

New Drugs Approved by the FDA in 2016

This is a running list of the new drugs approved by the FDA in 2016. We will continue to update this list throughout the year. The first section lists new molecular entities as they are approved in 2016...and the second and third sections list significant new biologicals and significant new dosage forms of previously approved drugs. Some of these drugs are not yet commercially available. You'll also find a list of important drug withdrawals of 2016. Descriptions and advice about using the most significant products appear in the monthly issues of *Pharmacist's Letter*, *Pharmacy Technician's Letter*, and *Prescriber's Letter*...and more details can be found in our *PL Detail-Documents*. Subscribers can get the *PL Detail-Documents* from www.PharmacistsLetter.com, www.PharmacyTechniciansLetter.com, and www.PrescribersLetter.com.

New Molecular Entities

BRAND	GENERIC	COMPANY	DESCRIPTION
<i>Adlyxin</i>	lixisenatide	Sanofi-Aventis	An injectable GLP-1 agonist for type 2 diabetes.
<i>Axumin</i>	fluciclovine F 18	Blue Earth Diagnostics	A radioactive diagnostic agent for PET imaging for suspected prostate cancer recurrence.
<i>Briviact</i>	brivaracetam	UCB	New anticonvulsant for use as add-on therapy for partial-onset seizures.
<i>Defitelio</i>	defibrotide	Jazz Pharm.	A profibrinolytic agent for hepatic veno-occlusive disease following stem cell transplant.
<i>Epclusa</i>	sofosbuvir/ velpatasvir	Gilead Sciences	New oral fixed-dose combination tablet for chronic hepatitis C.
<i>Netspot</i>	dotatate/ buffer solution	Advanced Accelerator Applications	Kit for the preparation of gallium Ga 68 dotatate injection (a diagnostic agent) for PET imaging of certain neuroendocrine tumors.
<i>Nuplazid</i>	pimavanserin	Acadia	An atypical antipsychotic for Parkinson's disease psychosis.
<i>Venclexta</i>	venetoclax	AbbVie	A BCL-2 inhibitor for chronic lymphocytic leukemia.
<i>Xiidra</i>	lifitegrast	Shire	A lymphocyte function-associated antigen-1 (LFA-1) antagonist ophthalmic solution for dry eye disease.
<i>Zepatier</i>	elbasvir/grazoprevir	Merck	New oral fixed-dose combination tablet for chronic hepatitis C.

Significant New Biologicals

BRAND	GENERIC	COMPANY	DESCRIPTION
<i>Anthim</i>	obiltoximab	Elusys	A monoclonal antibody for prophylaxis and treatment (with antibiotics) of inhalational anthrax.
<i>Cinqair</i>	reslizumab	Teva	An interleukin-5 antagonist for add-on maintenance treatment of severe asthma.
<i>Inflectra</i>	infliximab-dyyb	Celltrion	A tumor necrosis factor blocker and biosimilar to <i>Remicade</i> .
<i>Taltz</i>	ixekizumab	Lilly	An interleukin-17A antagonist for moderate to severe plaque psoriasis.
<i>Tecentriq</i>	atezolizumab	Genentech	A programmed death-ligand 1 blocking antibody for advanced urothelial carcinoma.
<i>Zinbryta</i>	daclizumab	Biogen	An interleukin-2 receptor blocking antibody for relapsing forms of multiple sclerosis.

Significant New Dosage Forms

BRAND	GENERIC	COMPANY	DESCRIPTION
<i>Adzenys XR-ODT</i>	amphetamine	Neos	New orally disintegrating extended-release formulation for ADHD.
<i>Ameluz</i>	aminolevulinic acid hydrochloride	Biofrontera	New gel formulation for actinic keratoses on the face and scalp.
<i>Belviq XR</i>	lorcaserin	Eisai	New extended-release tablet formulation for weight loss.
<i>Bevespi Aerosphere</i>	glycopyrrolate/formoterol	AstraZeneca	New combination anticholinergic/LABA for COPD.
<i>Byvalson</i>	nebivolol/valsartan	Actavis	New combination beta-blocker and ARB for hypertension.
<i>Cabometyx</i>	cabozantinib	Exelixis	New tablet formulation for advanced renal cell carcinoma.
<i>Cetylev</i>	acetylcysteine	Arbor	New effervescent tablet for oral solution formulation for acetaminophen overdose.
<i>Descovy</i>	emtricitabine/tenofovir alafenamide	Gilead Sciences	New combination oral tablet for HIV-1 infection.
<i>Gonitro</i>	nitroglycerin	Espero Pharm.	Sublingual powder formulation for prophylaxis or acute relief of angina.
<i>Jentadueto XR</i>	linagliptin/metformin	Boehringer Ingelheim	New extended-release tablets for type 2 diabetes.
<i>Kovanaze</i>	tetracaine/oxymetazoline	St. Renatus	New nasal spray formulation regional anesthesia for certain dental procedures.
<i>Odefsey</i>	emtricitabine/rilpivirine/tenofovir alafenamide	Gilead Sciences	New combination oral tablet for HIV-1 infection.
<i>Onzetra Xsail</i>	sumatriptan	Avanir	New nasal powder inhalation for acute migraine treatment.
<i>Otovel</i>	ciprofloxacin/fluocinolone	Arbor	New combination otic solution for acute otitis media in patients with tympanostomy tubes.
<i>Photrexa</i>	riboflavin 5'-phosphate	Avedro	New topical ophthalmic solution for progressive keratoconus and corneal ectasia following refractive surgery.
<i>Probuphine</i>	buprenorphine	Braeburn	New implant for subdermal administration of buprenorphine for treatment of opioid dependence.
<i>Qbrelis</i>	lisinopril	Silvergate Pharm.	New oral solution formulation for hypertension, heart failure, and acute MI.
<i>Royaldee</i>	calcifediol	Opko Pharm.	New extended-release (capsule) vitamin D3 analog for secondary hyperparathyroidism in patients with chronic kidney disease.
<i>Relistor</i>	methylnaltrexone	Valeant	New tablet formulation for opioid-induced constipation.
<i>Sernivo</i>	betamethasone dipropionate	Promius	New topical spray formulation for mild to moderate plaque psoriasis.
<i>Syndros</i>	dronabinol	Insys Therapeutics	New oral solution formulation for AIDS-associated anorexia/weight loss and chemo-induced nausea/vomiting.
<i>Viekira XR</i>	dasabuvir/ombitasvir/paritaprevir/ritonavir	AbbVie	New extended-release tablet formulation for chronic hepatitis C.
<i>Xeljanz XR</i>	tofacitinib	Pfizer	New extended-release tablet formulation for rheumatoid arthritis.
<i>Xtampza ER</i>	oxycodone	Collegium	New opioid formulation for chronic, severe pain.
<i>Zembrace SymTouch</i>	sumatriptan	Promius	New injectable formulation for acute migraine treatment.

Important Drug Withdrawals

BRAND	GENERIC	COMPANY	DESCRIPTION
<i>Advicor</i>	niacin ER/ lovastatin	AbbVie	Withdrawn from sale for reasons of safety and effectiveness.
<i>Simcor</i>	niacin ER/ simvastatin	AbbVie	Withdrawn from sale for reasons of safety and effectiveness.