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pharmacy & THERAPEUTICS®

AUTHORIZED GENERICS. WHAT ARE THEY?

Authorized generics (AGs) are brand-name drugs that are approved to be marketed without the brand name on the label. Other than not having the brand name on its label, it is the exact same drug product as the brand-name and is often manufactured in the same factory. Authorized generics can be marketed by either the brand-name company or another company with the brand company's permission. Some companies may choose to sell the authorized generic at a lower cost than the brand-name drug, even though it is the same product.

Generics vs. Authorized Generics

Authorized generics are not the same as generic drugs. Generic drugs must be the same as the brand-name drugs in active ingredients, condition of use, dosage form, strength, route of administration, and labeling, but are manufactured by a different company. Generic drugs may have some minor differences from the brand-name drugs, such as different inactive ingredients. For a manufacturer to get approval of a generic, they must submit an Abbreviated New Drug Application (aNDA) to the FDA and prove that it is "bioequivalent" to the brand-name drug. Approval of a generic does not require the manufacturer to prove safety and efficacy. Because this burden of evidence does not exist for a generic, the cost of development is lower, and this is usually reflected in the price of the generic drug.

Authorized generics do not need to submit an aNDA because they are marketed under the New Drug Application (NDA). They just need to notify the FDA if they decide to market an AG because it is automatically considered therapeutically equivalent to its brand-name.

Impact of Authorized Generics

Authorized generics can have an impact in the market. They are usually sold at a lower cost than the brand-name, so they may be more affordable to patients. Authorized generics increase competition in the market by having both the brand and generic available.

Others in the industry believe that authorized generics reduce competition instead. The Generic Pharmaceutical Association (GPhA) says that brand companies usually increase the price of the branded product before the authorized generic goes into the market. This may result in higher cost for patients. Some companies release an authorized generic prior to other generic competitors being marketed. This allows the brand company to gain generic market share. Because generic companies are entering the market with lower prices, they may receive lower profits in the long term, which may affect a company's decision to produce the generic version of the drug.

Examples of authorized generics recently marketed

Authorized Generic	Brand	Use
Ledipasvir/sofosbuvir	Harvoni	Hepatitis C
Insulin lispro	Humalog	Diabetes
Fluticasone/salmeterol	Advair Diskus	Asthma/COPD
Pregabalin	Lyrica	Seizures
Alogliptin	Nesina	Diabetes

References: fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs

pfe-pfizercom-prod.s3.amazonaws.com/about/Authorized_Generics_2018.pdf

xtalks.com/pharmaceutical-industry-authorized-generics/

uspharmacist.com/article/authorized-generic-drugs

FDA WARNINGS

FDA alerts consumers not to use Kratom NC's products

The FDA is warning consumers not to use products marketed by Kratom NC due to microbial contamination. Laboratory analysis of Kratom NC's materials and products identified various microorganisms that may cause serious illness in vulnerable patient populations. FDA contacted Kratom NC to recommend a recall on all its currently marketed products; however, the company has not taken any action to recall these potentially dangerous products. In addition, the FDA issued a warning letter to Kratom NC for illegally selling unapproved, misbranded kratom-containing drug products with unproven claims about their ability to treat or cure opioid addition and withdrawal symptoms. Consumers are urged not to consume kratom and to seek appropriate care from their healthcare provider.

fda.gov/drugs/drug-safety-and-availability/fda-alerts-consumers-not-use-kratom-ncs-products

FDA advises patients not to use Herbal Doctor Remedies' medications

The FDA advises patients against using any drugs manufactured by Herbal Doctor Remedies due to these drugs being made under poor conditions. Herbal Doctor Remedies manufactures a variety of unapproved new drugs, including Brain Forte, Lump Shrinker, Anemia Off, and Bone Fixer offered on various websites. During FDA's inspection of Herbal Doctor Remedies' facility, investigators reported unsanitary conditions and numerous violations of current manufacturing best practices, so the quality and safety of the products cannot be assured. On July 11, 2019, FDA recommended a recall on all unexpired drugs; however, the company has not acted to remove these potentially dangerous drugs from the market. The FDA recommends patients stop using these drugs and dispose of them.

fda.gov/drugs/drug-safety-and-availability/fda-advises-patients-not-use-herbal-doctor-remedies-medications

FDA approves Boxed Warning about increased risk of blood clots and death with higher dose of arthritis and ulcerative colitis medicine tofacitinib (Xeljanz, Xeljanz XR)

The FDA approved a new Boxed Warning about an increased risk of blood clots and death with the 10-mg twice daily dose of tofacitinib (Xeljanz, Xeljanz XR), which is used for initial treatment and long-term use in limited situations in patients with ulcerative colitis (UC). Additionally, the approved use of tofacitinib for UC is limited to patients who are not treated effectively or who experience severe side effects with other certain medications. The warning was approved after the FDA reviewed interim data from an ongoing safety trial of tofacitinib in patients with rheumatoid arthritis (RA). Increased occurrence of blood clots and death was seen in patients taking the 10-mg twice daily dose for RA, and these risks may also apply to those taking tofacitinib for UC. The safety trial is ongoing, and the FDA will reassess these safety issues when the trial has completed and verified data is available.

fda.gov/drugs/drug-safety-and-availability/fda-approves-boxed-warning-about-increased-risk-blood-clots-and-death-higher-dose-arthritis-and

FDA review finds no increased risk of prostate cancer with Parkinson's disease medications containing entacapone (Comtan, Stalevo)

The FDA review of additional data found that there is no increased risk of prostate cancer with the use of entacapone to treat Parkinson's disease. The review was conducted after an earlier trial suggesting this possible risk. Stalevo manufacturer (Novartis) was required to conduct a study to further evaluate the potential risk of more prostate cancer with the entacapone component. As a result of the review, the FDA concluded that entacapone use is not associated with an increased risk of prostate cancer and the recommendation for using medications containing entacapone (Comtan and Stalevo) will remain the same in the prescribing information.

fda.gov/drugs/drug-safety-and-availability/fda-review-finds-no-increased-risk-prostate-cancer-parkinsons-disease-medicines-containing

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FDA WARNINGS

FDA warns about rare occurrence of serious liver injury with use of hepatitis C medications, Mavyret, Zepatier, and Vosevi in some patients with advanced liver disease

The FDA received reports that use of Mavyret, Zepatier, or Vosevi to treat chronic hepatitis C in patients with moderate-to-severe liver impairment has resulted in rare cases of worsening liver function or liver failure. These medications all contain a hepatitis C virus (HCV) protease inhibitor and are not indicated for use in patients with moderate-to-severe liver impairment. Symptoms resolved or new onset worsening of liver function improved after stopping the medicine in most patients. Mavyret, Zepatier, and Vosevi are FDA approved to treat chronic hepatitis C in patients without liver impairment or with mild liver impairment (Child-Pugh A). In the cases that were reported, most of the patients had moderate-to-severe liver impairment (Child-Pugh B or C) or other serious liver problems and should not have been treated with these medications. These medications are safe and effective when prescribed as indicated.

fda.gov/drugs/drug-safety-and-availability/fda-warns-about-rare-occurrence-serious-liver-injury-use-hepatitis-c-medicines-mavyret-zepatier-and

Newly Available Generic Drug/Biosimilar/OTC Approvals

Brand-name	Generic Name	Use
Lyrica	pregabalin	Nerve Pain
Rozerem	ramelteon	Insomnia
Herceptin	trastuzumab	Breast Cancer
Avastin	bevacizumab	Cancer
Uloric	febuxostat	Gout
Firazyr	icatibant	Hereditary Angioedema

Future Generic Drug/Biosimilar/OTC Approvals

Brand-name	Generic Name	Use
Abstral	fentanyl sublingual tablet	Pain
Aptensio XR	methylphenidate ER capsule	ADHD
Evzio	naloxone	Opioid Overdose
Herceptin	trastuzumab	Breast Cancer
Restasis	cyclosporine ophthalmic	Dry Eye Disease
Toviaz	fesoterodine	Overactive Bladder
Treanda	bendamustine	Cancer

Biosimilars

The biosimilar pathway was created as a means to offer more treatment options, increase access to lifesaving medications, and lower healthcare costs by increasing competition. Biosimilar medications by definition are highly similar to their reference product and have no clinically meaningful differences from the reference product in terms of safety, purity, and potency of the product. The FDA uses a rigorous process to evaluate biosimilar medications, including analytical studies, animal studies, and clinical trials. Biosimilar products must also have the same route of administration, dosage form, and strength of the reference product.

As part of their Biosimilars Action Plan (BAP), the FDA has compiled educational materials for both providers and patients on its website **FDA.gov/biosimilars**. These materials answer frequently asked questions and ease concerns that may arise about prescribing or using biosimilar medications. Counseling patients and answering questions about biosimilar medications is an effective method for increasing adherence to therapy.

SelectHealth® offers commercial formulary coverage of the following biosimilar medications:

Reference product	Formulary status	Biosimilar	Formulary status
Filgrastim (Neupogen)	Formulary	Tbo-filgrastim (Granix)[a]	Formulary
		Filgrastim-sndz (Zarxio)	Formulary[b]
		Filgrastim-aafi (Nivestym)	Formulary[b]
Pegfilgrastim (Neulasta)	Formulary	Pegfilgrastim-cbqv (Udenyca)	Formulary
		Pegfilgrastim-jmdb (Fulphila)	Nonformulary
InFLIXimab (Remicade)	Formulary	InFLIXimab-abda (Renflexis)	Formularyb[b,c]
		InFLIXimab-dyyb (Inflectra)	Nonformulary

[a]Tbo-filgrastim (Granix) is not a true biosimilar

[b]Requires prior authorization

[c]InFLIXimab-abda (Renflexis) is preferred for new starts; switching established patients to infliximab-abda (Renflexis) is strongly encouraged

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