MC-Rx

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Insights on the Drug Pipeline

Exploring the changes in the drugs market.

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MC-Rx is dedicated to improved drug therapy vigilance, continuity of care, patient safety and effective formulary management. This edition is developed by our clinical team, which is comprised of registered clinical pharmacists, to provide you with continuous evaluation and insights of the drugs market and its impact as it evolves.

Here you will find

- Drug pipeline
- FDA drug approvals
- New indications
- Patent expirations
- Generic approvals
- FDA safety updates/ withdrawals/ recalls
- Drug shortages/ discontinuations

Clinical Pipeline

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

COVID-19 Therapies Update:

Therapy	FDA status	IDSA recommended usage
Remdesivir	FDA approved to treat COVID-19	Recommended for hospitalized severe or critically ill patients with COVID-19.
Bamlanvimab/Etesevimab	Nationwide pause in distribution	Ambulatory patients with mild to moderate COVID-19 are at high risk for progression to severe disease.
Baricitinib with remdesivir	EUA to treat COVID-19	Hospitalized patients with severe COVID-19 who cannot receive corticosteroids because of a contraindication.
Tocilizumab in addition to standard of care	EUA to treat COVID-19	Hospitalized adults with progressive severe or critical COVID-19 disease who have elevated markers of systemic inflammation.
Casirivimab and imdevimab	EUA to treat COVID-19	Ambulatory patients with mild to moderate COVID-19 are at high risk for progression to severe disease.
Sotrovimab	EUA to treat COVID-19	Ambulatory patients with mild to moderate COVID-19 are at high risk for progression to severe disease.

**IDSA: Infectious Disease Society of America, FDA: Food and Drug Administration, EUA: Emergency Use Authorization*

Currently, three vaccines are authorized and recommended to prevent COVID-19 by the FDA.

- Pfizer-BioNTech COVID-19 vaccine
- Moderna COVID-19 vaccine
- Johnson & Johnson's Janssen COVID-19 vaccine
  On July 12th, 2021 the FDA added a warning about the risk of Guillain-Barre Syndrome (GBS) to the vaccine. There have been 100 preliminary reports of GBS following vaccination with the Janssen vaccine after approximately 12.5 million doses were administered. Of these reports, 95 were serious and required hospitalization (0.00076%). There was one reported death (0.000008%).

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

COVID-19 Authorized Vaccines Comparative Table

Vaccine	Pfizer/BioNTech	Moderna	Johnson & Johnson
Effectiveness	First Dose: 80% Second Dose: 95%	First Dose: 80% Second Dose: 94%	First Dose: 66%
Common Side Effects	Injection site pain, fatigue, headache, chills, muscle pain.	Injection site pain, fever, muscle aches, headaches lasting a few days.	Injection site pain, headache, fatigue, muscle pain.
Route/Doses	Intramuscular Two doses, 3 weeks apart	Intramuscular Two doses, 4 weeks apart	Intramuscular 1 dose
Authorized Population	Individuals 12 years and older	Individuals 18 years and older	Individuals 18 years and older
Date of EUA issuance	December 11, 2020	December 18, 2020	February 27, 2021
Booster shot needed for variants	Not yet indicated (CDC & FDA)	Not yet indicated (CDC & FDA)	Not yet indicated (CDC & FDA)

*CDC: Centers for Disease Control and Prevention, FDA: Food and Drug Administration

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Specialty Pipeline

There is a growing trend of specialty drugs in the market. It is predicted that 2021 will be the year when specialty drugs account for at least half of pharmacy drug spend. The therapeutic class of oncology is the leading category of specialty drugs. Other therapeutic areas where the specialty drug pipeline could yield new approvals in the coming years include treatments for immune-related, inflammatory conditions (especially TNF-inhibitors and biosimilars), Alzheimer's, hemophilia, genetic disorders, among others.

Table 1. Top 20 Specialty Pipeline Drugs

Pipeline Drug/ (Manufacturer)	Indication	Current Status	Expected Approval
bardoxolone methyl (Reata Pharmaceuticals)	Antioxidant inflammation inhibitor that acts on Nrf2 for the treatment of chronic kidney disease caused by Alport Syndrome; oral	NDA Filed	02/25/2022
belumosudil (Kadmon Pharmaceuticals)	A selective oral inhibitor of rho-associated coiled-coil kinase 2 (ROCK2) for the treatment of chronic graft-versus-host disease (cGVHD) who have failed to respond to two or more prior lines of systemic therapies; oral therapy	NDA Filed	08/31/2021
odevixibat (Albireo)	IBAT inhibitor for the treatment of progressive familial intrahepatic cholestasis (PFIC); oral	NDA Filed	07/20/2021
pegunigalsidase alfa (Protalix BioTherapeutics)	Plant cell-expressed, recombinant alpha-galac-tosidase-A enzyme for the treatment of Fabry disease; IV infusion (monthly)	Complete Response	2022
teplizumab (Provention Bio)	Humanized monoclonal antibody engineered to alter the function of the T lymphocytes that mediate the destruction of the insulin-producing beta cells of the islets of the pancreas to delay or prevent the onset of type 1 diabetes in at-risk individuals; IV	BLA Filed	07/02/2022

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Traditional Pipeline

The therapeutic class of mental health/neurology is the leading category of traditional drugs. Other therapeutic areas where the traditional drug pipeline could yield new approvals in the coming years include treatments for, oncology, diabetes, cardiovascular diseases, and biosimilar products.

Table 1. Top 20 Traditional Pipeline Drugs

Pipeline Drug/ (Manufacturer)	Indication	Current Status	Expected Approval
ansofaxine (Luye Pharma)	A serotonin-norepinephrine-dopamine triple reuptake inhibitor for the treatment of major depressive disorder; Oral therapy	NDA Filed	2021
atogepant (Allergan)	CGRP receptor antagonist for preventive treatment of migraines, without aura, in adults who meet the criteria for episodic migraine; oral	NDA Filed	2021
budesonide oral suspension (Eohilia - Takeda)	Topically active, oral viscous formulation of budesonide for improving esophageal eosinophil counts and endoscopic findings in adults with a new diagnosis of eosinophilic esophagitis (EoE); topical/oral	NDA Filed	2021
bupropion/ dextromethorphan (AXS05 - Axsome)	Fixed-dose combination of dextromethorphan (NMDA receptor antagonist) and bupropion (norepinephrine and dopamine reuptake inhibitor) for the treatment of major depressive disorder; oral therapy	NDA Filed	08/22/2021
daridorexant (Idorsia)	Dual orexin receptor antagonist (DORA) for the treatment of insomnia; oral therapy	NDA Filed	08/01/2022
dihydroergotamine mesylate (Trudhesa - Impel NeuroPharma)	Dihydroergotamine mesylate for the acute treatment of migraine headaches with or without aura in adult patients; intranasal	NDA Filed	09/06/2021
donepezil transdermal system (Adlarity - Corium)	Once-weekly transdermal patch formulation of donepezil (a cholinesterase inhibitor) for treatment of dementia of the Alzheimer's type; patch.	NDA Filed	2021

Clinical Pipeline

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Pipeline Drug/ (Manufacturer)	Indication	Current Status	Expected Approval
eflornithine/sulindac (Cancer Prevention Pharmaceuticals)	Combination of the ornithine decarboxylase inhibitor and the non-steroidal anti-inflammatory drug for the pharmaco-preventive treatment of adults with familial adenomatous polyposis (FAP); oral	NDA Filed	2021
gefapixant (MK-7264 - Merck)	Selective P2X3 receptor antagonist for the treatment of refractory chronic cough (RCC) or unexplained chronic cough (UCC) in adults; oral	NDA Filed	11/21/2021
insulin aspart biosimilar (Kixelle - Viatris/Biocon)	Biosimilar formulation of rapid-acting insulin aspart (NovoLog); sc	351(k) Filed	2021
insulin glargine (Semglee - Mylan/Biocon)	Data submitted to classify Semglee as a biosimilar and an interchangeable biosimilar product; SQ therapy	351(k) Filed	2021
mavacamten (Bristol Myers Squibb)	Cardiac myosin modulator for the treatment of patients with obstructive hypertrophic cardiomyopathy (oHCM); oral	NDA Filed	01/28/2022
naloxone injection (Zimhi - Adamis)	Higher dose of naloxone, an opioid antagonist, formulated in a prefilled syringe for an injection to treat an opioid overdose; IM injection	NDA Filed	11/12/2021
pilocarpine 1.25% (Presbysol - Allergan)	The optimized formulation of pilocarpine, a cholinergic muscarinic receptor agonist, for the treatment of presbyopia; ophthalmic solution	NDA Filed	10/25/2021

Clinical Pipeline

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Pipeline Drug/ (Manufacturer)	Indication	Current Status	Expected Approval
pneumococcal vaccine, 15-valent (V114 - Merck)	15-valent pneumococcal conjugate vaccine for use in adults 18 years of age and older; IM.	BLA Filed	07/18/2021
sodium thiosulfate (Pedmark - Fennec)	Formulation of sodium thiosulfate to prevent cisplatin-related ototoxicity in pediatric patients with standard-risk hepatoblastoma; intravenous therapy	NDA Filed	11/28/2021
tadalafil / finasteride (Tadfin - Veru)	Combination of tadalafil (5mg) and finasteride (5mg) for treating benign prostatic hyperplasia (BPH); oral therapy.	NDA Filed	12/23/2021
testosterone undecanoate (Kyzatrex - Marius Pharmaceuticals)	Oral soft gelatin capsule formulation of the testosterone replacement therapy for the treatment of primary and secondary hypogonadism in adult men; oral	NDA Filed	10/31/2021
topiramate oral solution (ET-101 - Eton Pharmaceuticals)	Oral liquid formulation of topiramate as mono-therapy for the treatment of partial-onset or primary general tonic-clonic seizures in pediatric patients aged 2 years and older; for adjunctive therapy for partial-onset seizures, including LennoxGastaut syndrome, in patients aged 2 yrs and up; and for preventative treatment of migraine in patients 12 yrs and older; oral therapy	NDA Filed	08/06/2022

New Drug Formulations

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Mirabegron extended-release (Myrbetriq)

Dose: Oral Suspension 8mg/mL
Indication: Neurogenic detrusor overactivity (NDO) in pediatric patients aged 3 years and older and weighing 35 kg or more.
Guidelines: Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU Guideline 2019
Comparable: Solifenacin (Vesicare) Susp.

Bupivacaine and meloxicam (Zynrelef)

Dose: The extended-release solution is available in four dosage strengths as single-dose glass vials: (a) 400 mg bupivacaine and 12 mg meloxicam (b) 300 mg bupivacaine and 9 mg meloxicam (c) 200 mg bupivacaine and 6 mg meloxicam (d) 60 mg bupivacaine and 1.8 mg meloxicam.
Indication: is indicated in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after a bunionectomy, open inguinal herniorrhaphy, and total knee arthroplasty.

Naloxone hydrochloride (Kloxxado)

Dose: Nasal spray: naloxone hydrochloride 8 mg in 0.1 mL
Indication: for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression, for adult and pediatric patients.
Comparables: Naloxone (Narcan)

Isatuximab-irfc (Sarclisa)

Dose: Injection: 100 mg/5 mL (20 mg/mL) solution in single-dose vial; 500 mg/25 mL (20 mg/mL) solution in single-dose vial
Indication: In combination with carfilzomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy.
Comparables: Daratumumab (Darzalex)
Guidelines: NCCN Clinical Practices Guidelines in Oncology. Multiple Myeloma. Version 7.2021. April 26, 2021 https://www.nccn.org/professionals/physician_gls/pdf/myeloma_blocks.pdf

Dapagliflozin (Farxiga)

Dose: 10mg tablet
Indication: To reduce the risk of sustained eGFR decline, end-stage kidney disease cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression.
Guidelines: KDIGO 2020 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. https://doi.org/10.1016/j.kint.2020.06.019

New Indications

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Sacituzumab govitecan-hziy (Trodelvy)

Dose: Injection: 180 mg in single-dose vials
Indication: (1)Unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease.
(2) Locally advanced or metastatic urothelial cancer (mUC) who have previously received platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PDL1) inhibitor.
Comparables: Pembrolizumab (Keytruda), Atezolizumab (Tecentriq)
Guidelines: NCCN Clinical Practices Guidelines in Oncology. Breast Cancer. Version 4.2021. April 28, 2021, https://www.nccn.org/professionals/physician_gls/pdf/breast_blocks.pdf

NCCN Clinical Practices Guidelines in Oncology. Bladder Cancer. Version 3.2021. April 27, 2021, https://www.nccn.org/professionals/physician_gls/pdf/bladder_blocks.pdf

Pembrolizumab (Keytruda)

Dose: Injection: 100 mg/4 mL (25 mg/mL) solution in a single-dose vial.
Indication: In combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of patients with locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma.
Guidelines: NCCN Clinical Practices Guidelines in Oncology. Gastric Cancer. Version 3.2021. June 22, 2021, https://www.nccn.org/professionals/physician_gls/pdf/gastric_blocks.pdf

Nivolumab (Opdivo)

Dose: Injection: 40 mg/4 mL, 100 mg/10 mL, and 240 mg/24 mL solution in a single-dose vial.
Indication: (1) Patients with completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease, who have received neo-adjuvant chemoradiotherapy (CRT).
(2) For patients with advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma in combination with fluoropyrimidine- and platinum-containing chemotherapy.
Comparables: Pembrolizumab (Keytruda)
Guidelines: NCCN Clinical Practices Guidelines in Oncology. Esophageal and Esophagogastric Cancer. Version 3.2021. June 22, 2021
https://www.nccn.org/professionals/physician_gls/pdf/esophageal_blocks.pdf

Treprostinil (Tyvaso)

Dose: Oral inhalation: 2.9 mL ampule containing 1.74 mg treprostinil (0.6 mg per mL).
Indication: Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability.
Guidelines: Therapy for Pulmonary Arterial Hypertension in Adults, CHEST Guideline 2019
https://journal.chestnet.org/article/S0012-3692(19)30002-9/fulltext?_ga=2.104461641.833263084.1613400793-762494354.1613400793

In Market Brand

R&D | FDA Approval | **In Market Brand** | Generic Available | Off Market

Idecabtagene vicleucel (Abecma)

Dose: The dose range is 300 to 460 x 106 CAR-positive T cells.
Indication: for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.
Guidelines: NCCN Clinical Practices Guidelines in Oncology. Multiple Myeloma. Version 7.2021. April 26, 2021, https://www.nccn.org/professionals/physician_gls/pdf/myeloma_blocks.pdf

Viloxazine extended-release (Qelbree)

Dose: Extended-release capsules: 100 mg, 150 mg and 200 mg.
Indication: For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age.
Comparables: Atomoxetine (Strattera)

Drospirenone and estetrol (Nextstellis)

Dose: 28 tablets in the following order: 24 active tablets each containing drospirenone 3 mg and estetrol 14.2 mg and 4 white inert tablets.
Indication: Indicated for use by females of reproductive potential to prevent pregnancy.
Comparables: Ethinyl Estradiol/Drosperidone

Dostarlimab-gxly (Jemperli)

Dose: Injection: 500 mg/10 mL (50 mg/mL) solution in a single-dose vial.
Indication: for the treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer, as determined by an FDA-approved test, that has progressed on or following prior treatment with complications of allogeneic HSCT after PD-1/L-1–blocking antibody: a platinum-containing regimen.
Comparables: Pembrolizumab (Keytruda)
Guidelines: NCCN Clinical Practices Guidelines in Oncology. Uterine Neoplasms. Version 3.2021. June 03, 2021, https://www.nccn.org/professionals/physician_gls/pdf/uterine_blocks.pdf

Loncastuximab tesirine-lpy (Zynlonta)

Dose: For injection: 10 mg of loncastuximab tesirine-lpyl as a lyophilized powder in a single-dose vial.
Indication: for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low-grade lymphoma, and high-grade B-cell lymphoma.
Comparables: Rituximab (Rituxan), Xpovio, Monjuvi, Yescarta, Kymrhia, Breyanzi
Guidelines: NCCN Clinical Practices Guidelines in Oncology. B-Cell Lymphomas. Version 4.2021. May 5, 2021, https://www.nccn.org/professionals/physician_gls/pdf/b-cell_blocks.pdf

Pegcetaclopan (Empaveli)

Dose: Injection: 1,080 mg/20 mL (54 mg/mL) in a single-dose vial.
Indication: for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).
Comparables: Ravulizumab (Ultomiris), Eculizumab (Soliris)

Generic Available -
First-Time Generic Approval

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Generic Name	Manufacturer	Brand Name	Approval Date	Indication
Lenalidomide Capsules, 5 mg, 10 mg, 15 mg and 25 mg	Natco Pharma Limited	Revlimid (Lenalidomide) Capsules, 5 mg, 10 mg, 15 mg and 25 mg	5/21/2021	For the treatment of multiple myeloma; transfusion-dependent anemia; mantle cell lymphoma; previously treated follicular lymphoma; previously-treated marginal zone lymphoma
Calcitonin Salmon Injection USP, 400 USP units per 2 mL (200 USP units per mL) Multi-Dose Vial	Custopharm, Inc.	Miacalcin (Calcitonin Salmon) Injection USP, 400 USP units per 2 mL (200 USP units per mL) Multi-Dose Vial	5/14/2021	Treatment of symptomatic Paget's disease; hypercalcemia; postmenopausal osteoporosis
Enzalutamide Capsules, 40 mg	Actavis Laboratories FL, Inc	Xtandi (Enzalutamide) Capsules, 40 mg	5/14/2021	For the treatment of patients with castration-resistant prostate cancer
Tiopronin Tablets, 100 mg	Teva Pharmaceuticals USA, Inc	Thiola (Tiopronin) Tablets, 100 mg	4/26/2021	For the prevention of cystine stone formation in adults and pediatric patients 9 years of age and older with severe homozygous cystinuria, who are not responsive to these measures alone
Pregabalin Extended-Release Pregabalin Extended-Release Tablets, 165 mg, 330 mg	Apotex, MSN Laboratories Private Limited, Mylan Pharmaceuticals Inc., Sun Pharmaceutical Industries Limited, Alvogen Pine Brook LLC,	Lyrica CR (Pregabalin) Extended-Release Tablets, 165 mg, 330 mg	4/13/2021	For the management of neuropathic pain associated with diabetic peripheral neuropathy; post-herpetic neuralgia
Tirofiban Hydrochloride Injection, 12.5 mg/250 mL (50 mcg/mL) Single-Dose Container	Gland Pharma Limited	Aggrastat (Tirofiban Hydrochloride) Injection, 12.5 mg/250 mL (50 mcg/mL)	4/8/2021	For the treatment of acute coronary syndrome, including patients who are to be managed medically and those undergoing PTCA or atherectomy
Macitentan Tablets, 10 mg	Zydus Worldwide DMCC	Opsumit (Macitentan) Tablets, 10 mg	4/6/2021	For the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to reduce the risks of disease progression and hospitalization for PAH

Drug Recalls and Safety Alerts

R&D | FDA Approval | In Market Brand | Generic Available | Recalls Safety

Injectable Semorelin / Ipamorelin 3mg and injectable AOD-9604 3mg

Brand/Manufacturer: Innoveix Pharmaceuticals, Inc.
Recall reason: Innoveix Pharmaceuticals, Inc. is voluntarily recalling the following lots of sterile compounded drug products, within expiry. The products are being recalled due to a lack of assurance of sterility. These concerns arose following a routine inspection of the pharmacy by the FDA.
Date of recall: 07/13/2021

Topotecan Injection 4 mg/4 mL (1 mg/mL)

Brand/Manufacturer: Teva
Recall reason: Teva Pharmaceuticals has initiated a voluntary recall of lot 31328962B of Topotecan Injection 4 mg/4 mL (1 mg/mL), to the retail/institutional level in the United States. This voluntary recall was initiated based on a complaint received from a pharmacy after a single glass particle was observed inside one vial. After further examination of the complaint sample, two other particulates were found and identified as one (1) grey silicone particle and one (1) translucent, colorless cotton fiber.
Date of recall: 07/01/2021

Metformin Hydrochloride Extended-Release Tablets

Brand/Manufacturer: Viona Pharmaceuticals Inc.
Recall reason: Viona Pharmaceuticals Inc., is voluntarily recalling 2 (two) lots of Metformin Hydrochloride Extended-Release Tablets, USP 750 mg to the retail level. The 2 (two) lots of Metformin Hydrochloride Extended-Release Tablets, USP 750 mg have been found to contain levels of Nitrosodimethylamine (NDMA) impurities above acceptable daily limits. This product was manufactured by Cadila Healthcare Limited, Ahmedabad, India in November 2019, for U.S. distribution by Viona Pharmaceuticals Inc.
Date of recall: 06/11/2021

NP Thyroid (Thyroid Tablets, USP)

Brand/Manufacturer: Acella
Recall Reason: Acella Pharmaceuticals, LLC, is voluntarily recalling certain lots listed in Tables 1 and 2 below of 15-mg, 30-mg, 60-mg, 90-mg, and 120-mg NP Thyroid®, Thyroid Tablets, USP [levothyroxine (T4) and liothyronine (T3)] to the consumer level. The products are being recalled because routine testing has found these lots to be sub potent. The product contains less than 90% of the labeled amount of liothyronine (T3) and/or levothyroxine (T4).
Date of Recall: 04/30/2021

Drug Shortages

For the most up to date list of drug shortages visit:

https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

https://www.ashp.org/Coronavirus

- ASHP is providing free access to its AHFS Clinical Drug Information application, which also includes access to drug shortages information. AHFS Drug Information® - Open Access Effective March 16, 2020
  - Username: ahfs@ashp.org
  - Password: covid-19

Sources:

- https://www.ashp.org/COVID-19
- https://www.ashp.org/COVID-19
- https://www.cdc.gov/media/releases/2021/s-07082021.html
- https://www.cdc.gov/mmwr/volumes/70/wr/mm7020e2.htm
- https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls
- https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts
- https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2021
- https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals
- https://clinicaltrials.gov

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