

## The Year in Review: A Quick View of FDA Approvals in 2024:

FDA approvals of Novel Drugs this year decreased again: 44 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/novel-drug-approvals-fda/novel-drug-approvals-2024>
  - To search by month: <http://www.accessdata.fda.gov/scripts/cder/daf/>
  - To see generic drug approvals (58 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*
11/22/2024	Rapiblyk	landiolol	To treat <b>supraventricular tachycardia</b>
11/22/2024	Attruby	acoramidis	To treat <b>cardiomyopathy</b> of wild-type or variant transthyretin-mediated amyloidosis
10/25/2024	Orlynvah	sulopenem etzadroxil, probenecid	To treat uncomplicated <b>urinary tract infections</b> (uUTI)
10/16/2024	Vyalev	Foscarbidopa and foslevodeopa	To treat motor fluctuations in adults with advanced <b>Parkinson’s disease</b>
9/26/2024	Cobenfy	xanomeline and trospium chloride	To treat <b>schizophrenia</b>
9/24/2024	Aqneursa	levacetylleucine	To treat Niemann-Pick disease type C
9/20/2024	Miplyffa	arimoclomol	To treat Niemann-Pick disease type C
9/13/2024	Ebglyss	lebrikizumab-lbkz	To treat moderate-to-severe <b>atopic dermatitis</b>
8/19/2024	Lazcluze	lazertinib	To treat non-small cell lung cancer
8/14/2024	Niktimvo	axatilimab-csfr	To treat chronic graft-versus-host disease (cGVHD)
8/14/2024	Livdelzi	seladelpar	To treat primary <b>biliary cholangitis</b> (PBC)
8/12/2024	Nemluvio	nemolizumab-ilto	To treat <b>prurigo nodularis</b>
8/9/2024	Yorvipath	palopegteriparatide	To treat <b>hypoparathyroidism</b>
7/25/2024	Leqselvi	deuruxolitinib	To treat severe <b>alopecia areata</b>

7/2/2024	Kisunla	donanemab-azbt	To treat <b>Alzheimer's disease</b>
6/26/2024	Ohtuvayre	ensifentrine	To treat <b>chronic obstructive pulmonary disease</b>
6/20/2024	Piasky	crovalimab-akkz	To treat <b>paroxysmal nocturnal hemoglobinuria</b>
6/18/2024	Sofdra	sofpironium	To treat primary axillary <b>hyperhidrosis</b>
6/10/2024	Iqirvo	elafibranor	To treat primary <b>biliary cholangitis</b> in combination with ursodeoxycholic acid
6/6/2024	Rytelo	imetelstat	To treat low- to intermediate-1 risk <b>myelodysplastic syndromes</b>
4/26/2024	Xolremdi	mavorixafor	To treat WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis)
4/3/2024	Zevtera	ceftobiprole medocaril sodium	To treat certain bloodstream <b>infections</b> , bacterial skin and associated tissue infections, and community-acquired bacterial pneumonia
3/29/2024	Voydeya	danicopan	To treat extravascular hemolysis with paroxysmal nocturnal hemoglobinuria
3/27/2024	Vafseo	vadadustat	To treat <b>anemia</b> due to chronic kidney disease
3/26/2024	Winrevair	sotatercept-csrk	To treat <b>pulmonary arterial hypertension</b>
3/21/2024	Duvyzat	givinostat	To treat <b>Duchenne muscular dystrophy</b> in individuals aged 6 years and older
3/19/2024	Tryvio	aprocitentan	To treat <b>hypertension</b>
3/14/2024	Rezdiffra	resmetirom	To treat noncirrhotic non-alcoholic <b>steatohepatitis</b> with moderate to advanced liver scarring
2/29/2024	Letybo	letibotulinumtoxinA-wlbg	To temporarily improve the appearance of moderate-to-severe glabellar lines
2/22/2024	Exblifep	cefepime, enmetazobactam	To treat complicated <b>urinary tract infections</b>
1/5/2024	Zelsuvmi	berdazimer	To treat <b>molluscum contagiosum</b>

**Table 2: New Drug Entities in Oncology**

Approval Date	Drug Name	Active Ingredient	FDA-approved use on approval date*
12/4/2024	Bizengri	zenocutuzumab-zbco	To treat non-small cell lung cancer and pancreatic adenocarcinoma
11/20/2024	Ziihera	zanidatamab-hrii	To treat unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer
11/15/2024	Revuforj	revumenib	To treat relapsed or refractory acute leukemia
10/18/2024	Vyloy	zolbetuximab-clzb	To treat gastric or gastroesophageal junction adenocarcinoma s: VYLOY
10/11/2024	Hympavzi	marstacimab-hncq	To prevent or reduce bleeding episodes related to hemophilia A or B
10/10/2024	Itovebi	inavolisib	To treat locally advanced or metastatic breast cancer
8/6/2024	Voranigo	vorasidenib	To treat Grade 2 astrocytoma or oligodendroglioma
5/16/2024	Imdelltra	tarlatamab-dlle	To treat extensive stage small cell lung cancer
4/23/2024	Ojemda	tovorafenib	To treat relapsed or refractory pediatric low-grade glioma

4/22/2024	Anktiva	nogapendekin alfa inbakicept-pmln	To treat bladder cancer
4/17/2024	Lumisight	pegulicianine	To use as an optical imaging agent for the detection of cancerous tissue
3/13/2024	Tevimbra	tislelizumab-jsgr	To treat unresectable or metastatic esophageal squamous cell carcinoma

**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 and comments
11/19/2024	Byetta	Exenatide 300 mcg/1.2 ml and 600mcg/2.4ml	GLP1-RA for Diabetes BID dosing, needs renal adjustment, no evidence for reducing MACE
10/31/2024	Eprontia	Topiramate Oral Solution 25 mg/ml	Epilepsy, migraines
9/30/2024	Slynd	Drospirenone Tablets 4 mg	Progestin for Prevention of Pregnancy
8/26/2024	Gocovri	Amantadine ER capsules	Parkinson's Disease
8/26/2024	Relistor	Methylnaltrexone SQ Soln	Opioid Induced Constipation
8/22/2024	Tiglutik	Riluzole Oral Susp 50mg/10ml	ALS
8/20/2024	Lucemyra	Lofexidine Tablets 0.18mg	Opiate Withdrawal
8/02/2024	Pred Forte	Prednisolone Acetate Ophthalmic Susp	Ocular Inflammation
7/15/2024	Tazorac Cream	Tazarotene Topical Cream 0.05%	Plaque Psoriasis
7/8/2024	Endari	L-Glutamine Powder for Oral Susp	Sickle Cell Disease
6/25/2024	Qsymia	Phentermine and Topiramate ER Caps	Obesity
6/14/2024	Stendra	Avanafil Tablets	Erectile Dysfunction
5/29/2024	Astepro Allergy	Azelastine Nasal Spray	Allergic Rhinitis
5/21/2024	Entresto	Sacubitril and Valsartan Tablets	Heart Failure
5/17/2024	Descovy	Emtricitabine and Tenofovir Alafenamide Fumarate Tablets	HIV Infection
5/06/2024	Radicava	Edaravone IV Soln	ALS
4/22/2024	EstroGel	Estradiol Transdermal Gel	Menopausal Symptoms
4/8/2024	Oracea	Doxycycline Capsules	Rosacea
4/05/2024	Ingrezza	Valbenazine Capsules	Tardive Dyskinesia
3/18/2024	Nuessa	Metronidazole Vaginal Gel	Bacterial Vaginosis

3/15/2024	Entadfi	Finasteride and Tadalafil caps	BPH
2/13/2024	Osphena	Ospemifene Tablets	Menopause Symptoms
2/07/2024	Tybost	Cobicistat Tablets	HIV Infection
1/31/2024	Multaq	Dronedarone Tablets	Atrial Fibrillation
1/16/2024	Dificid	Fidaxomicin Tablets	Clostridioides difficile-Associated Diarrhea