

The Year in Review: A Quick View of FDA Approvals in 2023:

FDA approvals of Novel Drugs this year decreased: 53 products were considered “New Molecular Entities” by the FDA. The table includes comments on the products that may have an impact on primary care. Please note that this list covers new molecular entities, not biologicals.

References and Best Resources for information on New Drug Approvals:

- FDA: New Molecular Entity Product Approvals
 - New Molecular Entities: <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2023>
 - To search by month: <http://www.accessdata.fda.gov/scripts/cder/daf/>
 - To see generic drug approvals (78 so far this year):
<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ANDAGenericDrugApprovals/default.htm>
- Drugs.com:
 - New drug approvals with summary: <http://www.drugs.com/newdrugs.html>
 - Generic approvals: <https://www.drugs.com/generic-approvals.html>
- To see the biological approvals:
 - <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biological-approvals-year>
- **Table 1: Actual New Drug Entities** – includes orals, Injectables, Biologicals and Biosimilar product approvals
- **Table 2: New Drug Entities in Oncology**
- **Table 3: Generic Approvals** – includes all generic approvals *potentially relevant to Primary Care*

Table 1: Actual New Drug Entities

Approval Date	Drug Name	Active Ingredient	FDA-approved use on approval date*
1/6/2023	Leqembi	lecanemab-irmb	Alzheimer’s disease
1/20/2023	Brenzavvy	bexagliflozin	To improve glycemic control in adults with type 2 diabetes mellitus as an adjunct to diet and exercise NEW SGLT2-Inhibitor
2/1/2023	Jesduvroq	daprodustat	Anemia caused by chronic kidney disease for adults on dialysis for at least four months
2/16/2023	Lamzede	velmanase alfa-tycv	Non-central nervous system manifestations of alpha-mannosidosis
2/17/2023	Filspari	sparsentan	To reduce proteinuria in adults with primary immunoglobulin A nephropathy at risk of rapid disease progression
2/28/2023	Skyclarys	omaveloxolone	Friedrich’s ataxia
3/9/2023	Zavzpret	zavegepant	Migraine
3/10/2023	Daybue	trofinetide	Rett syndrome
3/22/2023	Rezzayo	rezafungin	Candidemia and invasive candidiasis
3/24/2023	Joenja	leniolisib	Activated phosphoinositide 3-kinase delta syndrome
4/25/2023	Qalsody	tofersen	Amyotrophic lateral sclerosis in adults who have a SOD1 gene mutation
5/9/2023	Elfabrio	pegunigalsidase alfa-iwxj	Confirmed Fabry disease

5/12/2023	Veozah	fezolinetant	Moderate to severe hot flashes caused by menopause
5/18/2023	Miebo	perfluorhexyloctane	Signs and symptoms of dry eye disease
5/23/2023	Xacduro	sulbactam, durlobactam	Hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia caused by susceptible isolates of Acinetobacter baumannii-calcoaceticus complex
5/25/2023	Paxlovid	nirmatrelvir, ritonavir	Mild-to-moderate COVID-19 in adults at high risk for progression to severe COVID-19
5/26/2023	Inpefa	sotagliflozin	Heart failure – Dual SGLT1 and SGLT2 inhibitor (NEW)
6/23/2023	Litfulo	ritlecitinib	Severely patchy hair loss
6/26/2023	Rystiggo	rozanolixizumab-noli	Generalized myasthenia gravis in adults who are anti-acetylcholine receptor- or anti-muscle-specific tyrosine kinase antibody-positive
6/27/2023	Ngenla	somatrogon-ghla	Growth failure due to inadequate secretion of endogenous growth hormone
7/17/2023	Beyfortus	nirsevimab-alip	To prevent respiratory syncytial virus (RSV) lower respiratory tract disease
7/25/2023	Xdemvy	lotilaner	Demodex blepharitis
8/4/2023	Zurzuvae	zuranolone	Postpartum depression
8/4/2023	Izervay	avacincaptad pegol	Geographic atrophy secondary to age-related macular degeneration
8/18/2023	Veopoz	pozelimab-bbfg	Patients 1 year old and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease
9/22/2023	Exxua	gepirone	Major depressive disorder
9/28/2023	Pombiliti	cipaglucosidase alfa-atga	Late-onset Pompe disease
9/29/2023	Rivfloza	nedosiran	To lower urinary oxalate levels in patients 9 years and older with primary hyperoxaluria type 1 and relatively preserved kidney function
10/12/2023	Velsipity	etrasimod	Moderately to severely active ulcerative colitis in adults
10/17/2023	Zilbrysq	zilucoplan	To treat generalized myasthenia gravis in adults who are anti-acetylcholine receptor (AChR) antibody positive
10/17/2023	Bimzelx	bimekizumab	Moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy
10/26/2023	Agamree	vamorolone	Duchenne muscular dystrophy
10/26/2023	OmvoH	mirikizumab-mrkz	Ulcerative Colitis
11/15/2023	Defencath	taurolidine, heparin	To reduce the incidence of catheter-related bloodstream infections in adults with kidney failure receiving chronic hemodialysis through a central venous catheter
11/16/2023	Ryzneuta	efbemalenograstim alfa-vuxw	Neutropenia
12/5/2023	Fabhalta	iptacopan	Paroxysmal nocturnal hemoglobinuria

Table 2: New Drug Entities in Oncology

Approval Date	Drug Name	Active Ingredient	FDA-approved use on approval date*
1/27/2023	Jaypirca	pirtobrutinib	Relapsed or refractory mantle cell lymphoma in adults who have had at least two lines of systemic therapy, including a BTK inhibitor
1/27/2023	Orserdu	elacestrant	Estrogen receptor-positive, human epidermal growth factor receptor 2-negative, ESR1-mutated, advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy
3/22/2023	Zynyz	retifanlimab-dlwr	Metastatic or recurrent locally advanced Merkel cell carcinoma
5/19/2023	Epkinly	epcoritamab-bysp	Relapsed or refractory diffuse large B-cell lymphoma (not otherwise specified) and high-grade B-cell lymphoma after two or more lines of systemic therapy
5/25/2023	Posluma	flotufolastat F 18	To use with positron emission tomography imaging in certain patients with prostate cancer
6/15/2023	Columvi	glofitamab-gxbm	Diffuse large B-cell lymphoma, not otherwise specified, or large B-cell lymphoma arising from follicular lymphoma after two or more lines of systemic therapy
7/20/2023	Vanflyta	quizartinib	To use as part of a treatment regimen for newly diagnosed acute myeloid leukemia that meets certain criteria
8/9/2023	Talvey	talquetamab-tgvs	Adults with relapsed or refractory multiple myeloma who have received at least four prior therapies
8/14/2023	Elrexfio	elranatamab-bcmm	Adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy
8/16/2023	Sohonos	palovarotene	To reduce the volume of new heterotopic ossification in adults and pediatric patients (aged 8 years and older for females and 10 years and older for males) with fibrodysplasia ossificans progressiva
9/8/2023	Aphexda	motixafortide	To use with filgrastim (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma
9/15/2023	Ojjaara	momelotinib	Intermediate or high-risk myelofibrosis in adults with anemia
10/27/2023	Loqtorzi	toripalimab-tpzi	Recurrent or metastatic nasopharyngeal carcinoma when used together with or following other therapies
11/8/2023	Fruzaqla	fruquintinib	Refractory, metastatic colorectal cancer
11/15/2023	Augtyro	repotrectinib	ROS1-positive non-small cell lung cancer
11/16/2023	Truqap	capivasertib	Breast cancer that meets certain disease criteria
11/27/2023	Ogsiveo	nirogacestat	Adults with progressing desmoid tumors who require systemic treatment

Table 3: FIRST-TIME GENERIC APPROVALS
 (Price might not be lower yet, but the potential exists)

Approval Date	Brand Name	Generic Name	Class/ used for
2/17/23	Zonalon	Doxepin Topical Cream 5%	Pruritus
2/24/23	Thoila EC	Tiopronin DR Tabs	Cystinuria
3/6/23	Pylera	Bismuth Sub citrate Potassium, Metronidazole and Tetracycline Hydrochloride Capsules	Helicobacter Pylori Infection
3/21/23	Enstilar	Betamethasone Dipropionate and Calcipotriene Topical Aerosol Foam 0.064% / 0.005%	Plaque Psoriasis
3/30/23	Vemlidy	Tenofovir Alafenamide Fumarate 25 mg	Hepatitis B
4/12/23	Uceris	Budesonide Rectal Foam 2mg/actuation	Ulcerative Colitis
4/12/23	Alrex	Loteprednol Etabonate Ophthalmic Susp 0.2%	Seasonal Allergic Conjunctivitis
4/17/23	Menostar	Estradiol Transdermal System 0.014mg/24hr	Prevent Postmenopausal Osteoporosis
6/8/23	Fleqsuvy	Baclofen Oral Susp 25mg/5ml	Spasticity
6/13/23	Katerzia	Amlodipine Oral Susp 1 mg/ml	HTN/CAD
6/14/23	Xadago	Safinamide Mesylate 50mg and 100mg tabs	Parkinson's Disease
6/14/23	Nasonex 24HR	Mometasone Furoate Nasal Spray 0.05 mg/spray	Allergic Rhinitis
6/20/23	Spiriva	Tiotropium Bromide Inhalation Powder 0.018mg	COPD
6/22/23	Adzenys XR-ODT	Amphetamine Extended-Release Orally Disintegrating Tablets	ADHD
6/23/23	Lastacaft	Alcaftadine Opth Soln 0.25%	Allergic Conjunctivitis
6/30/23	Nascobal	Cyanocobalamin Metered Nasal Spray 0.5mg	Vitamin B12 Deficiency
7/6/23	Vivitrol	Naltrexone for Extended-Release Injectable Suspension 380 mg/vial	Alcohol and/or Opioid Dependence
7/13/23	Steglatro	Ertugliflozin Tablets 5mg and 15 mg Lacks the CKD/HF data of other SGLT2-i	Type 2 Diabetes (SGLT2-I)
7/31/23	Onglyza	Saxagliptin Tablets 2.5mg and 5 mg TAKEN OFF THE MARKET 2023	Type 2 Diabetes (DPP4-I)
7/31/23	Kombiglyze XR	Saxagliptin and Metformin Extended-Release	Type 2 Diabetes
8/4/23	Xiidra	Lifitegrast Opth SOln 5%	Dry Eye Disease
8/22/23	Retin-A Micro	Tretinoin Gel 0.08%	Acne Vulgaris
8/25/23	Vyvanse	Lisdexamfetamine Dimesylate Capsules	ADHD; Binge Eating Disorder
9/5/23	Carospir	Spironolactone Oral Susp 25mg/5ml	Heart Failure and Reduced Ejection Fraction