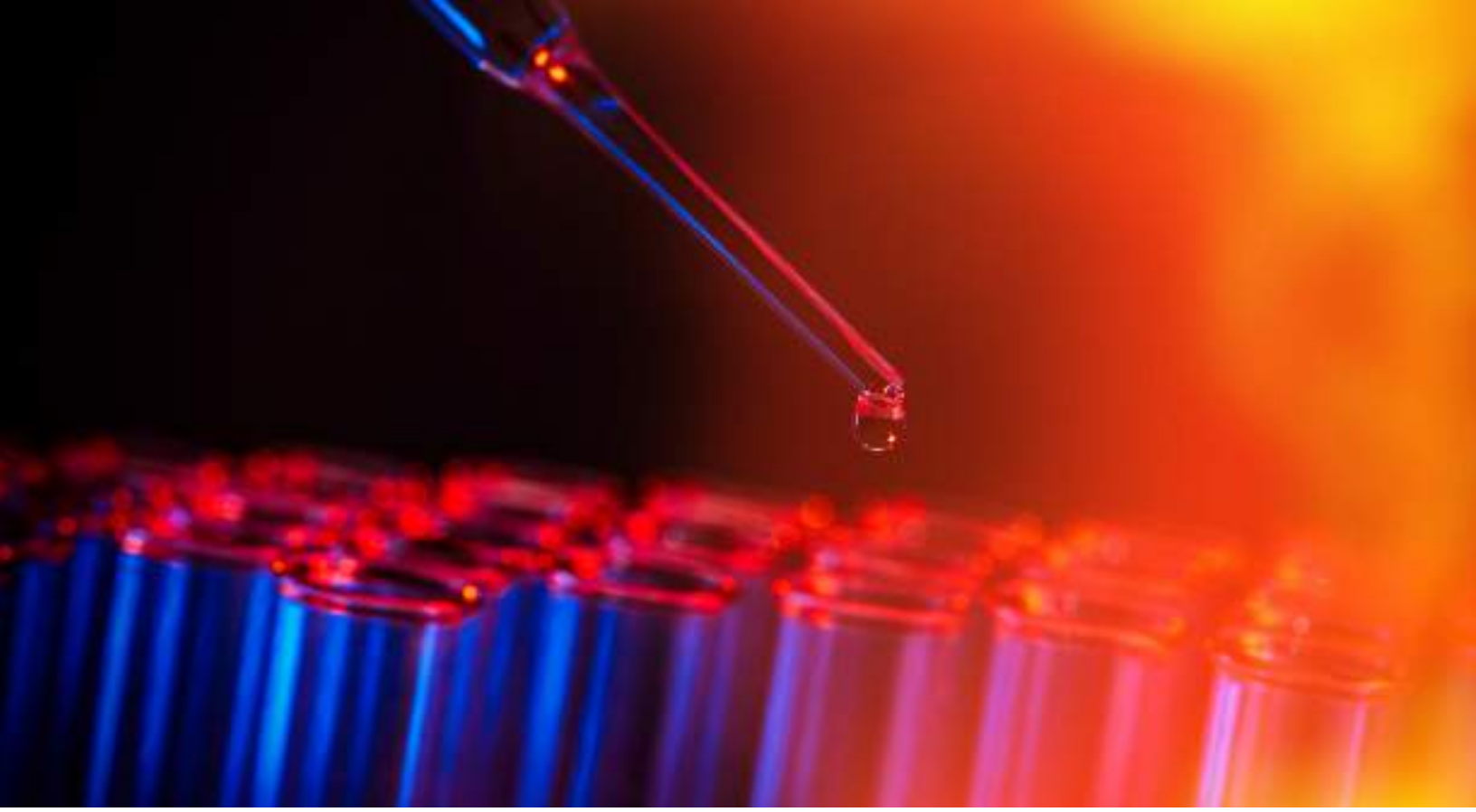
- **Ztalmy (ganaxolone)** oral suspension to treat seizures associated with cyclin-dependent kinase-like 5 deficiency disorder (CDD) in patients aged two years and older. This is the first treatment for seizures associated with CDD and the first treatment specifically for CDD, a type of brain dysfunction caused by gene mutations.

Other Novel Drug Approvals

In addition to the first-in-class and drugs for rare diseases, CDER approved these notable approvals in 2022:

- **Cibinqo (abrocitinib)** tablets to treat unmanageable, moderate-to-severe atopic dermatitis (eczema).
- **Vtama (tapinarof)** cream for the topical treatment of adults with plaque psoriasis, a condition that causes dry, itchy, raised skin patches.

In 2022, CDER approved the first drug to treat patients with generalized pustular psoriasis, a skin disease.



Innovation: Expedited Development and Review Pathways

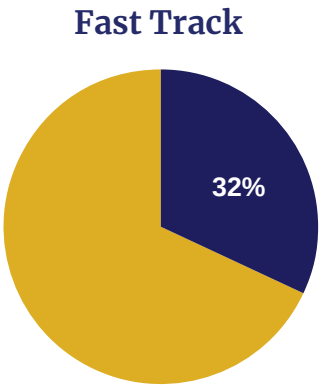
CDER used diverse regulatory approaches to enhance and expedite drug review in 2022. These approaches enable increased flexibility, efficiency, and interactions between CDER staff and drug developers. These approaches often also allow shorter review times to speed the availability of new therapies to patients with serious conditions, especially in cases where there are no satisfactory alternative therapies, while preserving FDA's rigorous standards for safety and effectiveness.

Fast Track

CDER granted Fast Track status to 12 of the 37 novel drugs (32%) approved in 2022. Fast Track speeds development and review of new drug and biological products 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:

Amvuttra, Elahere, Krazati, Lytgobi, Opdualag, Pyrukynd, Sunlenca, Terlivaz, Vivjoa, Vonjo, Voquezna Triple Pak, Xenpozyme



CDER designated 12 of the 37 novel drugs (32%) as Fast Track.

Breakthrough Therapy

CDER designated 13 of the 37 novel drugs (35%) in 2022 as Breakthrough Therapies. A Breakthrough Therapy designation includes all the Fast Track program features and also offers intensive FDA guidance during drug development, including involvement from senior managers.

Drugs designated Breakthrough Therapy for the indication approved were:

Camzyos, Cibinqo, Enjaymo, Kimmtrak, Krazati, Lunsumio, Lytgobi, Pluvicto, Spevigo, Sunlenca, Tecvayli, Tzield, Xenpozyme

Priority Review

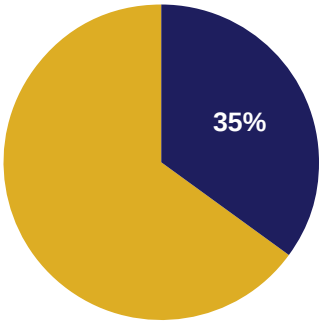
In 2022, 21 of the 37 novel drugs approved (57%) were designated Priority Review. A drug receives a Priority Review designation if CDER determines that the drug treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions. 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).

(In some instances, sponsors may redeem a priority review voucher under CDER's Priority Review Voucher program. Such drugs are not included in the list below.)

Drugs designated Priority Review in 2022 were:

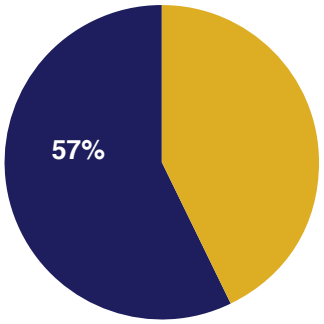
Cibinqo, Elahere, Elucirem, Enjaymo, Kimmtrak, Lunsumio, Lytgobi, Opdualag, Pluvicto, Pyrukynd, Relyvrio, Spevigo, Sunlenca, Tecvayli, Terlivaz, Tzield, Vivjoa, Vonjo, Voquezna Triple Pak, Xenpozyme, Ztalmy

Breakthrough Therapy



CDER identified 13 of the 37 (35%) novel drugs of 2022 as Breakthrough Therapies.

Priority Review



CDER identified 21 of the 37 (57%) drugs approved in 2022 as Priority Review.

Accelerated Approval

CDER approved six of the 37 novel drugs (16%) in 2022 under Accelerated Approval. This program aims to bring to market drugs that can provide important treatment advances on a faster timeline than through a traditional approval pathway. 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 eligible for Accelerated Approval, 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.

Such alternate endpoints may enable the drug to be studied for a shorter treatment duration and to receive Accelerated Approval. For products approved under Accelerated Approval, FDA requires post-approval studies designed to confirm clinical benefit, and, among other things, may withdraw the product from the market for failure to confirm clinical benefit.

The novel drugs approved in 2022 via Accelerated Approval were:

Elahere, Krazati, Lunsumio, Lytgobi, Tecvayli, Vonjo

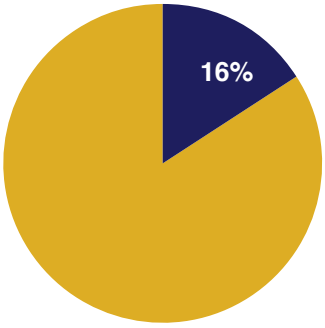
Overall Use of Expedited Development and Review Methods

24 of the 37 novel drug approvals of 2022 (65%) used one or more expedited programs, specifically Fast Track, Breakthrough Therapy, Priority Review, or Accelerated Approval.

Novel drugs approved in 2022 that used at least one expedited program were:

Amvuttra, Camzyos, Cibinqo, Elahere, Elucirem, Enjaymo, Kimmtrak, Krazati, Lunsumio, Lytgobi, Opdualag, Pluvicto, Pyrukynd, Relyvrio, Spevigo, Sunlenca, Tecvayli, Terlivaz, Tzield, Vivjoa, Vonjo, Voquezna Triple Pak, Xenpozyme, Ztalmy

Accelerated Approval



CDER identified 6 of the 37 (16%) novel drugs as Accelerated Approvals.

CDER used at least one expedited program to speed approval of 65% of all novel drugs approved in 2022.

Predictability: Meeting PDUFA Goals

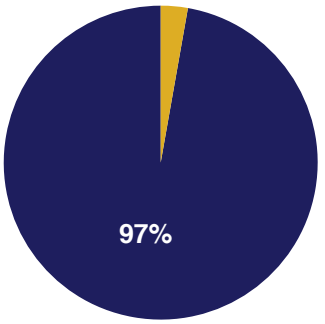
Under PDUFA, CDER reviews new drug and biologic applications targeting specific goal dates. Throughout 2022, CDER met or exceeded the PDUFA goal date for taking action on 97% (36 of 37) of the novel drugs approved.

Novel drugs approved in 2022 on or before their PDUFA goal dates were:

Amvuttra, Briumvi, Camzyos, Daxxify, Elahere, Elucirem, Enjaymo, Imjudo, Kimmtrak, Krazati, Lunsumio, Lytgobi, Mounjaro, NexoBrid, Omlonti, Opdualag, Pluvicto, Pyrukynd, Quviviq, Relyvrio, Rezlidhia, Rolvedon, Sotyktu, Spevigo, Sunlenca, Tecvayli, Terlivaz, Tzield, Vabysmo, Vivjoa, Vonjo, Voquezna Triple Pak, Vtama, Xenoview, Xenpozyme, Ztalmy

CDER met or exceeded its PDUFA goal date for 97% of the novel drugs approved in 2022.

Meeting PDUFA Goals



In 2022, 36 (97%) of 37 novel drugs were approved on or before their PDUFA goal date.

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

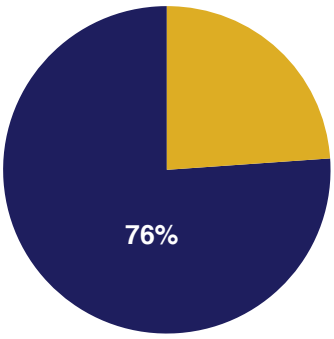
First Cycle Approvals

CDER approved 28 of the 37 novel drugs of 2022 (76%) on the "first cycle" of review. This high percentage partly 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 2022 on the first cycle were:

Amvuttra, Briumvi, Camzyos, Cibinqo, Elahere, Elucirem, Imjudo, Kimmtrak, Krazati, Lunsumio, Lytgobi, Mounjaro, Opdualag, Pluvicto, Pyrukynd, Quviviq, Relyvrio, Rezlidhia, Sotyktu, Spevigo, Tecvayli, Vabysmo, Vivjoa, Vonjo, Voquezna Triple Pak, Vtama, Xenpozyme, Ztalmy

First Cycle Approvals



CDER approved 28 of the 37 novel drugs of 2022 (76%) on the first cycle.

Approval in the U.S. Before Other Countries

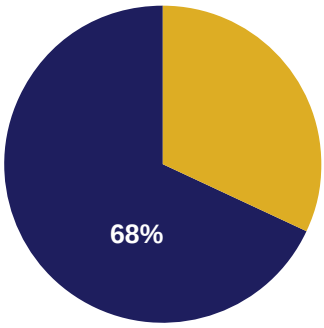
25 of the 37 novel drugs approved in 2022 (68%) were approved in the U.S. before any other country.

Novel drugs of 2022 approved first in the U.S. were:

Amvuttra, Briumvi, Camzyos, Daxxify, Elahere, Elucirem, Enjaymo, Imjudo, Kimmtrak, Krazati, Lytgobi, Mounjaro, Opdualag, Pluvicto, Pyrukynd, Quviviq, Rezlidhia, Sotyktu, Spevigo, Tzield, Vabysmo, Vivjoa, Vonjo, Xenoview, Ztalmy

68% of the novel drugs approved in 2022 were approved in the U.S. before any other country.

First in the U.S.



25 of the 37 novel drugs (68%) approved in 2022 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 approved 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 notable 2022 approvals for new uses or indications of an approved drug:

- **Cytalux (pafolacianine)** injection was approved in 2021 to help identify ovarian cancer lesions. In 2022, the drug was approved to help identify pulmonary nodules (abnormal lung growths) during surgery among adults with known or suspected lung cancer.
- **Dupixent (dupilumab)** injection, which CDER approved originally in 2017 for atopic dermatitis, was approved in 2022 as the first treatment for eosinophilic esophagitis, a chronic inflammatory disorder in which eosinophils, a type of white blood cell, are found in esophagus tissue, causing difficulty with swallowing and eating.

  Dupixent was also approved in 2022 for adults with prurigo nodularis, a chronic skin disorder characterized by hard, extremely itchy bumps known as nodules. Dupixent is the first approved therapy for this disorder.

The first drug to treat eosinophilic esophagitis, a chronic immune disorder, was approved in 2022.

- **Enhertu (fam-trastuzumab deruxtecan-nxki)** intravenous infusion was originally approved in 2019. In 2022, CDER approved Enhertu to treat patients with unresectable or metastatic HER2-low breast cancer through the Accelerated Approval program. This is the first approved therapy targeted to patients with the HER2-low breast cancer subtype, a newly defined subset of HER2-negative breast cancer in which there are some HER2 proteins on the cell surface, but not enough to be classified as HER2-positive.

  Enhertu was also approved in 2022 for adults with unresectable or metastatic HER2-positive breast cancer who had received a prior anti-HER2-based regimen; as well as for adults with unresectable or metastatic non-small cell lung cancer whose tumors have an activating HER2 mutation who received prior systemic (treating the whole body) therapy.

In 2022, CDER approved the first therapy for HER2-low breast cancer, a newly defined subset of HER2-negative breast cancer.

- **Fintepla (fenfluramine)** oral solution was approved in 2020 for Dravet syndrome, a type of epilepsy, in patients aged two years and older. In 2022, CDER approved Fintepla to treat Lennox-Gastaut syndrome, another form of epilepsy, in patients aged two years and older.
- **Imcivree (setmelanotide)** injection, which CDER originally approved in 2020, was approved in 2022 for patients six years and older with obesity due to Bardet-Biedl syndrome, a rare genetic disorder. This is the first drug approved for chronic weight management in patients with Bardet-Biedl syndrome.

- **Imfinzi (durvalumab)** injection was initially approved in 2017. In 2022, CDER approved it to treat unresectable hepatocellular carcinoma, the most common liver cancer, together with Imjudo [see below and page 8]. In 2022, Imfinzi was also approved, in combination with chemotherapy, to treat locally advanced or metastatic biliary tract cancer, a rare and highly fatal type of cancer.
- **Imjudo (tremelimumab-actl)** injection, which was first approved in 2022 to treat unresectable hepatocellular carcinoma, was later approved in the same year in combination with other therapies to treat adults with metastatic non-small cell lung cancer with no sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations. [see above and page 8]
- **Jardiance (empagliflozin)** tablets, which were first approved in 2014 for type 2 diabetes, were approved in 2022 to reduce the risk of cardiovascular death and hospitalization for heart failure.
- **Locametz (kit for preparation of 68Ga-gozetotide)** injection has an active ingredient that was approved in 2021 to image prostate cancer lesions. In 2022, CDER approved Locametz to help select patients with metastatic prostate cancer for whom a certain therapy [see Pluvicto on page 7] is appropriate.
- **Lynparza (olaparib)** tablets, which were first approved in 2014, were approved in 2022 for the adjuvant treatment of adults with germline BRCA-mutated (gBRCAm) HER2-negative high-risk early breast cancer who were previously treated with (neo)adjuvant chemotherapy.
- **Mekinist (trametinib)** tablets were initially approved in 2013 to treat patients with certain melanomas. In 2022, CDER approved Mekinist in combination with Tafinlar [see page 18] to treat patients aged six years and older with specific genetically mutated solid tumors (a gene called BRAF V600E) whose disease has progressed and who have no other treatment options.
- **Nubeqa (darolutamide)** tablets were first approved in 2019. CDER approved it in 2022 to treat metastatic hormone-sensitive prostate cancer in combination with another drug, docetaxel.
- **Olumiant (baricitinib)** oral tablets, which were initially approved in 2018 for rheumatoid arthritis, were approved in 2022 to treat hospitalized adults with COVID-19 who need breathing assistance. This was the first immunosuppressant (therapy that reduces the body's immune response) approved for COVID-19.

  Olumiant was also approved in 2022 to treat adults with severe alopecia areata, an autoimmune disorder that causes hair to fall out, often in clumps. Olumiant is first CDER approval of a systemic treatment for alopecia.

- **Opdivo (nivolumab)** injection was first approved in 2014. In 2022, CDER approved it to treat neoadjuvant (before surgery) non-small cell lung cancer. It is the first CDER-approved treatment for neoadjuvant lung cancer.
- **Opzelura (ruxolitinib)** cream was first approved in 2021 for atopic dermatitis. In 2022, CDER approved the drug to treat nonsegmental vitiligo, a condition that involves loss of skin coloring in patches of skin. Opzelura is the first CDER-approved drug to improve skin coloring for patients with this condition.
- **Pemazyre (pemigatinib)** tablets were approved in 2020 to treat adults with types of cholangiocarcinoma, a group of cancers that begin in the bile ducts. In 2022, CDER approved it for patients with myeloid and lymphoid neoplasms (new and abnormal tissue growth) with a certain genetic mutation, either as a short-term treatment before stem cell transplantation or as a long-term treatment for people who cannot receive stem cell transplants.
- **Retevmo (selpercatinib)** capsules were initially approved in 2020. In 2022, it was approved for adults with metastatic solid tumors with a RET gene fusion who have progressed while on or following systemic treatment or who have no satisfactory treatment options.
- **Rinvoq (upadacitinib)** tablets were originally approved in 2019. In 2022, Rinvoq was approved to treat adults with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to another type of treatment. Ulcerative colitis is a type of inflammatory bowel disease.
- **Skyrizi (risankizumab-rzaa)** injection, which was originally approved in 2019 for plaque psoriasis, was approved in 2022 to treat moderately to severely active Crohn's disease, a type of inflammatory bowel disease. Skyrizi is the first new treatment for Crohn's disease in six years. Skyrizi was also approved in 2022 for adults with active psoriatic arthritis, a systemic inflammatory disease that affects the skin and joints.
- **Pedmark (sodium thiosulfate)** injection was initially approved in 2012 for cyanide poisoning. In 2022, CDER approved it to reduce the risk of hearing loss (ototoxicity) associated with cisplatin (a type of chemotherapy) in pediatric patients. It is the first treatment for this indication.
- **Tafinlar (dabrafenib)** capsules were initially approved in 2013 to treat patients with certain melanomas. In 2022, it was approved for use in combination with Mekinist [see page 17] to treat patients aged six years and older who have specific genetically mutated solid tumors (a gene called BRAF V600E) whose disease has progressed and who have no other treatment options.
- **Tymlos (abaloparatide)** injection was first approved in 2017 to treat postmenopausal women with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy. In 2022, it was approved to increase bone density in men with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy.

In 2022, CDER approved the first therapy to treat the loss of skin coloring.

- **Vidaza (azacitidine)** injection was first approved in 2004 for types of myelodysplastic syndrome and chronic myelomonocytic leukemia. In 2022, CDER approved Vidaza to treat pediatric patients aged one month and older with newly diagnosed juvenile myelomonocytic leukemia, a rare blood cancer that predominately affects young children. Vidaza is the first therapy approved for this type of leukemia.
- **Vijoice (alpelisib)** tablets were first approved in 2019. In 2022, Vijoice was approved for a rare overgrowth syndrome (PIK3CA-related overgrowth spectrum [PROS]) that mainly affects children. It is the first therapy for this syndrome.
- **Xalkori (crizotinib)** capsules were initially approved in 2011 for patients with types of non-small cell lung cancer. In 2022, CDER approved Xalkori for patients aged one year and older with unresectable, recurrent, or refractory inflammatory anaplastic lymphoma kinase-positive myofibroblastic tumors (IMT). IMT are usually non-cancerous, but they can invade nearby tissue. Xalkori is the first drug approved for IMT.

Drugs in brackets refer to other treatments for the same or similar disease.

Approved Drugs Expanded for New Pediatric Populations

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 including pediatric information in the labeling for many drugs.

Upon drug approval, CDER may require pediatric studies of that drug under PREA. In response to that requirement, sponsors may submit new data to support the safe and effective use of the drug in the pediatric population studied. Sponsors submit this data in an application to expand the patient population. Under BPCA, sponsors may obtain additional marketing exclusivity for pediatric studies requested in a Pediatric Written Request.

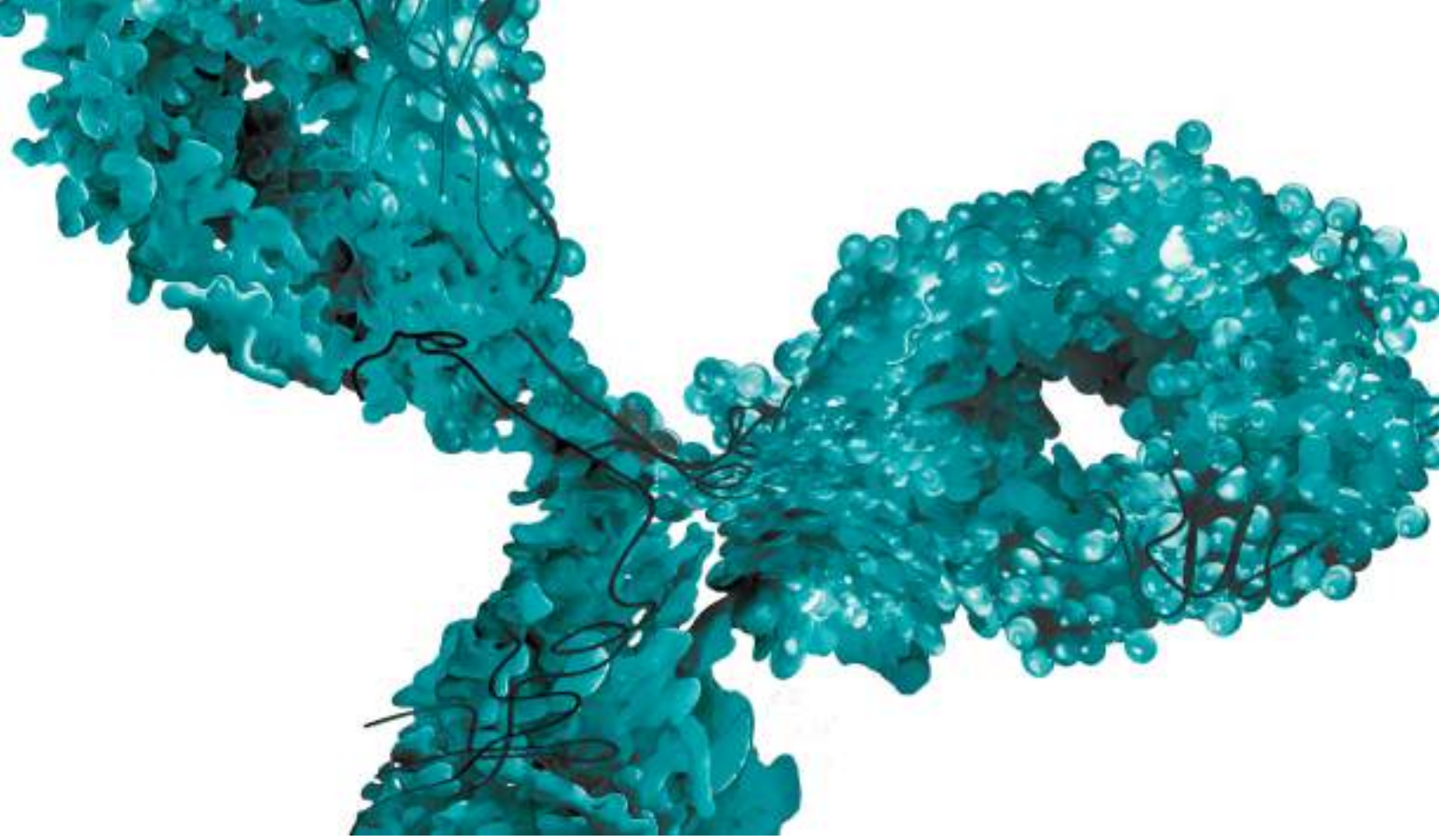
The products below are certain approvals of 2022 for drugs expanded to include new pediatric populations:

- **Benlysta (belimumab)** injection was approved in 2022 for patients aged 5-17 years with active lupus nephritis, a serious kidney disease associated with lupus, who are receiving standard therapy. The drug was previously approved for adults with this disease.
- **Cabenuva (extended-release cabotegravir, extended-release rilpivirine)** co-packaged for intramuscular injection, was first approved in 2021 as a complete regimen to treat HIV infection in adults who met certain criteria. In 2022, CDER extended this approval to patients aged 12 years and older and weighing at least 35 kg. This is the first intramuscular injectable HIV drug approved for adolescents.
- **CellCept (mycophenolate mofetil)** capsules were previously approved to prevent organ rejection in adults receiving heart or liver transplants. In 2022, the patient population was expanded to include pediatric heart or liver transplant patients.
- **Evrysdi (risdiplam)** oral solution was approved in 2020 for patients aged two months and older with spinal muscular atrophy, a rare and often fatal genetic disease affecting muscle strength and movement. In 2022, CDER extended the patient population to include infants younger than two months.
- **Imbruvica (ibrutinib)** capsules have been approved to treat adults with chronic graft-versus-host disease (cGVHD), a complication of a stem or bone marrow transplant, after at least one line of systemic therapy. In 2022, CDER broadened the population to include patients aged one year and older. Imbruvica is the first treatment for cGVHD in this patient population.

In 2022, CDER approved the first intramuscular injectable HIV treatment for adolescents.

- **Qsymia (phentermine and topiramate)** extended-release capsules were first approved in 2012 for chronic weight management in adults with obesity or overweight. In 2022, it was approved for the same use in pediatric patients aged 12 years and older with a body mass index in the 95th percentile or greater, standardized for age and sex.
- **SMOFlipid (lipid injectable emulsion)** was originally approved for adults in 2016 as a source of calories and essential fatty acids for parenteral nutrition (injecting nutrition into the body through the bloodstream) when other sources or routes of nutrition are not possible, insufficient, or may cause harm. In 2022, CDER expanded use for the pediatric patient population, including preterm babies.
- **Stelara (ustekinumab)** injection was initially approved in 2013 to treat adults with active psoriatic arthritis, among other uses. In 2022, CDER broadened the population to patients aged 6-17 years with active psoriatic arthritis.
- **Triumeq (a fixed dose combination product containing abacavir, dolutegravir, and lamivudine)** tablets were first approved in 2014 to treat HIV infection. In 2022, with the approval of Triumeq PD tablet for oral suspension, the indicated population was expanded to include pediatric patients weighing at least 10 kg.
- **Veklury (remdesivir)** injection was approved in 2020 to treat COVID-19 in certain patients aged 12 years and older who are hospitalized or have mild-to-moderate disease and are at high risk of progression to severe COVID-19, including hospitalization or death. In 2022, CDER expanded the patient population to include pediatric patients aged 28 days and older and weighing at least 3 kg.
- **Wegovy (semaglutide)** injection was approved in 2021 for chronic weight management, in addition to diet and exercise, in adults with obesity or overweight. In 2022, CDER expanded the population to patients aged 12 years and older.
- **Xofluza (baloxavir marboxil)** tablets were first approved in 2018. Xofluza is used to treat acute uncomplicated influenza (flu) in adult and pediatric patients 12 years and older who have been symptomatic for no more than 48 hours. Xofluza is also indicated for post-exposure prophylaxis (prevention) of flu in people 12 years and older following contact with an individual who has flu. In 2022, the population was expanded to include pediatric patients five years and older.

As the pandemic continues, in 2022, CDER approved the first antiviral COVID-19 treatment for young children.



Biosimilar and Interchangeable Biosimilar Approvals

The biosimilar pathway is an abbreviated approval pathway for biological products that are highly similar to and have no clinically meaningfully differences from a CDER-approved biological reference product. This pathway was established to provide more treatment options, increase patient access, and potentially reduce the cost of therapies for serious conditions through competition.

In 2022, CDER approved seven new biosimilars. Of particular note, CDER approved two interchangeable biosimilars, which may be substituted for the reference product at the pharmacy without the intervention of a prescriber, subject to state law, similar to how generic drugs are substituted for brand name drugs.

In 2022, CDER approved seven new biosimilars.

- **Alymsys (bevacizumab-maly)** injection was approved for multiple cancer indications *(reference product: Avastin)*.
- **Cimerli (ranibizumab-eqrn)** injection was approved to treat neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy, and myopic choroidal neovascularization *(reference product: Lucentis)*. These are a variety of retinal diseases or pathologies affecting the thin layer of tissue lining the back of the eye. Cimerli is the first interchangeable biosimilar for ranibizumab.

- **Fylnetra (pegfilgrastim-pbbk)** injection was approved to decrease the incidence of infection in patients with nonmyeloid malignancies receiving certain types of anti-cancer drugs *(reference product: Neulasta)*.
- **Idacio (adalimumab-aacf)** injection was approved to treat a variety of inflammatory conditions *(reference product: Humira)*.
- **Releuko (filgrastim-ayow)** injection was approved to treat and prevent the chemotherapy complication febrile neutropenia (a condition marked by fever and a lower-than-normal number of neutrophils, a type of white blood cell) in patients with cancer *(reference product: Neupogen)*.
- **Stimufend (pegfilgrastim-fpgk)** injection was approved to decrease the incidence of infection in patients with non-myeloid malignancies receiving certain types of anti-cancer drugs *(reference product: Neulasta)*.
- **Vegzelma (bevacizumab-abcd)** injection was approved for multiple cancer indications *(reference product: Avastin)*.

In 2022, CDER also approved notable changes to two biosimilar products:

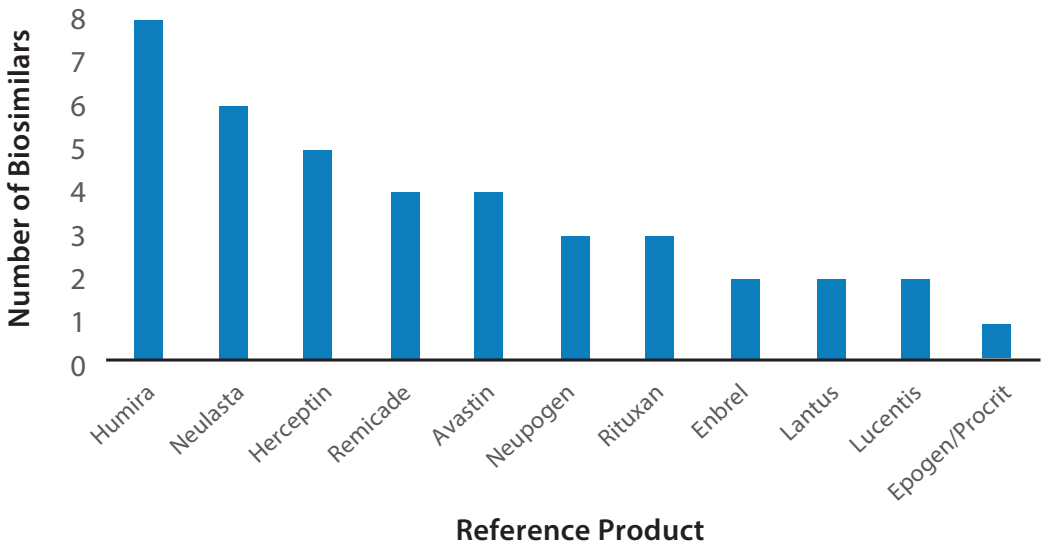
- **Rezvoglar (insulin glargine-aglr)** injection, originally approved in 2021, was approved in 2022 as an interchangeable biosimilar to improve glycemic control in adults and pediatric patients with diabetes mellitus. Rezvoglar is the second approved interchangeable biosimilar insulin product in the U.S. *(reference product: Lantus)*.
- **Udenyca (pegfilgrastim-cbqv)** injection, initially approved in 2018, was approved for acute radiation syndrome, an acute illness caused by irradiation of the entire body (or most of the body) by a high dose of penetrating radiation in a very short period of time *(reference product: Neupogen)*. This action means that Udencya can be used as a medical countermeasure. Neupogen is already approved for this indication.

CDER has approved a total of 40 biosimilars for 11 different reference products since 2015. This includes at least one biosimilar for each of these top selling biological products in the U.S.

CDER approved the 40th biosimilar product in 2022.

CDER has now approved: eight biosimilars to Humira; six biosimilars to Neulasta; five biosimilars to Herceptin; four biosimilars to Remicade and Avastin; three biosimilars to Rituxan and Neupogen; two biosimilars to Lantus, Enbrel, and Lucentis; and one biosimilar to Epogen/Procit. There are now also four approved interchangeable biosimilars. Multiple biosimilar products for an approved reference product can enhance competition, which may lead to reduced costs for both patients and our health care system.

Approved Biosimilars



Other CDER Actions

New formulations of approved drugs can offer significant advances in therapy. Similarly, new dosage forms (such as from a capsule to a chewable tablet for those unable to swallow pills) can improve patient health by helping to increase adherence, making sure patients take the proper dose, and improving the quality of life for patients who must use the medication on a prolonged basis. Below are examples of new formulations, new dosage forms, and a prescription to nonprescription "switch" that CDER approved in 2022.

- **Cuvrior (trientine tetrahydrochloride)** tablets were approved in 2022 with the previously approved active ingredient trientine to treat patients with stable Wilson's disease, a genetic disorder in which excess copper builds up in the body. Copper accumulation can result in brain and liver injury that can lead to severe neurologic and psychiatric impairment as well as acute and chronic liver failure. Cuvrior can be used in patients who have had copper removed from their body and who can tolerate Cuprimine, another treatment for Wilson's disease. Cuvrior does not require refrigeration, unlike the original formulation of trientine.
- **Nasonex (mometasone furoate)** nasal spray was previously approved as a prescription drug. In 2022, CDER approved Nasonex 24HR Allergy nasal spray as a nonprescription drug to relieve symptoms due to hay fever or other upper respiratory allergies.
- **Radicava ORS (edaravone)** oral suspension was approved in a new oral dosage form for ALS. The drug was originally approved in 2017 as an injection for ALS.
- **Tpoxx (tecovirimat)** capsules were originally approved in 2018 to treat human smallpox disease in adults and pediatric patients. In 2022, an intravenous formulation was approved for the same use. Also in 2022, the pediatric population was expanded to include patients weighing at least 3kg. Although the World Health Organization declared smallpox, a contagious and sometimes fatal infectious disease, eradicated in 1980, there have been longstanding concerns that smallpox could be used as a bioweapon.
- **Zoryve (roflumilast)** cream was previously approved as an oral tablet and marketed as Daliresp for chronic obstructive pulmonary disease. In 2022, CDER approved Zoryve as a cream to treat plaque psoriasis, including in skin folds, in patients aged 12 years and older.

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

Conclusion

Approving a drug is a well-coordinated process that involves scientific, regulatory, and policy experts from throughout CDER. For each application, we carefully weigh the benefits and risks of treatment as we decide whether to approve the drug. If we decide to approve the therapy, we must also find consensus on the intended patient population, use, labeling, and other relevant parameters. These decisions are complex and require CDER to work as a team on behalf of the American public.

We also consider input from stakeholders outside of CDER and FDA. We consult outside scientific experts, patients and patient advocates, industry representatives, academics, and other community members in the drug development and review process. We consider their expertise and opinions very carefully. We want to ensure we have the perspectives of many different stakeholders before making regulatory decisions that may affect the health and well-being of Americans.

It's important to recognize that our staff—as well as our outside experts—continue to contend with the COVID-19 pandemic. We have all had to deal with health issues and other pandemic-related disruptions as we perform our critical work of reviewing drug applications and deciding to approve therapies. Yet, despite these ongoing disturbances, our staff remains committed to the task at hand: ensuring new safe and effective drugs are approved for patients and consumers in a timely manner.

Our staff remains committed to the task at hand: ensuring new safe and effective drugs are approved for patients and consumers in a timely manner.

Appendix A: CDER's Novel Approvals of 2022
(in alphabetical order)

For information about vaccines, allergenic products, blood and blood products, and cellular and gene therapy products go to 2022 Biologics License Application Approvals.

Approval Date	Proprietary Name	Active Ingredient(s)	Summary of FDA-approved use on approval date (see Drugs@FDA for complete indication)	Dosage Form
6/13/2022	Amvuttra	vutrisiran	To treat polyneuropathy of hereditary transthyretin-mediated amyloidosis	Injection
12/28/2022	Briumvi	ublituximab-xiiy	To treat relapsing forms of multiple sclerosis	Injection
4/28/2022	Camzyos	mavacamten	To treat certain classes of obstructive hypertrophic cardiomyopathy	Capsule
1/14/2022	Cibinqo	abrocitinib	To treat refractory, moderate-to-severe atopic dermatitis	Tablet
9/7/2022	Daxxify	daxibotulinumtoxinA-lanm	To treat moderate-to-severe glabellar lines associated with corrugator and/or procerus muscle activity	Injection
11/14/2022	Elahere	mirvetuximab soravtansine-gynx	To treat patients with recurrent ovarian cancer that is resistant to platinum therapy	Injection
9/21/2022	Elucirem	gadopiclenol	To detect and visualize lesions, together with MRI, with abnormal vascularity in the central nervous system and the body	Injection
2/4/2022	Enjaymo	sutimlimab-jome	To decrease the need for red blood cell transfusion due to hemolysis in cold agglutinin disease	Injection
10/21/2022	Imjudo	tremelimumab-actl	To treat unresectable hepatocellular carcinoma	Injection
1/25/2022	Kimmtrak	tebentafusp-tebn	To treat unresectable or metastatic uveal melanoma	Injection
12/12/2022	Krazati	adagrasib	To treat KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer in adults who have received at least one prior systemic therapy	Tablet
12/22/2022	Lunsumio	mosunetuzumab-axgb	To treat adults with relapsed or refractory follicular lymphoma, a type of non-Hodgkin lymphoma	Injection

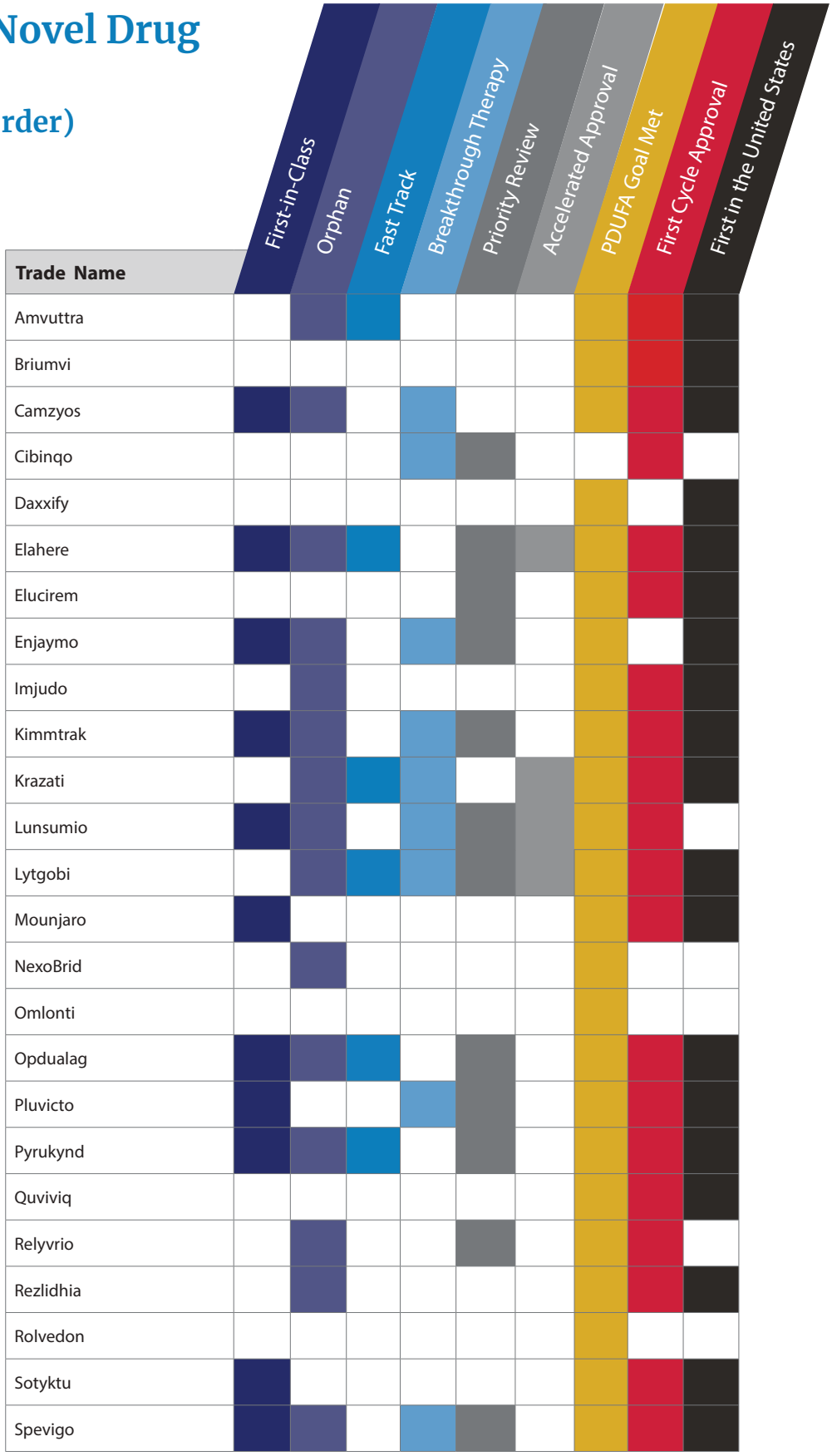
Appendix A (continued)

Approval Date	Proprietary Name	Active Ingredient(s)	Summary of FDA-approved use on approval date (see Drugs@FDA for complete indication)	Dosage Form
9/30/2022	Lytgobi	futibatinib	To treat intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements	Tablet
5/13/2022	Mounjaro	tirzepatide	To improve blood sugar control in diabetes, in addition to diet and exercise	Injection
12/28/2022	Nexobrid	anacaulase-bcdb	To remove eschar in adults with deep partial thickness or full thickness thermal burns	Injection
9/22/2022	Omlonti	omidenepag isopropyl	To reduce elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension	Ophthalmic Solution
3/18/2022	Opdualag	nivolumab and relatlimab-rmbw	To treat unresectable or metastatic melanoma	Injection
3/23/2022	Pluvicto	lutetium Lu 177 vipivotide tetraxetan	To treat prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer following other therapies	Injection
2/17/2022	Pyrukynd	mitapivat	To treat hemolytic anemia in pyruvate kinase deficiency	Tablet
1/7/2022	Quviviq	daridorexant	To treat insomnia	Tablet
9/29/2022	Relyvrio	sodium phenylbutyrate and taurursodiol	To treat amyotrophic lateral sclerosis (ALS)	Powder for Oral Suspension
12/1/2022	Rezlidhia	olutasidenib	To treat relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation	Capsule
9/9/2022	Rolvedon	eflapegrastim-xnst	To decrease the incidence of infection in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia	Injection
9/9/2022	Sotyktu	deucravacitinib	To treat moderate-to-severe plaque psoriasis	Tablet
9/1/2022	Spevigo	spesolimab-sbzo	To treat generalized pustular psoriasis flares	Injection

Appendix A (continued)

Approval Date	Proprietary Name	Active Ingredient(s)	Summary of FDA-approved use on approval date (see Drugs@FDA for complete indication)	Dosage Form
12/22/2022	Sunlenca	lenacapavir	To treat adults with HIV whose HIV infections cannot be successfully treated with other available treatments due to resistance, intolerance, or safety considerations	Tablet and Injection
10/25/2022	Tecvayli	teclistamab-cqyv	To treat relapsed or refractory multiple myeloma among adults who have received at least four specific lines of therapy	Injection
9/14/2022	Terlivaz	terlipressin	To improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function	Injection
11/17/2022	Tzield	teplizumab-mzwv	To delay the onset of Stage 3 type 1 diabetes	Injection
1/28/2022	Vabysmo	faricimab-svoa	To treat neovascular (wet) aged-related macular degeneration and diabetic macular edema	Injection
4/26/2022	Vivjoa	oteseconazole	To reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are not of reproductive potential	Capsule
2/28/2022	Vonjo	pacritinib	To treat intermediate or high-risk primary or secondary myelofibrosis in adults with low platelets	Capsule
5/3/2022	Voquezna Triple Pak	vonoprazan, amoxicillin, clarithromycin	To treat *H. pylori* infection	Co-packaged Tablet and Capsules
5/23/2022	Vtama	tapinarof	To treat plaque psoriasis	Cream
12/23/2022	Xenoview	hyperpolarized Xe-129	To evaluate pulmonary function and imaging	Gas
8/31/2022	Xenpozyme	olipudase alfa-rpcp	To treat acid sphingomyelinase deficiency	Injection
3/18/2022	Ztalmy	ganaxolone	To treat seizures in cyclin-dependent kinase-like 5 deficiency disorder	Oral Suspension

Appendix B: Novel Drug Designations
(in alphabetical order)



Trade Name
Amvuttra
Briumvi
Camzyos
Cibinqo
Daxxify
Elahere
Elucirem
Enjaymo
Imjudo
Kimmtrak
Krazati
Lunsumio
Lytgobi
Mounjaro
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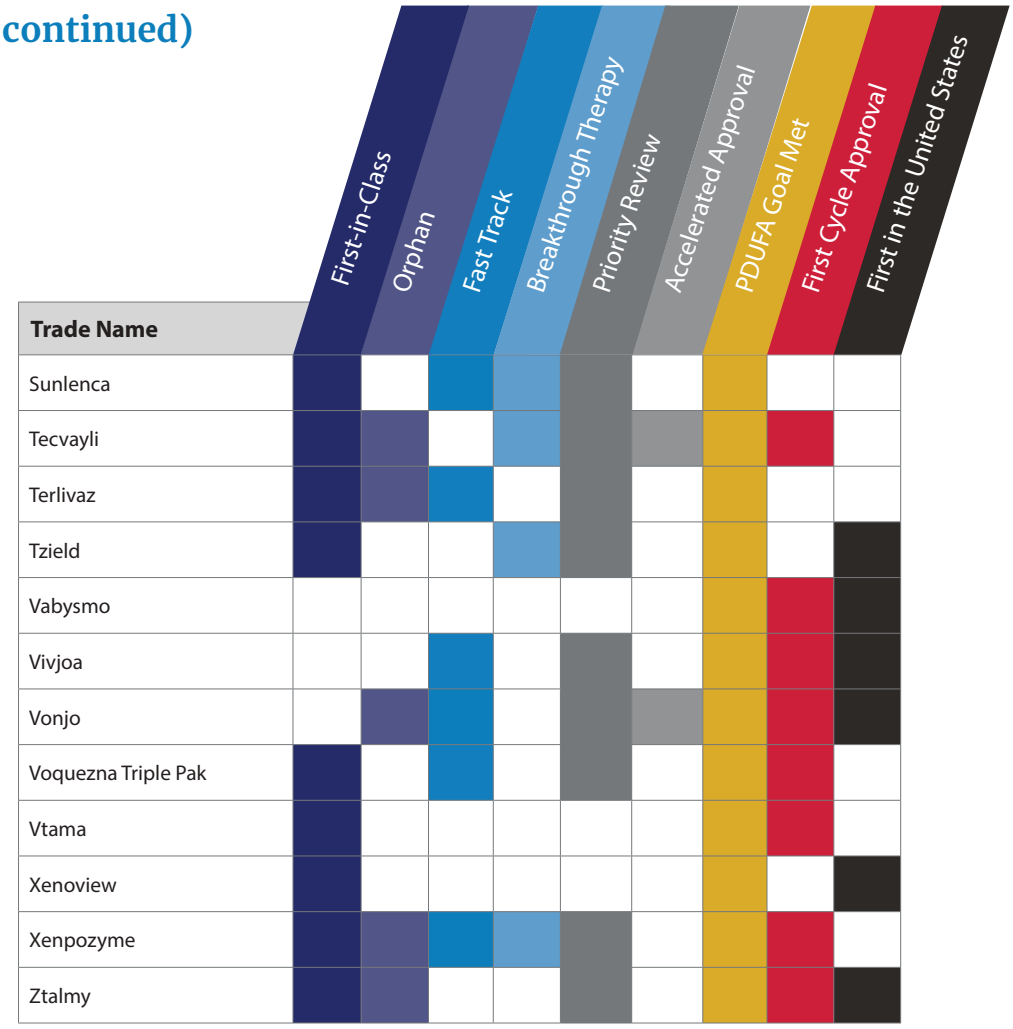
Spevigo

Appendix B (continued)



Trade Name
Sunlenca
Tecvayli
Terlivaz
Tzield
Vabysmo
Vivjoa
Vonjo
Voquezna Triple Pak
Vtama
Xenoview
Xenpozyme
Ztalmy

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U.S. Food and Drug Administration
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Silver Spring, Maryland 20993