Drugs Coming Off Patent by 2022

Generic versions of the following drugs may be on their way. The following is a list of the drugs coming off patent by 2022.

Drugs for 2016

Brand	Generic Name
Absorica	isotretinoin
Aczone	dapsone
Amitiza	lubiprostone
Astagraf XL	tacrolimus
Axiron	testosterone
Azor	amlodipine/olmesartan
Benicar	olmesartan
Benicar HCT	olmesartan/hct
Canasa	mesalamine suppository
Clindesse	clindamycin
Crestor	rosuvastatin
Cubicin	daptomycin
Daliresp	roflumilast
Edarbi	azilsartan
Edarbyclor	azilsartan/ chlorthalidone
Effient	prasugrel
Enablex	darifenacin
Epogen	retacrit
Epzicom	abacavir/lamivudine
Erbitux	cetuximab
Fanapt	iloperidone
Folotyn	pralatrexate
Gleevec	imatinib
Glumetza	metformin er
Humira	adalimumab
Jevtana	cabazitaxel
Kaletra	lopinavir/ritonavir
Lantus	basalgar
Lantus solostar	basalgar
Letairis	ambrisentan
Lialda	mesalamine dr tab
Mirvaso	brimonidine
Multaq	dronedarone
Neulasta	pegfilgrastim
Nexavar	sorafenib
Nucynta ER	tapentadol er
Nuvaring	ethinyl estradiol/ etonogestrel
Nuvigil	armodafinil
Oxycontin	oxycodone er
Panretin	alitretinoin
Pennsaid 2%	diclofenac
Potiga	ezogabine
Proair HFA	albuterol
Procrit	retacrit
Prolensa	bromfenac
Qsymia	phentermine/ topiramate
Rayos	prednisone dr
Relpax	eletriptan
Remicade	infliximab
Savella	milnaciprin
Seroquel XR	quetiapine xr
Suboxone Film	buprenorphine/ naloxone
Toviaz	fesoterodine
Treanda	bendamustine
Tribenzor	amlodipine/olmesartan/hctz
Truvada	emtricitabine/ tenofovir
Tygacil	tigecycline
Vascepa	icosapent ethyl
Viibryd	vilazodone
Ziana	clindamycin/tretinoin
Zytiga	abiraterone

Drugs for 2017

Brand	Generic Name
Acthar Gel	corticotropin
Aggrenox	aspirin/dipyridamole
Alimta	pemetrexed
Alinia	nitazoxanide
Alvesco	ciclesonide
Ampyra	dalfampridine
Arranon	nelarabine
Aubagio	teriflunomide
Azilect	rasagiline
Butrans	buprenorphine
Byetta	exenatide
Cancidas	caspofungin
Carbaglu	carglumic acid
Cialis	tadalafil
Combigan	timolol/brimonidine
Contrave	buproprion er/naloxone
Copaxone 40 mg	glatiramer
Invanz	ertapenem
Liptruzet	atorvastatin/ ezetimibe
Macugen	pegaptanib
Naftin	naftifine
Nasonex	mometasone
Noxafil	posaconazole
Omnaris	ciclesonide
Quillivant XR	methylphenidate
Reyataz	atazanavir
Sabril	vigabatrin
Sandostatin lar	octreotide
Somavert	pegvisomant
Strattera	atomoxetine
Sustiva	efavirenz
Tamiflu	oseltamivir
Tivicay	dolutegravir
Uceris tablet	budesonide
Velcade	bortezomib
Viagra	sildenafil
Victoza	liraglutide
Viread	tenofovir
Vytorin	ezetimibe/simvastatin
Zetia	ezetimibe
Zioptan	tafluprost
Zolpimist	zolpidem
Zubsolv	buprenorphine/ naloxone

Drugs for 2018

Brand	Generic Name
Acanya	benzoyl peroxide/clindamycin
Adcirca	tadalafil
Apidra	insulin glulisine
Astepro	azelastine
Atripla	efavirenz/ emtricitabine/ tenofovir
Fentora	fentanyl
Finacea	azelaic acid
Follistim	follitropin beta
Fortesta	testosterone
Levitra	vardenafil
Lexiva	fosamprenavir
Lotronex	alosetron
Lyrica	pregabalin
Makena	hydroxyprogesterone
Namzaric	memantine/donepezil
Pradaxa	dabigatran
Promacta	eltrombopag
Remodulin	treprostinil
Revlimid	lenalidomide
Sensipar tablet	cinacalcet
Spiriva	tiotripium
Staxyn	vardenafil
Symbicort	budesonide/ formoterol
Tekamlo	aliskerin/amlodipine
Tekturna	aliskerin
Tekturna HCT	aliskerin/hctz
Tikosyn	dofetilide
Treximet	naproxen/sumatriptan
Tyvaso	treprostinil
Vesicare	solifenacin
Xolair	omalizumab

Drugs for 2019

Brand	Generic Name
Afinitor	everolimus
Avastin	bevacizumab
Azasite	azithromycin
Eliquis	apixiban
Emend INJ	fosaprepitant
Exelon patch	rivastigmine
Exjade	deferasirox
Factive	gemifloxacin
Firazyr	icatibant
Gilenya	fingolimod
Invega sustenna	paliperidone
Orencia	abatacept
Prezista	darunavir
Ranexa	ranolazine
Rozerem	ramelteon
Tarceva	erlotinib
Uloric	febuxostat
Xyrem	sodium oxybate
Zyclara	imiquimod

Drugs for 2020

Brand	Generic Name
Atrovent HFA	ipratropium hfa
Bydureon	exenatide
Chantix	varenicline
Dexilant	dexlansoprazole
Inlyta	axitinib
Namenda XR	memantine er
Safyral	drospirenone/ ethinyl estradiol/ levomefolate
Saphris	asenapine
Silenor	doxepin
Sprycel	dasatinib
Tykerb	lapatinib
Vigamox	moxifloxacin

Drugs for 2021

Brand	Generic Name
Bystolic	nebivolol
Crixivan	indinavir
Emtriva	emtricitabine
Hysingla ER	hydrocodone er
Perforomist	formoterol
Sutent	sunitinib
Veramyst	fluticasone fuoroate
Xarelto	rivaroxaban
Zomig ns	zolmitriptan

Drugs for 2022

Brand	Generic Name
Januvia	sitagliptin
Oxecta	oxycodone
Pristiq	desvenlafaxine
Selzentry	maraviroc
Victrelis	boceprevir
Vimovo	esomeprazole/ naproxen
Vimpat	lacosamide

NPS National Pharmaceutical Services®
A Division of Pharmaceutical Technologies, Inc.

About Brand Drugs

The patent life of a drug is 17 years from the time the chemical entity is identified in the lab. It can take another 10 years before the drug is tested on humans. Therefore, each new drug is guaranteed a minimum of five years patent exclusivity before any generic drugs can be manufactured and marketed. Patent dates are subject to change based on pediatric exclusivity extensions, new indication extensions, and new dosage forms identified for the original chemical entity. Patent dates are continuously being updated and changed. Please consult the FDA Orange Book at www.accessdata.fda.gov/scripts/cder/ob/ for current information.

The Patent Protection Process

The U.S. Food and Drug Administration (FDA) approval process for the patent of a new drug entity is extremely costly and time consuming. It may take a new drug prospect 12 years to reach the market. The drug approval process costs drug manufacturers approximately $360 million dollars. Only five chemical compounds out of 5,000 actually make it to human testing. Furthermore, only one of those five tested compounds will become approved. The manufacturer must follow a complicated protocol.

First, a chemical compound is synthesized that will theoretically have biological activity on a disease state, physiological pathway, or metabolic process. This is known as preclinical testing. If the compound proves to have beneficial activity and safety on desired parameters, an investigational new drug application (IND) is submitted to the FDA. This process takes about three or four years to complete. The submitted IND must include information on the chemical structure of the drug, any adverse side effects noted in animals, proposed mechanism of action for the drug in the body, how the chemical is manufactured, and a specific protocol for human Phase I clinical studies. If the IND submitted by the company is not rejected by the FDA within 30 days, clinical trials on humans may begin.

Phase I clinical trials are performed on healthy volunteers to determine absorption, distribution, excretion, and metabolism of the drug. Pharmacologic efficacy, adverse effects, tolerance, therapeutic levels, and dosage ranges are also determined. Phase I studies usually last one or two years. Phase II clinical trials consist of a larger group of 100 to 300 volunteers who have the disease or condition for which the drug is being tested. These volunteers are used to determine the drug's usefulness and any additional adverse effects or risks that may be seen in this population. This process usually takes approximately two years. Phase III clinical trials have a larger population of 1,000 to 3,000 patients to collect specific information on special indications, effectiveness, and the best means of administration. Physicians monitor patients for adverse reactions not seen in the smaller patient populations. Phase III clinical trials take about three years to complete.

After all three phases are completed, the manufacturer files for a new drug application (NDA). The NDA includes all of the information the company has gathered since the synthesis of the compound. The NDA is usually 100,000 pages or more in length. The FDA is allowed six months to review the NDA; however, the average review time is almost 30 months. If the NDA is approved, the drug may be marketed and prescribed by physicians. At this time phase IV clinical studies, also known as post-marketing studies, begin to monitor the drug for long-term side effects.

The patent life of a drug is 17 years. However, the patent is issued as soon as the IND is filed. From that point, it may be another 10 years before the drug is approved for the consumer market. Therefore, each new drug is guaranteed a minimum of 5 years patent exclusivity (no other company can market or manufacture that drug) for the drug company to regain monetary investment from research and development (R&D) that has gone into the drug. The patent may be extended beyond the original expiration date if a new indication for the drug is discovered, a new strength is made, a new dosage form for administering the medication is implemented, or the drug is found to be beneficial in the pediatric population. Such studies are submitted to the FDA and extensions of up to six months may be granted.

About one year before the expiration of a drug patent, companies wishing to provide a generic product may submit an abbreviated new drug application (ANDA) to the FDA. The approval process of an ANDA is much shorter than the process for the drug that the original brand name manufacturing company had to conduct. The result is a less expensive drug with nearly the exact profile of the original (brand name) drug. However, the ANDA must prove that the generic drug is therapeutically equivalent to the original product in that it contains the exact amount of active ingredient in the same dosage form and route of administration that the original (brand name) drug contains. Bioequivalence and pharmacokinetics must be proven within given federal parameters of five percent variation. If the FDA approves the ANDA, the generic may be marketed after the expiration of the NDA. In the meantime, managed care providers may rearrange their formulary and copays to save money for those covered under the plan.

Drugs that are developed to replicate the enzymes, proteins, or antibodies in our bodies are filed with the FDA with a Biologics License Application (BLA). These include monoclonal antibodies, therapeutic proteins, and vaccines. A manufacturer of the biosimilar product must submit a BLA with scientific data demonstrating that the product is biosimilar to the "brand" biological and has the same mechanism of action, condition of use, route of administration, dosage form, and strength. The biosimilar application can be submitted four years after the "brand" biological has been licensed. The biosimilar pathway is new to the FDA approval system as of 2013; the FDA approved the first biosimilar drug in 2015. A biosimilar may not be substituted by the dispensing pharmacist without first obtaining prescriber approval. The FDA has published the Purple Book, which lists all biologics, their date of licensure, and any biosimilar products that have been approved. It can be read at:

www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm

NPS National Pharmaceutical Services®
A Division of Pharmaceutical Technologies, Inc.
www.pti-nps.com (800) 546-5677 PO Box 407, Boys Town, NE 68010

05-110