

New Drug Approvals

Approval Date	Label Name	Generic Name	Strength	Dosage Form	Use	Launch
10/07/2019	Aklief®	trifarotene	0.005%	cream	acne	10/09/2019
10/07/2019	Beovu®	brolocizumab	6mg/0.05ml	eye injection	age related macular degeneration	10/10/2019
10/21/2019	Trikafta®	elexacaftor/ivacaftor / tezacaftor	100mg/75mg /50mg	tablet	cystic fibrosis	10/23/2019

Newly Available Brand Drugs

Approval Date	Label Name	Generic Name	Strength	Dosage Form	Use	Launch
12/20/2018	Asparlas®	calaspargase pegol-mknl	3750 units/5ml	intravenous	leukemia	10/04/2019
07/19/2019	Drizalma® Sprinkle	duloxetine	20, 40, 60, and 80mg	delayed release capsule	Depression, pain	10/02/2019
1/13/19	Gloperba®	colchicine	0.6mg/5ml	oral solution	prevention of gout	10/31/2019
09/10/2019	Gvoke®	glucagon	0.5mg/0.1ml and 1mg/0.2ml	solution for injection	low blood sugar	10/11/2019
05/20/2019	Nayzilam®	midazolam	5mg per spray	nasal spray	seizures	10/09/2019
12/21/2018	ProAir® Digihaler	albuterol sulfate	Delivers 90 mcg albuterol per puff	inhaler with web app	asthma	10/04/2019

*Specialty medications are listed in **bold** type

09/19/2019	Ozobax®	baclofen	5mg/5ml	oral solution	spasticity from Multiple Sclerosis	10/02/2019
08/24/2019	Wakix®	pitolisant	4.45 and 17.8mg	tablets	narcolepsy	10/01/2019

First Time Generic Approvals

Label Name	Generic Name	Strength	Dosage Form	Use
Levsin®	hyoscyamine	0.5mg/mL	injection	gut spasms
Naftin®	naftifine	1%	gel	fungal infections
Solu-Medrol®	methylprednisolone	500mg	injection	inflammation
Soolantra®	ivermectin	1%	cream	parasite infection

New Uses

Drug Name or Class	Previous Use	New Use
Descovy® (emtricitabine/tenofovir alafenamide)	treatment of active HIV-1 infections	pre-exposure prevention (PrEP) of HIV
Stelara® (ustekinumab)	plaque psoriasis, psoriatic arthritis, Crohn's disease	ulcerative colitis
Ultomiris® (ravulizumab-cwvz)	paroxysmal nocturnal hemoglobinuria	atypical hemolytic uremic syndrome

*Specialty medications are listed in **bold** type



Safety Updates and Recalls

Drug Name or Class	Use	Description	Impact
lorazepam	anxiety	Possible contamination of one lot from one manufacturer	Consumers were advised to contact manufacturer for instructions on how to return the product.
ranitidine	heartburn	Voluntary recall by multiple manufacturers due to potential impurity.	Consumers advised to stop taking ranitidine and consider using another similar drug.

References:

1. U.S. Food and Drug Administration. Novel Drug Approvals for 2019. Available at: <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2019>. Updated November 11, 2019. Accessed November 11, 2019.
2. U.S. Food and Drug Administration. Drugs@FDA: FDA Approved Drug Products. Available at: <https://www.accessdata.fda.gov/scripts/cder/daf/>. Updated November 11, 2019. Accessed November 11, 2019.
3. <https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>