



February 2016

Drug Information Update

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NEW GENERICS TO MARKET

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME	APPROVAL DATE
Imatinib Mesylate	100 Mg Tablet	Sun Pharmaceuticals	Gleevec	1/22/2016
Imatinib Mesylate	400 Mg Tablet	Sun Pharmaceuticals	Gleevec	1/22/2016
Benzoyl Peroxide	9 % Solution	Prasco Labs	Triaz	1/29/2016
Benzoyl Peroxide	3 % Solution	Prasco Labs	Triaz	1/29/2016
Naftifine HCl	2 % Cream	Renaissance Pharmaceuticals	Naftin	2/5/2016
Metformin HCl	500 Mg Er Tablet	Lupin Pharmaceuticals	Glumetza	2/5/2016
Metformin HCl	1,000 Mg Er Tablet	Lupin Pharmaceuticals	Glumetza	2/5/2016

RECENT GENERIC FDA APPROVALS

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME	FDA APPROVAL DATE
Valsartan	40mg, 80mg, 160mg, 320mg Tablet	Ivax Pharms	Valsartan	1/4/2016
Gemcitabine Hydrochloride	200mg, 1 gram vial for injection	Gland Pharma Ltd	Gemcitabine Hydrochloride	1/5/2016
Adapalene*	0.1% Topical Solution	Call Inc	Differin	1/5/2016
Vancomycin Hydrochloride*	100 gram for IV infusion	Samson Medcl	Vancomycin Hydrochloride In Plastic Container	1/6/2016
Naftifine Hydrochloride*	2% Topical Cream	Taro	Naftin Cream	1/6/2016
Nystatin	100,000 unit/mL oral suspension	Pharm Assoc	Nystatin	1/7/2016
Dapsone	25mg, 100mg tablet	Fera Pharms Llc	Dapsone	1/7/2016
Ampicillin Sodium; Sulbactam Sodium	500mg, 1 gram, 2 gram vial for injection	Sagent Pharms	Ampicillin and Sulbactam	1/8/2016
Norethindrone Acetate	5mg tablet	Aurobindo Pharma Ltd	Norethindrone Acetate	1/8/2016
Carbidopa	25mg tablet	Alvogen Malta	Carbidopa	1/8/2016
Ampicillin Sodium; Sulbactam Sodium	5 gram, 10 gram vial for injection	Sagent Pharms	Ampicillin and Sulbactam	1/11/2016
Valsartan	40mg, 80mg, 160mg, 320mg Tablet	Amneal Pharms	Valsartan	1/11/2016
Felbamate	400mg, 600mg tablet	Mylan Pharms Inc	Felbamate	1/11/2016
Levocetirizine Dihydrochloride	5mg tablet	Macleods Pharms Ltd	Levocetirizine Dihydrochloride	1/11/2016
Montelukast Sodium	10mg tablet	Anbison Lab Co Ltd	Montelukast Sodium	1/12/2016
Lansoprazole	15mg delayed-release capsule	Natco Pharma Ltd	Lansoprazole	1/13/2016
Paricalcitol	1mcg, 2mcg, 4mcg capsules	Amneal Pharms	Paricalcitol	1/13/2016
Pindolol	5mg 10mg tablet	Nostrum Labs Inc	Pindolol	1/13/2016
Tranexamic Acid	100mg/ml injection	Aurobindo Pharma Ltd	Tranexamic Acid	1/14/2016
Moxifloxacin Hydrochloride	400mg tablet	Crossmedika Sa	Moxifloxacin Hydrochloride	1/14/2016
Paricalcitol	1mcg, 2mcg, 4mcg	Aurobindo Pharma Ltd	Paricalcitol	1/14/2016
Hydrochlorothiazide; Irbesartan	12.5/150mg, 12.5/300mg, 25/300mg tablet	Intl Speclt Chems	Irbesartan and Hydrochlorothiazide	1/15/2016
Potassium Chloride	10mEq extended-release capsule	Glenmark Pharms Ltd	Potassium Chloride	1/19/2016
Rifampin	600mg vial for injection	Watson Pharms Inc	Rifampin	1/19/2016
Doxepin Hydrochloride	3mg, 6mg tablet	Mylan Pharms Inc	Doxepin Hydrochloride	1/20/2016

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME	FDA APPROVAL DATE
Ethinyl Estradiol; Norethindrone Acetate	0.02/1mg tablet	Glenmark Pharms Ltd	Norethindrone Acetate And Ethinyl Estradiol	1/20/2016
Vancomycin Hydrochloride	500mg, 1 gram vial for injection	Gland Pharma Ltd	Vancomycin Hydrochloride	1/21/2016
Potassium Chloride	10mEq, 20mEq extended-release tablet	Novel Labs Inc	Potassium Chloride	1/21/2016
Voriconazole	50mg, 200mg tablet	Aurobindo Pharma Ltd	Voriconazole	1/22/2016
Deferasirox*	125mg, 250mg, 500mg	Actavis Elizabeth	Exjade tablets for oral suspension	1/26/2016
Pantoprazole Sodium	20mg, 40mg delayed-release tablet	Amneal Pharms	Pantoprazole Sodium	1/26/2016
Fluvastatin Sodium	80mg extended-release tablet	Teva Pharms Usa	Fluvastatin Sodium	1/27/2016
Ethinyl Estradiol; Norgestimate	0.035/0.25mg tablet	Jai Pharma Ltd	Norgestimate And Ethinyl Estradiol	1/27/2016
Ethinyl Estradiol; Norgestimate	0.035/0.18mg, 0.035/0.215mg, 0.035/0.25mg tablet	Jai Pharma Ltd	Norgestimate And Ethinyl Estradiol	1/27/2016
Milnacipran*	12.5mg, 25mg, 50mg, 100mg tablets	Liberty Pharma	Savella	1/27/2016
Olanzapine	2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg tablet	Qilu Pharm Co Ltd	Olanzapine	1/27/2016
Dextroamphetamine Sulfate	5mg, 10mg, 15mg extended-release capsule	Mylan Pharms Inc	Dextroamphetamine Sulfate	1/27/2016
Alfuzosin Hydrochloride	10mg extended-release tablet	Unichem Labs Ltd	Alfuzosin Hydrochloride	1/28/2016
Minocycline Hydrochloride	50mg, 75mg, 100mg tablet	Sun Pharm Inds	Minocycline Hydrochloride	1/29/2016
Buprenorphine Hydrochloride	2mg, 8mg sublingual tablet	Sun Pharm Inds Ltd	Buprenorphine Hydrochloride	1/29/2016
Chlorhexidine Gluconate	0.12% oral solution	Colgate-Palmolive Co	Periogard	1/29/2016
Cefepime Hydrochloride	500mg, 1 gram, 2gram vials for injection	Qilu Pharm Co Ltd	Cefepime Hydrochloride	2/1/2016
Levetiracetam	500mg/5ml injection	Aurobindo Pharma Ltd	Keppra	2/1/2016
Lidocaine	5% ointment	Teligent Pharma Inc	Lidocaine ointment	2/1/2016
Celecoxib	50mg, 100mg, 200mg, 400mg capsule	Aurobindo Pharma Ltd	Celecoxib	2/1/2016
Isosulfan Blue	1% injection	Aurobindo Pharma Ltd	Isosulfan Blue	2/2/2016
Cefazolin Sodium	1 gram vial for injection	Hospira Inc	Cefazolin Sodium	2/3/2016
Tetrabenazine	12.5mg, 25mg tablet	Hetero Labs Ltd	Tetrabenazine	2/3/2016
Ammonia N-13	30mCi-300mCi/8ml injectable	Ma General Hosp	Ammonia N-13	2/3/2016

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME	FDA APPROVAL DATE
Gabapentin	600mg, 800mg tablet	Sciegen Pharms Inc	Gabapentin	2/4/2016
Linezolid	600mg tablet	Gate Pharms	Linezolid	2/5/2016
Ibandronate Sodium	3mg/3ml injectable	Accord Hlthcare	Ibandronate Sodium	2/5/2016
Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate	1.25mg, 1.875mg, 2.5mg, 3.125mg, 3.75mg, 5mg, 7.5mg tablet	Actavis Elizabeth	Adderall	2/5/2016
Hydrochlorothiazide; Valsartan	12.5/80mg, 12.5/160mg, 12.5/320mg, 25/160mg, 25/320mg tablet	Prinston Inc	Diovan	2/8/2016
Dexmedetomidine Hydrochloride	200mcg/2ml injectable	Accord Hlthcare Inc	Precedex	2/9/2016
Ethinyl Estradiol; Ethynodiol Diacetate	0.025mg/1mg	Jai Pharma Ltd	Ethinyl Estradiol; Ethynodiol Diacetate	2/9/2016
Bupropion Hydrochloride	100mg, 150mg, 200mg extended-release tablet	Invagen Pharms	Bupropion Hydrochloride	2/9/2016
Temozolomide	5mg, 20mg, 100mg, 140mg, 180mg, 250mg capsule	Kremers Urban Pharms	Temozolomide	2/10/2016
Levofloxacin in 5% dextrose in plastic containers	250mg/50ml, 500mg/100ml, 750mg/150ml injectable	Aurobindo Pharma Ltd	Levofloxacin in 5% dextrose in plastic containers	2/10/2016

*First time generic approval

NEW DRUG ENTITIES

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
Iron replacement	NUFERA	Iron Carb/FA#9/VitC/D3/B6/B12	125mg/1mg/170mg/1000u/15mg/ 16mcg	New Combination
Adrenergics, aromatic, non-catecholamine	DYANAVEL XR	Dextroamphetamine/ amphetamine	2.5mg/ml	New dosage strength and dosage form
Antiseborrheic Agents	SELENIUM SULFIDE	selenium sulfide	2.5%	New Dosage Form
Prenatal Vitamin Preparations	KOSHER PRENATAL PLUS IRON	Prenatal #108/Iron,Carbonyl/Fa	30 mg/1 mg	New Combination
Tx For Attention Deficit-Hyperact(Narcolepsy)	QUILLICHEW ER	Methylphenidate Hcl	20mg, 30mg, 40mg	New Dosage Form
Analgesics, Narcotics	MORPHINE SULFATE	Morphine Sulfate/Pf	1 MG/2 ML	New Strength (No Pricing)
Topical Hemostatics	EVICEL	Thrombin(Hum Plas)/Fibrinog/Ca	2mL, 5mL	New Entity
Topical Anti-Inflammatory, Nsaids	DS PREP PAK	Diclofenac/Benzalkonium Chlor	1%-0.13%	New Dosage Form
Nucleic Acid/Nucleotide Supplements	XURIDEN	Uridine Triacetate	2 gram	New Entity
Nasal Anti-Inflammatory Steroids	TICANASE	Fluticasone/Sod Chl/Sod Bicarb	50 mcg/actuation-0.9 %	New Entity
Neuromuscular Blocking Agents	XEOMIN	IncobotulinumtoxinA	200 unit	New Strength
Hepatitis C Virus- Ns5a And Ns3/4a Inhibitor Comb	ZEPATIER	Elbasvir/Grazoprevir	50 mg-100 mg	New Entity

NEW INDICATIONS (EXISTING DRUGS)

DRUG	NEW INDICATION	DATE OF APPROVAL	LINKS
Ibrance (palbociclib)	HR+, HER2- METASTATIC BREAST CANCER	2/19/2016	Ibrance [package insert] Pfizer Inc. February 2016.
Harvoni (ledipasvir/sofosbuvir)	HCV GENOTYPE 1 AND 4 POST-LIVER TRANSPLANT WITH OR WITHOUT CIRRHOSIS	2/12/2016	Harvoni [package insert] Gilead Sciences Inc. February 2016
Daklinza (daclatasvir)	HCV GENOTYPE 1 AND 3 IN PATIENTS THAT ARE CO-INFECTED WITH HIV, HAVE ADVANCED CIRRHOSIS, OR ARE POST-TRANSPLANT	2/5/2016	Daklinza [package insert] Bristol-Myers Squibb Co. February 2016
Halaven (eribulin mesylate)	UNRESECTABLE LIPOSARCOMA	1/28/2016	Halaven [package insert] Eisai Inc. January 2016
Zepatier (elbasvir/grazoprevir)	CHRONIC GENOTYPE 1 HCV WITH END-STAGE RENAL DISEASE	1/28/2016	Zepatier [package insert] Merck. January 2016
Kyprolis (carfilzomib)	COMBINATION THERAPY FOR RELAPSED OR REFRACTORY MULTIPLE MYELOMA	1/21/2016	Kyprolis [package insert] Onyx Pharmaceuticals. January 2016
Botox (onabotulinumtoxinA)	LOWER LIMB SPASTICITY	1/21/2016	Botox [package insert] Allergan Inc. January 2016.

FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

FDA announces Pharmakon Pharmaceuticals voluntary recall of morphine sulfate 0.5 mg/mL preservative free in 0.9% sodium chloride

[2/16/2016] The U.S. Food and Drug Administration is alerting health care professionals of a voluntary recall of morphine sulfate 0.5 mg/mL preservative free in 0.9% sodium chloride, 1 mL syringe, CII, for intravenous use made and distributed by Pharmakon Pharmaceuticals, in Noblesville, Indiana, because the product is super-potent. Pharmakon initiated the voluntary recall on February 11, 2016, after receiving laboratory results showing the product was super-potent.

Injecting a patient with super-potent morphine could result in serious consequences including respiratory depression, coma, and death. Health care professionals should immediately check their medical supplies, quarantine the recalled product from Pharmakon, and not administer them to patients.

The recalled product was made on February 3, 2016, with an expiration date of March 19, 2016, and labeled with lot E52418EV11C and NDC 45183-0322-78. The recalled product was distributed to two medical facilities – one in Indiana and one in Illinois.

On February 16, 2016, FDA was alerted of serious adverse events in three infants associated with the use of the recalled morphine sulfate products from Pharmakon. Patients who have received this drug product and who have concerns should contact their health care professionals.

FDA encourages health care professionals and patients to report adverse reactions to the FDA's MedWatch Adverse Event Reporting program:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm; or
- Download and complete the form, then submit it via fax at 1-800-FDA-0178.

FDA inspected Pharmakon in March and April 2014, and issued a warning letter in May 2015. Pharmakon is registered under section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA) as an outsourcing facility. The Drug Quality and Security Act, signed into law on November 27, 2013, added a new section 503B to the FDCA. Under section 503B, a compounder can elect to become an outsourcing facility. Outsourcing facilities:

Article Link:

<http://www.fda.gov/Drugs/DrugSafety/ucm486400.htm>

FDA alerts compounding pharmacies of a nationwide voluntary recall of Syrspend SF and Syrspend SF Grape suspending agents from Fagron Inc., due to microbial contamination with yeast

[2/10/2016] The U.S. Food and Drug Administration is alerting compounding pharmacies of the voluntary recall of certain lots of Syrspend SF and Syrspend SF Grape suspending agents used in compounding of various oral liquid drug products, due to the presence of yeast (*Candida galli*).

The Syrspend SF lots are:

- 15I21-U01-026920
- 15J26-U05-027457
- 15J26-U05-027473
- 15I21-U01-027370
- 15J19-U05-027406

The Syrspend SF Grape lots are:

- 15G29-U03-025975
- 15A05-U03-022765
- 15A05-U06-023277

If an immunocompromised patient or a child with an immature immune system ingests the contaminated product, there is a potential the patient will get an infection for which systemic antimicrobial therapy would be necessary.

FDA recommends that compounders not use the referenced lots of contaminated Syrspend SF and Syrspend SF Grape in compounding drug products for patients. Compounding pharmacies who have received the referenced lots of Syrspend SF and Syrspend SF Grape flavor should immediately discontinue use, quarantine the products, and return the products to Fagron, Inc.

FDA is not aware of adverse events reports with patients who may have used the suspending agents. FDA asks compounding pharmacies to report any adverse reactions to the FDA's MedWatch program:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm
- Download and complete the form, then submit it via fax at 1-800-FDA-0178

Article Link:

<http://www.fda.gov/Drugs/DrugSafety/ucm485868.htm>

FDA warns consumers about health risks with Alikay Naturals – Bentonite Me Baby – Bentonite Clay
Laboratory tests indicate elevated levels of lead

[1/18/2016] The U.S. Food and Drug Administration is warning consumers not to use “Bentonite Me Baby” by Alikay Naturals because of a potential lead poisoning risk.

“Bentonite Me Baby” is sold online and in retail outlets, including Target stores, Amazon.com, and Sally Beauty Supply, and is marketed as medicinal clay. The product’s labeling indicates that it can be ingested and applied topically to hair and skin for a variety of conditions.

Consumers should not purchase or use “Bentonite Me Baby.” Anyone who has used this product or provided it to a child should consult a health care professional immediately.

FDA laboratory analysis of the product found elevated lead levels. Exposure to lead can cause serious damage to the central nervous system, the kidneys, and the immune system. In children, chronic exposure to lead, even at low levels, is associated with impaired cognitive function, including reduced IQ, behavioral difficulties, and other problems.

FDA learned that this product may contain lead from the Minnesota Department of Health. FDA has not confirmed any cases of lead poisoning associated with the product.

Health care professionals and consumers are encouraged to report any adverse events potentially related to “Bentonite Me Baby” by Alikay Naturals, or any other alternative medicines, to FDA’s MedWatch Adverse Event Reporting program by:

- Completing and submitting the report online at MedWatch Online Voluntary Reporting Form
- Downloading and completing the form, then submitting it via fax at 1-800-FDA-0178

Article Link:

<http://www.fda.gov/Drugs/DrugSafety/ucm483838.htm>

FDA Warns Consumers Not to Use Viansilk's "Crema Piel De Seda" ("Silky Skin Cream")

[1/18/2016] The Food and Drug Administration (FDA) is warning consumers not to purchase or use a skin whitening cream called "Crema Piel De Seda," due to the risk of mercury poisoning.

FDA laboratory analysis identified mercury in the product. Exposure to mercury can cause serious health problems, such as kidney and nervous system damage. Mercury can also interfere with brain development in children. Signs and symptoms of mercury poisoning include, irritability, shyness, tremors, changes in vision or hearing, memory problems, depression, and numbness and tingling in hands, feet or around the mouth.

Crema Piel De Seda skin cream is labeled in Spanish and is sold primarily in Spanish-speaking communities in the U.S. The product can be found in flea markets and local retail outlets, and is promoted to whiten skin, treat acne, and remove warts and various skin blemishes. The product is manufactured in Mexico by Viansilk (www.viansilk.com).

Consumers are urged to immediately discontinue using Viansilk's Crema Piel De Seda. Anyone who has used this product should thoroughly wash their hands and any other parts of the body that have come in contact with the product, and should contact their health care professional or medical care clinic for medical advice. Consumers should seal the product in a plastic bag or leak-proof container and check with their local environmental, health, or solid waste agency for proper disposal.

FDA learned that the product contained mercury from the Arizona Department of Health Services and the Kansas Department of Health and Environment.

More information on topical skin products containing mercury can be found in FDA's consumer update article, "Mercury Poisoning Linked to Skin Products," located at: [Mercury Poisoning Linked to Skin Products](#).

Healthcare professionals and patients are encouraged to report any adverse events or side effects potentially related to the use of this product to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: [MedWatch Online Voluntary Reporting Form](#)
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Consumers are encouraged to report unlawful sales of products, including “Crema Piel De Seda,” to FDA through our website at: Reporting Unlawful Sales of Medical Products on the Internet.

Article Link:

<http://www.fda.gov/Drugs/DrugSafety/ucm483831.htm>

STUDIES and RECENT TOPICS

Prenatal Acetaminophen Use Tied to Higher Asthma Risk in Kids: Study

February 10, 2016

Pregnant women who take the painkiller acetaminophen -- best known under the brand name Tylenol -- may be more likely to have a child with asthma, new research suggests. Although the study wasn't designed to prove cause-and-effect, researchers found that prenatal exposure to the over-the-counter medicine was associated with an increased risk for asthma in children.

Article: <http://consumer.healthday.com/pregnancy-information-29/pregnancy-news-543/prenatal-acetaminophen-use-tied-to-higher-asthma-risk-in-kids-study-707917.html>

Protection from middle-school whooping cough vaccine fades fast

February 5, 2016

The protection offered by middle-school whooping cough vaccines fades with each passing year, leaving teens vulnerable to infection as they age, a new study finds. The shot protects 69% of 11- and 12-year-olds in the first year after vaccination, but within four years, just 9% of these children have sufficient protection from the infection, according to a study published Friday in Pediatrics.

Article: <http://www.usatoday.com/story/news/2016/02/05/protection-middle-school-whooping-cough-vaccine-fades-fast/79536144/>

C. diff Study Provides Insight Into Antibiotic Resistance and Risks for Infection

February 4, 2016

Exposure to specific antibiotics is linked to the development of certain strains of antibiotic-resistant C. difficile, one of the fastest growing bacteria superbugs, according to a new study published by Stuart Johnson, MD, of Loyola University Health System (LUHS), Loyola University Chicago Stritch School of Medicine (SSOM) and the Hines VA Medical Hospital.

Article: <http://www.infectioncontrolday.com/>

Anxiety Meds Valium, Xanax and Ativan May Not Lead to Dementia After All

February 4, 2016

The connection between benzodiazepines and dementia has not been especially clear in recent years. Last year, a widely publicized study again found that benzodiazepines—Ativan, Valium,

and Xanax—which are often used to treat anxiety and sleep problems, were linked to increased risk for Alzheimer’s disease in elderly people. This week, another study was published, finding that in the highest doses the same meds are not linked to any increased risk for dementia. And if there is a risk, the authors say, it may be because people with the earliest symptoms of Alzheimer’s, which happen to be anxiety and insomnia, may be treated with the very drugs in question. Which makes the connection all the more difficult to tease apart.

Article: <http://www.forbes.com/forbes/welcome/#646efecf408a>

Painkillers Don't Ease Disability Due to Nerve Damage: Study February 1, 2016

Taking prescription narcotic painkillers doesn't improve movement or reduce disability in people with pain related to nerve damage, researchers have found. "Even though [narcotic] medications can be a powerful pain killer, it does not necessarily mean improved function will follow. Pain is not the only factor in determining function," study lead author and pain expert Geoff Bostick, an associate professor of physical therapy at the University of Alberta in Canada, said in a university news release.

Article: <http://consumer.healthday.com/bone-and-joint-information-4/pain-health-news-520/painkillers-don-t-reduce-disability-study-says-707363.html>

Up in smoke? Study finds Pfizer’s Chantix is no better than nicotine patches February 1, 2016

In disappointing news for Pfizer, a study found that its controversial Chantix pill for quitting smoking failed to show any benefit over nicotine patches and lozenges among people trying to kick their habit. Although the study did not question the effectiveness of the product, the findings may represent another hurdle in the quest to transform Chantix into a blockbuster seller. Ever since it was approved a decade ago, Chantix has been dogged by safety concerns, lawsuits, and languishing sales.

Article: <http://www.statnews.com/pharmalot/2016/02/01/chantix-no-better-than-nicotine-patches/>

Opioid Prescriptions Alarming Among COPD Patients January 28, 2016

Researchers from St. Michael’s Hospital in Toronto, Canada, are raising safety concerns about chronic obstructive pulmonary disease (COPD) patients’ use of opioids at high rates, citing their

findings published in the British Journal of Clinical Pharmacology.

Article: <http://www.hcplive.com/medical-news/opioid-prescriptions-alarming-among-copd-patients>

First and Only Approved Extended-Release Orally Disintegrating Tablet for the Treatment of ADHD

January 27, 2016

Neos Therapeutics, Inc., a pharmaceutical company with a late-stage pipeline of innovative extended-release (XR) product candidates for the treatment of attention-deficit/hyperactivity disorder (ADHD), today announced that the U.S. Food and Drug Administration (FDA) approved Adzenys XR-ODT™ for the treatment of ADHD in patients six years and older. With this approval, Adzenys XR-ODT is the first and only extended-release orally disintegrating tablet (ODT) for the treatment of ADHD.

Article:

<http://investors.neostx.com/phoenix.zhtml?c=254075&p=RssLanding&cat=news&id=2132931>

Study: HIV can hide and grow in ‘sanctuaries’ in body after it’s undetectable in blood

January 27, 2016

A new study shows that HIV can still live and grow in the body even after disappearing from the blood following aggressive antiretroviral therapy. The research, published Wednesday in the journal Nature, involved looking at samples of cells from the lymph nodes of three patients who appeared to have cleared the virus. The researchers found that cells in the lymph node tissue can still produce new virus and infect new target cells.

Article: <https://www.washingtonpost.com/news/to-your-health/wp/2016/01/27/study-hiv-can-hide-and-grow-in-sanctuaries-in-body-after-its-undetectable-in-blood/>

Did Studies Lack Key Data on Link Between Antidepressants, Youth Suicides?

January 27, 2016

Antidepressants appear to be much more dangerous for children and teens than reported in medical journals, because initial published results from clinical trials did not accurately note instances of suicide and aggression, a new study suggests.

Article: <http://consumer.healthday.com/general-health-information-16/suicide-health-news-646/did-studies-lack-key-data-on-link-between-antidepressants-youth-suicides-707477.html>

Study: Anti-asthma drugs taken during pregnancy associated with autism risk
January 26, 2016

By comparing birth records over a period of nine years, Drexel researchers found that the children of mothers who took a certain asthma medication during pregnancy faced an elevated risk of being diagnosed with autism spectrum disorder.

Article: http://www.eurekalert.org/pub_releases/2016-01/du-sad012616.php

Coming to a High School Near You: Drugs that Reverse Heroin Overdoses
January 25, 2016

reverses an overdose from heroin and prescription painkillers is being offered for free to high schools across the country. The drugmaker, Adapt Pharma, made the announcement about the gift during a summit Monday held by the Clinton Foundation's Health Matters Initiative, which is collaborating on the project. They will be offering naloxone – known also by its brand name Narcan – to high schools through state departments of education.

Article: <http://www.usnews.com/news/articles/2016-01-25/overdose-reversal-drug-naloxone-offered-free-to-high-schools>

Opdivo + Yervoy
January 23, 2016

Bristol-Myers Squibb Company today announced that the U.S. Food and Drug Administration (FDA) has approved Opdivo (nivolumab) in combination with Yervoy (ipilimumab) for the treatment of patients with BRAF V600 wild-type and BRAF V600 mutation-positive unresectable or metastatic melanoma. This indication is approved under accelerated approval based on progression-free survival (PFS). Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.¹ This approval expands the original indication for the Opdivo + Yervoy Regimen for the treatment of patients with BRAF V600 wild-type unresectable or metastatic melanoma to include patients, regardless of BRAF mutational status, based on data from the Phase 3 CheckMate -067 trial, in which PFS and overall survival (OS) were co-primary endpoints.

Article: <http://news.bms.com/press-release/bmy/bristol-myers-squibbs-opdivo-nivolumab-yervoy-ipilimumab-regimen-receives-expanded>

Patients who are not prescribed opioids find more improvements in physical function, study January 22, 2016

Opioids such as morphine, codeine and Tylenol 3 can be effective for treating pain, however, a new University of Alberta study finds that patients with neuropathic pain taking opioids report no improvements in physical functioning compared to those who were not prescribed opioids.

Article: <http://medicalxpress.com/news/2016-01-patients-opioids-physical-function.html>

U.S. FDA Approves BOTOX® (onabotulinumtoxinA) for the Treatment of Lower Limb Spasticity in Adults January 22, 2016

Allergan, a leading global pharmaceutical company today announced that the U.S. Food and Drug Administration (FDA) has approved BOTOX® (onabotulinumtoxinA) for the treatment of lower limb spasticity in adult patients to decrease the severity of increased muscle stiffness in ankle and toe muscles. BOTOX® is the first and only botulinum toxin product to be approved by the FDA to treat multiple muscle groups of the upper (elbow, wrist, fingers, and thumb) and lower limbs that may be impacted by spasticity.

Article: <http://www.allergan.com/NEWS/News/Thomson-Reuters/U-S-FDA-Approves-BOTOX-onabotulinumtoxinA-for-the>

FDA Approves New Kyprolis® (Carfilzomib) Combination Therapy For The Treatment Of Patients With Relapsed Or Refractory Multiple Myeloma January 21, 2016

Amgen today announced that the U.S. Food and Drug Administration (FDA) has approved the supplemental New Drug Application (sNDA) of Kyprolis® (carfilzomib) for Injection in combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy. The FDA also approved Kyprolis as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy. This FDA decision converts to full approval the initial accelerated approval Kyprolis received in July 2012 as a single agent.

Article: <http://www.amgen.com/media/news-releases/2016/01/fda-approves-new-kyprolis-carfilzomib-combination-therapy-for-the-treatment-of-patients-with-relapsed-or-refractory-multiple-myeloma/>

Allergan Announces FDA Approval of Updated Label for New Dosing Regimen for DALVANCE® (dalbavancin)

January 21, 2016

Allergan plc, a leading global pharmaceutical company, today announced the U.S. Food and Drug Administration (FDA) has approved the company's supplemental new drug application (sNDA) to update the label for DALVANCE® (dalbavancin) for injection. The expanded label will include a single dose administered as a 30-minute intravenous (IV) infusion of DALVANCE for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible Gram-positive bacteria in adults, including infections caused by methicillin-resistant *Staphylococcus aureus* (MRSA).

Article: [http://www.allergan.com/NEWS/News/Thomson-Reuters/Allergan-Announces-FDA-Approval-of-Updated-Lab-\(1\)](http://www.allergan.com/NEWS/News/Thomson-Reuters/Allergan-Announces-FDA-Approval-of-Updated-Lab-(1))

Exposure to Antipsychotics May Increase Risk of Type 2 Diabetes in Youth

January 20, 2016

A meta-analysis published today in *JAMA Psychiatry* suggests that young people who take antipsychotics may be more likely to develop type 2 diabetes than those not taking the medications. The findings, wrote study author Chris Correll, M.D. (pictured left), a professor of psychiatry and molecular medicine at Hofstra North Shore-LIJ School of Medicine, and colleagues, emphasize the importance of routine and proactive monitoring of cardiovascular risk factors when prescribing antipsychotics to youth.

Article: <http://alert.psychnews.org/2016/01/exposure-to-antipsychotics-may-increase.html>

Two-Step Delivery Method Ups Cancer Drug's Concentration In Tumors

January 20, 2016

Researchers report that cancer therapies involving drugs such as Taxol (paclitaxel) might be made more effective if clinicians did the two-step when administering them. The team found that a two-step procedure—delivering a tumor-localizing, drug-absorbing nanoparticle followed by the actual therapeutic—can increase the amount of drug that reaches tumor cells and the amount of time the drug acts on the cells (*Scientific Reports* 2016, DOI: 10.1038/srep18720).

Article: <http://cen.acs.org/articles/94/web/2016/01/Two-Step-Delivery-Method-Ups.html?type=paidArticleContent>

Drug industry to fight superbugs together with governments

Jan 20, 2016

Dozens of makers of medicines and diagnostic tests have joined together in an unprecedented effort to tackle "superbugs" - infections that increasingly don't respond to drugs and threaten millions of people in countries rich and poor.

Article: ap.org

Lilly and Incyte Announce Submission of New Drug Application to FDA for Oral Once-Daily Baricitinib for Treatment of Moderate-to-Severe Rheumatoid Arthritis

Jan. 19, 2016

Eli Lilly and Company and Incyte Corporation today announced that Lilly has submitted a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for the approval of oral once-daily baricitinib for the treatment of moderately-to-severely active rheumatoid arthritis (RA).

Article: <http://newsroom.lilly.com/>

Cranberry Extract For Urinary Tract Infections In Infants Confirmed To Be Safe And Effective Treatment

Jan 19, 2016

Cranberry extract, which has already shown effectiveness in preventing urinary tract infections (UTIs) in adults, can also fight the infection in breastfed infants under a year old, according to a recent study. Although cranberries are commonly used to treat UTIs in adults, many were still unclear about the optimal dosage, and its potential usefulness in young children. But new research published in Annals of Pediatrics suggests using cranberries to prevent UTIs in young children in lieu of antibiotics prevents the risk of increasing antibiotic resistance.

Article: <http://www.medicaldaily.com/cranberry-extract-urinary-tract-infections-infants-confirmed-be-safe-and-370144>

Effort to curb overuse of antibiotics amid cold, flu seasons

Jan 19, 2016

It's cold season, and the miserable continue to trudge in, seeking antibiotics because of mucus turned green, or a cough that has nagged for weeks. Despite years of warnings, doctors still overprescribe antibiotics for acute respiratory infections even though most are caused by viruses that those drugs cannot help.

Article: ap.org

Arzerra®

January 19, 2016

Genmab A/S announced today that the U.S. Food and Drug Administration (FDA) has approved a supplemental Biologics License Application (sBLA) for the use of Arzerra® (ofatumumab) for extended treatment of patients who are in complete or partial response after at least two lines of therapy for recurrent or progressive chronic lymphocytic leukemia (CLL). The application was submitted by Novartis under the ofatumumab collaboration between the two companies

Article: <http://ir.genmab.com/releasedetail.cfm?ReleaseID=950799>

EMVERM Provides a New Option for Patients with Pinworm, Whipworm, Roundworm and Hookworm in Single or Mixed Infections

January 15, 2016

Impax Laboratories, Inc. today announced that the United States Food and Drug Administration (FDA) has approved the Company's supplemental new drug application (sNDA) for EMVERM (mebendazole) 100 mg chewable tablets.

EMVERM is indicated for the treatment of *Enterobius vermicularis* (pinworm), *Trichuris trichiura* (whipworm), *Ascaris lumbricoides* (common roundworm), *Ancylostoma duodenale* (common hookworm), *Necator americanus* (American hookworm) in single or mixed infections. Pinworm is a highly contagious parasite that infects approximately 40 million people in the United States each year.¹ Pinworm infection is three times more common than head lice.² EMVERM is not for persons who have shown hypersensitivity to the drug.

Article: <http://www.prnewswire.com/news-releases/impax-receivesapproval-of-emverm-mebendazole-chewable-tablets-100-mg-300205033.html>

Novartis receives two new FDA approvals for Cosentyx to treat patients with ankylosing spondylitis and psoriatic arthritis in the US

January 15, 2016

Novartis announced today that the US Food and Drug Administration (FDA) has approved Cosentyx® (secukinumab) for the treatment of two new indications — adults with active ankylosing spondylitis (AS) and active psoriatic arthritis (PsA). AS and PsA are both life-long, painful and debilitating inflammatory diseases that affect the joints and/or spine. If not treated effectively, both conditions can lead to irreversible joint and/or spinal bone damage caused by years of inflammation.

Article: <http://multimediacapsule.thomsonone.com/novartis/novartis-receives-fda-approvals-for-secukinumab-in-as-and-psa>

FDA approves expanded use of GSK Hib vaccine from booster dose to full series

January 15, 2016

GSK announced today that the U.S. Food and Drug Administration approved an expanded age indication for HIBERIX® [Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)]. HIBERIX® is now indicated for the immunization of children aged six weeks through four years (prior to 5th birthday) against invasive disease caused by Haemophilus influenzae type b (Hib). Hib infection is a serious disease caused by bacteria usually affecting children under the age of five, and Hib vaccination for appropriate children is routinely recommended.

Article: <http://us.gsk.com/en-us/media/press-releases/2016/fda-approves-expanded-use-of-gsk-hib-vaccine-from-booster-dose-to-full-series/>

Paroxetine in early pregnancy once again linked to birth defects

January 13, 2016

Women who take the antidepressant paroxetine (Paxil, Seroxat) early in pregnancy may be more likely to have babies with birth defects, a review of previous research suggests. While the absolute risk of birth defects remains small at 1 percent to 3 percent across all pregnancies, researchers found that using paroxetine during the first trimester was linked to a 23 percent increase in risk for major congenital malformations and a 28 percent higher risk of heart defects.

Article: <http://www.reuters.com/article/us-health-pregnancy-paroxetine-idUSKCN0UR2QS20160113>

Taking drugs for depression linked to better diabetes control

January 13, 2016

People who have both diabetes and depression may have an easier time keeping their blood sugar levels under control if they also take medication to address their mental health symptoms, a U.S. study suggests.

Article: <http://in.reuters.com/article/us-health-diabetes-depression-idINKCN0UQ2O020160112>

Statin use before heart surgery reduces complications

January 12, 2016

According to the Centers for Disease Control and Prevention (CDC), cholesterol-lowering medication is used by 28% of Americans over the age of 40, and statins account for more than 90% of these drugs.

Dr. Amr F. Baraka, from the Cleveland Clinic Foundation, OH, took a look at the effects of statins on a number of cardiac surgery outcomes.

Article: <http://www.medicalnewstoday.com/articles/304922.php>

Heartburn pills linked to increased risk of kidney disease

January 11, 2016

People who take popular heartburn pills known as proton pump inhibitors (PPIs) may be more likely to develop chronic kidney disease than individuals who don't use these drugs, a study suggests.

Article: <http://news.yahoo.com/heartburn-pills-linked-increased-risk-kidney-disease-163055951.html>

RECALLS*

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
CLASS I					
Drugs	Morphine Sulfate, 2mg per mL in sodium chloride	Lot #:151370066M, Exp. 08/15/2015	Class I	Subpotent Drug	Pharmedium Services, LLC
CLASS II					
Drugs	Domperidone BP, Active Pharmaceutical Ingredient for Prescription Compounding	Lot #: F10349, F10349A, F10349B, F10349C, F10349D, F10349E, Exp 01/15; F10829, F10829A, F10829B, F10829C, F10829-2, F10829-2A, F10829-2B, F10829-2D, F10829-2E, F10829-3, F10829-3A, F10829-3B, F10829-3C, F10829-3D, Exp 01/17; F11035, F11035A, F11035B, F11035C, Exp 08/17	Class II	Penicillin Cross Contamination: Potential for products to be cross-contaminated with penicillin.	Freedom Pharmaceuticals Inc
Drugs	HYDROCHLOROTHIAZIDE CAPSULES	Lot # 151379 and Lot #151380; Exp 12/16	Class II	Presence of Particulate Matter	Amerisource Health Services
Drugs	DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE Tablets (Mixed Salts of a Single Entity Amphetamine Product)	Lot #: 34015516A, Exp 05/16	Class II	Failed Impurities/Degradation Specifications: High out of specification test result for impurities during stability testing.	Teva Pharmaceuticals USA
Drugs	Sulfamethoxazole and Trimethoprim Tablets, USP, 800 mg/160 mg DOUBLE STRENGTH	Lot # 6727001 Exp 01/18	Class II	Presence of foreign substance -This recall has been initiated due to the presence of a polyethylene piece on the finished product.	Mutual Pharmaceutical Company, Inc.
Drugs	Bevacizumab 1.25 mg/0.05	Lot #: 1956@2, exp.	Class II	Presence of	Pine

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
	mL in 3/10 mL 31 G 5/16" Syringe	2/2/2016; 1954@1, exp. 2/2/2016; 1958@3, exp. 2/2/2016; 1943@2, exp. 2/1/2016; 1942@1, exp. 2/1/2016; 1944@3, exp. 2/1/2016; 1938@1, exp. 1/31/2016; 1939@2, exp. 1/31/2016; 1931@1, exp. 1/28/2016; 1932@2, exp. 1/28/2016; 1935@3, exp. 1/28/2016; 1925@1, exp. 1/27/2016; 1927@2, exp. 1/27/2016; 1928@3, exp. 1/27/2016; 1913@3, exp. 1/26/2016; 1917@4, exp. 1/26/2016		particulate matter: Presence of silicone oil microdroplets in bevacizumab syringes for intravitreal use.	Pharmaceuticals, LLC
Drugs	Bevacizumab 1.25 mg/0.05	Lot #: 1648@7, exp. 12/20/2015; 1428@4, exp. 11/17/2015	Class II	Presence of particulate matter: Presence of silicone oil microdroplets in bevacizumab syringes for intravitreal use.	Pine Pharmaceuticals, LLC
Drugs	Bevacizumab 2 mg/0.08 mL in 3/10 mL 31 G 5/16" Syringe for intravitreal	Lot #: 1837@2, exp. 1/17/2016; 1646@6, exp. 12/20/2015	Class II	Presence of particulate matter: Presence of silicone oil microdroplets in bevacizumab syringes for intravitreal use.	Pine Pharmaceuticals, LLC
Drugs	Bevacizumab 2.5 mg/0.1 mL in 3/10 mL 31 G 5/16" Syringe for intravitreal injection	Lot #: 1918@5, exp. 1/26/2016; 1820@5, exp. 1/12/2016; 1773@5, exp. 1/6/2016; 1665@5,	Class II	Presence of particulate matter: Presence of silicone oil	Pine Pharmaceuticals, LLC

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
		exp. 12/22/2015; 1542@5, exp. 12/1/2015; 1544@6, exp. 12/1/2015.		microdroplets in bevacizumab syringes for intravitreal use.	
Drugs	Baclofen USP powder, packaged	Lot #: F10918, F10918-2, Exp: 07/24/2016; F10867, F10867A, Exp date: 03/11/2016	Class II	Presence of Foreign Substance	Freedom Pharmaceuticals Inc
Drugs	Energique, Homeopathic Remedy, Skin Irritant & Healing Support, Topical Spray	Lot: G9471	Class II	Microbial Contamination of Non Sterile Products; testing revealed out of specification results for total aerobic microbiological count	Grato Holdings, Inc.
Drugs		Lot # 112621/E; Exp 12/15	Class II	Lack of Assurance of Sterility	Amerita Specialty Infusion Services
Drugs	IT Custom Compound (BC) Baclofen 2000 mcg/ml, Clonidine 2 mcg/ml 40 ml PF syringe, FOR INTRATHECAL USE ONLY	Lot # 112621/E; Exp. 10/15	Class II	Lack of Assurance of Sterility	Amerita Specialty Infusion Services
Drugs	Bromfenac Ophthalmic Solution 0.09%	a) Lot numbers: 0378-7110-35 AD4819, Exp. Date: 08-2016; 0378-7110-35 AC7894, Exp. Date: 05-2016; 0378-7110-35 AD2527, Exp. Date: 06-2016; 0378-7110-35 AC6330, Exp. Date: 05-2016; 0378-7110-35 AC2330, Exp. Date: 04-2016 and b) Lot numbers: 0378-7109-35 AD4515, Exp. Date: 04-2016 and 0378-7109-35 AC2328, Exp. Date: 01-2016.	Class II	Lack of Assurance of Sterility: Failed preservative effectiveness testing	Mayne Pharma Usa
Drugs	Ephedrine Sulfate 5 mg/mL in 0.9% Sodium Chloride,	All lots with expiration dates up to 11/17/2015	Class II	Stability data does not	Pharmakon Pharmaceuticals

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
	injectable packed in syringes			support expiry.	
Drugs	Epinephrine (PF) 10 mcg/mL in 0.9% Sodium Chloride, injectable packed in syringes	All lots with expiration dates up to 11/17/2015	Class II	Subpotent drug.	Pharmakon Pharmaceuticals
Drugs	Phenylephrine (PF) 100 mcg/mL in 0.9% Sodium Chloride, injectable packed in syringes	All lots with expiration dates up to 11/17/2015	Class II	Stability data does not support expiry.	Pharmakon Pharmaceuticals
Drugs	Rocuronium 10 mg/mL, injectable packed in syringes,	All lots with expiration dates up to 11/17/2015	Class II	Stability data does not support expiry.	Pharmakon Pharmaceuticals
Drugs	Succinylcholine 20 mg/mL, injectable packed in syringes,	All lots with expiration dates up to 11/17/2015	Class II	Stability data does not support expiry.	Pharmakon Pharmaceuticals
Drugs	Midazolam (PF) 0.5 mg/mL in 0.9% Sodium Chloride, injectable packed in syringes	All lots with expiration dates up to 11/17/2015	Class II	Subpotent drug.	Pharmakon Pharmaceuticals
Drugs	Ondansetron 2 mg/mL, injectable packed in syringes	All lots with expiration dates up to 11/17/2015	Class II	Stability data does not support expiry.	Pharmakon Pharmaceuticals
Drugs	Midazolam (PF) 0.1 mg/mL in 0.9% Sodium Chloride, injectable packed in syringes	All lots with expiration dates up to 11/17/2015	Class II	Stability data does not support expiry.	Pharmakon Pharmaceuticals
Drugs	Fentanyl Citrate (PF) 50 mcg/mL, injectable packed in syringes	All lots with expiration dates up to 11/17/2015	Class II	Stability data does not support expiry.	Pharmakon Pharmaceuticals
Drugs	Morphine Sulfate (PF) 0.5 mg/mL in 0.9% Sodium Chloride, injectable packed in syringes	All lots with expiration dates up to 11/17/2015	Class II	Stability data does not support expiry.	Pharmakon Pharmaceuticals
Drugs	Hydromorphone HCl 1 mg/mL in 0.9% Sodium Chloride, injectable packed in syringes	All lots with expiration dates up to 11/17/2015	Class II	Stability data does not support expiry.	Pharmakon Pharmaceuticals
Drugs	Glycopyrrolate 0.2 mg/mL, injectable packed in syringes	All lots with expiration dates up to 11/17/2015	Class II	Stability data does not support expiry.	Pharmakon Pharmaceuticals
Drugs	Ketamine 100 mg/mL, injectable packed in syringe	All lots with expiration dates up to 11/17/2015	Class II	Stability data does not support expiry.	Pharmakon Pharmaceuticals
Drugs	Morphine Sulfate (PF) 0.1	All lots with expiration	Class II	Stability data	Pharmakon

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
	mg/mL in 0.9% Sodium Chloride, injectable packed in syringes	dates up to 11/17/2015		does not support expiry.	Pharmaceuticals
Drugs	Ketamine 50 mg/mL, injectable packed in syringes	All lots with expiration dates up to 11/17/2015	Class II	Stability data does not support expiry.	Pharmakon Pharmaceuticals
Drugs	Midazolam 1 mg/mL in 0.9% Sodium Chloride, injectable packed in syringes	All lots with expiration dates up to 11/17/2015	Class II	Stability data does not support expiry.	Pharmakon Pharmaceuticals
Drugs	Lidocaine HCl (PF) Inj, USP 2%, injectable packed in syringes	All lots with expiration dates up to 11/17/2015	Class II	Stability data does not support expiry.	Pharmakon Pharmaceuticals
Drugs	Provocholine Pre-diluted Set II in 0.9% Sodium Chloride	All lots with expiration dates up to 11/17/2015	Class II	Stability data does not support expiry.	Pharmakon Pharmaceuticals
Drugs	MEROPENEM in NS	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiries: a) 18-Sep-15, 20-Sep-15, 21-Sep-15, 22-Sep-15, 23-Sep-15, 24-Sep-15 b) 16-Sep-15, 19-Sep-15, 21-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	CUBICIN (daptomycin) in NS	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiries: a) 24-Sep-15, b) 24-Sep-15, 27-Sep-15, c) 26-Sep-15, d) 24-Sep-15, e) 27-Sep-15, f) 26-Sep-15, 27-Sept-15, g) 24-Sep-15, h) 26-Sep-15, i) 27-Sep-15, j) 26-Sep-15, k) 21-Sep-15 l) 24-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	SOD CHLORIDE (Sodium Chloride)	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiries: a) 28-Sep-15, 1-Oct-15, b) 22-Sep-15, c) 30-Sep-15 d) 29-Sep-15, e) 25-Sep-15, f) 28-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
Drugs	Parenteral Amino Acid Infusion 10%	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiries: a) 26-Sep-15, b) 16-Sep-15 c) 25-Sep-15, d) 25-Sep-15 e) 20-Sep-15, 26-Sep-15, f) 20-Sep-15, 24-Sep-15, g) 20-Sep-15, 26-Sep-15, h) 20-Sep-15, i) 15-Sep-15, j) 26-Sep-15, k) 25-Sep-15, 26-Sep-15, l) 20-Sep-15, 23-Sep-15, m) 20-Sep-15, 24-Sep-15, 26-Sep-15, n) 23-Sep-15, o) 20-Sep-15, p) 26-Sep-15, q) 20-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	CEFAZOLIN	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiries: a) 1-Oct-15, b) 28-Sep-15, 29-Sep-15, c) 30-Sep-15 d) 28-Sep-15, 1-Oct-15 e) 25-Sep-15, 28-Sep-15, 29-Sep-15, 30-Sep-15, 1-Oct-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	Milrinone in 0.45% NS	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiries: a) 1-Oct-15, b) 29-Sep-15, c) 25-Sep-15, 30-Sep-15, d) 25-Sep-15, e) 1-Oct-15, f) 29-Sep-15, g) 26-Sep-15, h) 1-Oct-15, i) 29-Sep-15, j) 25-Sep-15, k) 1-Oct-15, l) 25-Sep-15, m) 27-Sep-15, 1-Oct-15, n) 24-Sep-15, 30-Sep-15, o) 25-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	SOLUMEDROL (methylprednisolone succinate) 1GM in NS	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expires: 22-Sep-15, 23-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be	Sentara Enterprises

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
				guaranteed.	
Drugs	INTRALIPID (fat emulsion)	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiries: a) 25-Sep-15, b) 20-Sep-15, c) 24-Sep-15, d) 20-Sep-15, e) 24-Sep-15, f) 26-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	POTASSIUM CHLORIDE in D 5 1/2NS	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiries: a) 30-Sep-15, b) 30-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	Dextrose-NaCl (D5-1/2NS) in NS	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiries: a) 25-Sep-15, b) 30-Sep-15, c) 28-Sep-15, 1-Oct-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	CEFTRIAXONE in NS	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiries: a) 26-Sep-15, 27-Sep-15, b) 21-Sep-15, 24-Sep-15, 25-Sep-15, 26-Sep-15, 27-Sep-15, c) 25-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	DOBUTAMINE HCL in D5W	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiries: a) 30-Sep-15, b) 25-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	VANCOMYCIN HCL	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiries: a) 29-Sep-15, 30-Sep-15, b) 25-Sep-15, 29-Sep-15, c) 25-Sep-15 d) 25-Sep-15, 26-Sep-15, 29-Sep-15, e) 25-Sep-15, 1-Oct-15, f) 28-Sep-15, 29-Sep-	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
		15, 1-Oct-15, g) 25-Sep-15, h) 25-Sep-15, 27-Sep-15, 29-Sep-15, i) 29-Sep-15, j) 25-Sep-15, 26-Sep-15, k) 29-Sep-15, l) 25-Sep-15, 27-Sep-15, 30-Sep-15, m) 1-Oct-15			
Drugs	ONDANSETRON HCL 8MG	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expires: 25-Sep-15, 28-Sep-15, 29-Sep-15, 1-Oct-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	HYDROMORPHONE HCL	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiries: a) 29-Sep-15 b) 30-Sep-15 c) 1-Oct-15, d) 30-Sep-15, e) 30-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	GANCICLOVIR in NS	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiries: a) 25-Sep-15, 1-Oct-15, b) 28-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	ASCORBIC ACID 500MG/Syringe	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiry: 27-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	Invanz (ertapenem)	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiries: a) 22-Sep-15, b) 19-Sep-15, 20-Sep-15, 22-Sep-15, 23-Sep-15, 24-Sep-15, 25-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	CEFEPIME	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiries: a) 1-Oct-15, b)	Class II	Lack of Assurance of Sterility: Product sterility	Sentara Enterprises

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
		30-Sep-15, 1-Oct-15, c) 28-Sep-15		cannot be guaranteed.	
Drugs	ZOSYN (piperacillin/tazobactam) in NS	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiries: a) 1-Oct-15 b) 28-Sep-15 c) 25-Sep-15, 29-Sep-15, d) 26-Sep-15, 29-Sep-15 e) 1-Oct-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	MORPHINE 10MG/ML in NS	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiries: a) 25-Sep-15, b) 30-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	PENICILLIN in D5W	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiries: a) 27-Sep-15, b) 28-Sep-15, 30-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	FLUCONAZOLE IN NAACL 400MG in NS	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiry: 25-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	Ampicillin/Sulbactam 12GM in NS	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expires: 17-Sep-15, 19-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	Nafcillin 2GM in NS	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiry: 27-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	Lactated Ringers	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiries: a) 28-Sep-15 b) 14-Sept-15 c) 1-Oct-	Class II	Lack of Assurance of Sterility: Product sterility cannot be	Sentara Enterprises

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
		15		guaranteed.	
Drugs	Candidas (caspofungin acetate) 58.4MG in NS	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiry: 30-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	AZACTAM (aztreonam) 2GM in NS	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiry: 30-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	CLINDAMYCIN 120MG in NS	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiry: 29-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	Solu-Cortef (hydrocortisone) 1MG in NS	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiries: 28-Sep-15, 30-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	GENTAMICIN	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiries: a) 30-Sep-15, b) 25-Sep-15, c) 24-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	Tobramycin 120MG	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiry: 29-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	Dextrose-5% Lactated Ringers	All Lots compounded between 11-Sep-15 and 17-Sep-15. Expiry: 28-Sep-15	Class II	Lack of Assurance of Sterility: Product sterility cannot be guaranteed.	Sentara Enterprises
Drugs	MYCAMINE (micafungin sodium) 150MG	All Lots compounded between 11-Sep-15	Class II	Lack of Assurance of	Sentara Enterprises

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
		and 17-Sep-15. Expiries: 24-Sep-15, 27-Sep-15		Sterility: Product sterility cannot be guaranteed.	
Drugs	Guaifenesin Grape liquid 100 mg/5 mL	Lot #: 5MK0340, 5LK0592, Exp 08/17	Class II	Defective Delivery System: Firm recalled Guaifenesin liquid and Guaifenesin DM liquid due incorrect dose markings on the dosing cups.	Perrigo Company PLC
Drugs	Guaifenesin DM Cherry liquid (guaifenesin 100 mg/5 mL and Dextromethorphan HBr 5 mg/5 mL)	Lot #: 5LK0528, 5LK0630, 5LK0779, Exp 03/17	Class II	Defective Delivery System: Firm recalled Guaifenesin liquid and Guaifenesin DM liquid due incorrect dose markings on the dosing cups.	Perrigo Company PLC
Drugs	Levofloxacin Tablets USP, 500 mg	Lot # 151387, Exp 10/31/16	Class II	Failed Dissolution Specifications: Unexplained low out of specification results for dissolution.	Amerisource Health Services
Drugs	Lyrica (pregabalin) capsules, 50 mg	Lot #: M07861, Exp 05/2018	Class II	FAILED TABLET/CAPSULE SPECIFICATIONS : Firm is recalling specific lots of pregabalin capsules due to the potential presence of deformed or damaged	Pfizer Inc.

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
				capsules.	
Drugs	Lyrica (pregabalin) capsules, 75 mg	Lot #: M07862, Exp 05/2018; M07865, Exp 06/2018	Class II	FAILED TABLET/CAPSULE SPECIFICATIONS : Firm is recalling specific lots of pregabalin capsules due to the potential presence of deformed or damaged capsules.	Pfizer Inc.
Drugs	Nystatin, USP Powder for Rx compounding	Lot #: 2015050194, Exp 2/2016	Class II	Labeling: label error on declared strength.	Perrigo Company PLC
Drugs	Nystatin, USP Powder for Rx compounding	Lot #: 2015080484, Exp 02/2016	Class II	Labeling: label error on declared strength.	Perrigo Company PLC
Drugs	SyrSpend SF, a convenient, sweetened, sugar-free syrup-suspending vehicle	Lot #: 15I21-U01-027370; 15I21-U01-026920; 15J19-U05-027406	Class II	Microbial Contamination of Non-Sterile Products: Syrspend SF and Syrspend SF Grape Flavor are being recalled due to the presence of yeast.	Fagron, Inc
Drugs	SyrSpend SF, Suspending Base	Lot #: 15A05-U03-022765; 15G29-U03-025975; 15A05-U06-023277	Class II	Microbial Contamination of Non-Sterile Products: Syrspend SF and Syrspend SF Grape Flavor are being recalled due to the presence of yeast.	Fagron, Inc

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
Drugs	Pramipexole Dihydrochloride Tablets 0.125 mg	Lot #: BPA512A; Expiry: 06/2017.	Class II	Presence of Foreign Tablets/Capsules: Presence of a comingled Carbimazole 5 mg tablet	Macleods Pharma Usa Inc
Drugs	Midazolam HCl Syrup, 10 mg/5 mL	Lot: 932333, Exp 08/04/16	Class II	Presence of Foreign Substance: customer complaint that one unit dose cup contained a small piece of cardboard contaminant.	Safecor Health, LLC
CLASS III					
Drugs	Life-Line DOCUSATE CALCIUM Sodium Free STOOL SOFTENER 240 mg each	Lot #: 5EA46, Exp 02/17	Class III	Labeling: Label mix-up. Docusate Sodium 100mg Softgels were mislabeled as Docusate Calcium 240mg.	National Vitamin Co Inc
Drugs	Lindane Lotion, USP 1%	Lot #: UP1103, Exp 04/2016; UQ1001, Exp 04/2017	Class III	Super-Potent Drug: Out of Specification Assay test results were reported for stability samples.	Morton Grove Pharmaceuticals, Inc.
Drugs	Phentermine Hydrochloride Capsules	Lot #: a) H14C80, Exp 08/16; I14G36, Exp 09/16; b) H14A86, Exp 07/16; c) H14C83, Exp 08/16, K14A21, Exp 11/16; d) H14F25, Exp 08/16; e) L14C42, Exp 12/16.	Class III	Failed impurities/Degradation specifications: out of specification results for individual unknown and total impurity at the 12th month	PD-Rx Pharmaceuticals, Inc.

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
				room temperature stability test station	
Drugs	Tropicamide Ophthalmic Solution USP, 0.5%	Lot #:199001, Expiry: 01/2016; Lot #: 222591, Expiry: 04/2016; Lot #: 224491, Expiry: 06/2016; Lot #: 229241, Expiry: 08/2016; Lot #: 232941, Expiry: 11/2016; Lot #: 239921, Expiry: 02/2017; Lot #: 241701, Expiry: 04/2017; Lot #: 246851, Expiry: 07/2017.	Class III	Labeling: Incorrect or Missing Package Insert: Package insert is missing updates compared with reference drug insert.	Bausch & Lomb, Inc.
Drugs	Clonazepam Tablets, USP, 0.5 mg	Lot # 3063759, Exp.07/16	Class III	Failed Impurities/Degradation Specifications: out of specification result for known impurity at 6 month timepoint.	Mylan Institutional, Inc. (d.b.a. UDL Laboratories)
Drugs	Candesartan Cilexetil Tablets, 16 mg	a) 3022288 12/2015 3025988 03/2016 3025989 04/2016 3030459 08/2016 3030460 08/2016 3032087 10/2016 3032088 10/2016 3034506 12/2016 3035952 01/2017 3035953 01/2017 b) 3022287 12/2015 3025990 04/2016 3030458 08/2016 3032086 09/2016 3035954 01/2017	Class III	Failed Impurities/Degradation Specifications; 9 month stability timepoint	Sandoz Inc.

Product Type	Product Description	Code Info	Class	Reason for Recall	Recalling Firm
Drugs	Candesartan Cilexetil Tablets, 16 mg, 30	Lot # 153855, exp 01/2017	Class III	Failed Impurities/Degradation Specifications; 9 month stability (manufacturer)	Amerisource Health Services
VACCINES					
None					

*Please refer to FDA website for further information; <http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm>

CURRENT DRUG SHORTAGES

Vitamin E Aqueous Oral Solution

January 13, 2016

Reason for the Shortage

- Hospira is changing manufacturing sites from a 3rd party manufacturer to in-house manufacturing. This has caused a delay in production.
- Geritrex could not provide a reason for the vitamin E drops shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=965>

Vecuronium Bromide Injection

January 13, 2016

Reason for the Shortage

- Hospira states the shortage is due to manufacturing delays.^{1,2}
- Teva states the shortage is due to manufacturing delays.³
- Pfizer sold vecuronium injection to Mylan Institutional in December 2013.^{4,5}
- Ben Venue has stopped production in its plant in Bedford, Ohio and closed in 2014.⁶
- Caraco has vecuronium injection available. NDCs changed in mid-2015.⁷
- Sagent temporarily suspended the manufacture of vecuronium 10 mg and 20 mg vials.⁸

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=490>

PCA Sterile Empty Vials and Injector

January 13, 2016

Reason for the Shortage

- Hospira has Lifecare PCA Sterile empty vials with injector on shortage due to quality assurance issues.
- These vials are only compatible with Lifecare PCA systems.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=886>

Caffeine and Sodium Benzoate Injection

January 13, 2016

Reason for the Shortage

- American Regent had caffeine and sodium benzoate injection on shortage due to manufacturing delays.¹
- American Regent is the sole manufacturer of caffeine and sodium benzoate injection.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=817>

PCA Sterile Empty Vials and Injector

January 13, 2016

Reason for the Shortage

- Hospira has Lifecare PCA Sterile empty vials with injector on shortage due to quality assurance issues.
- These vials are only compatible with Lifecare PCA systems.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=886>

Aminocaproic Acid Oral Presentations

January 13, 2016

Reason for the Shortage

- Akorn acquired Versapharm in 2014.
- Akorn stopped distributing and marketing Versapharm's aminocaproic acid product on June 22, 2015.
- Akorn launched Amicar oral solution and 500 mg tablets on June 29, 2015.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1190>

Tropicamide 1% Ophthalmic Solution

January 14, 2016

Reason for the Shortage

- Akorn cannot provide a reason for the shortage of tropicamide 1% ophthalmic solution.
- Sandoz cannot provide a reason for the shortage of tropicamide 1% ophthalmic solution.

- Valeant cannot provide a reason for the shortage of tropicamide 1% ophthalmic solution.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1215>

Lidocaine Injection

January 14, 2016

Reason for the Shortage

- Amphastar had lidocaine 2% emergency syringes on shortage due to increase demand for the product.
- AuroMedics introduced lidocaine injection in February 2014.
- Fresenius Kabi has generic lidocaine presentations on shortage due to a supply interruption of API. Xylocaine products are not affected.
- Hospira has lidocaine presentations on shortage due to manufacturing delays and increased demand.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=859>

Heparin Premixed Bags

January 14, 2016

Reason for the Shortage

- Baxter had product on allocation due to increased demand.
- Hospira states the reason for the shortage is increased demand and manufacturing delays.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1169>

Cefotetan Disodium Injection

January 14, 2016

Reason for the Shortage

- BBraun has cefotetan on allocation due to current market conditions.
- Fresenius Kabi states the reason for the shortage is manufacturing delay.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1097>

Fomepizole Injection

January 15, 2016

Reason for the Shortage

- Sandoz could not provide a reason for the shortage.¹ However, fomepizole injection is manufactured by Emcure for Sandoz.² An Emcure manufacturing site was recently noted to have FDA observations related to GMP and aseptic practices.³
- X-Gen did not provide a reason for the fomepizole shortage.⁴
- Mylan Institutional has fomepizole injection available.⁵

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1173>

Neomycin and Polymyxin B Sulfates and Dexamethasone Ophthalmic Ointment

January 19, 2016

Reason for the Shortage

- Perrigo has neomycin and polymyxin B sulfates and dexamethasone ophthalmic ointment on shortage due to manufacturing issues.
- Sandoz has neomycin and polymyxin B sulfates and dexamethasone ophthalmic ointment on shortage due to increased demand.
- Valeant has neomycin and polymyxin B sulfates and dexamethasone ophthalmic ointment on shortage due to manufacturing delay.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1225>

Mupirocin Calcium 2% Cream

January 20, 2016

Reason for the Shortage

- GlaxoSmithKline could not provide a reason for the shortage.
- Prasco could not provide a reason for the shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1206>

Meningococcal Vaccines

January 20, 2016

Reason for the Shortage

- Sanofi Pasteur cannot provide a reason for the shortage.¹
- GlaxoSmithKline acquired Bexsero and Menveo from Novartis Vaccines and Diagnostics in 2015.²
- Pfizer has Trumenba available.³

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1192>

Hydralazine Injection

January 20, 2016

Reason for the Shortage

- Akorn had hydralazine injection on shortage due to increased demand.
- American Regent has hydralazine injection on shortage due to manufacturing delays.
- Fresenius Kabi had hydralazine injection on shortage due to manufacturing delays.
- X-Gen launched hydralazine injection in September 2015.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1129>

Fenoldopam Mesylate Injection

January 20, 2016

Reason for the Shortage

- Hospira has Corlopam vials on shortage due to manufacturing delays.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1031>

Dextrose (25%) Injection

January 20, 2016

Reason for the Shortage

- Hospira has 25% dextrose syringes on shortage due to increased demand.
- Hospira is the sole supplier of 25% dextrose syringes.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1011>

Deferoxamine Mesylate Injection

January 20, 2016

Deferoxamine injection, Fresenius Kabi
2 gram, vial, 1 count (NDC 63323-0599-30)

Reason for the Shortage

- Fresenius Kabi states the shortage was due to increased demand.
- Hospira has deferoxamine available.
- Novartis discontinued Desferal 2 gram vials in 2015.
- Teva discontinued all deferoxamine presentations in 2013.
- West-Ward discontinued deferoxamine in September 2014.
- Watson discontinued all deferoxamine presentations.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1008>

Ammonium Molybdate Injection

January 20, 2016

Reason for the Shortage

- American Regent has ammonium molybdate injection on shortage due to manufacturing delays.
- American Regent is the sole supplier of ammonium molybdate injection.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1003>

Reserpine Oral Tablets

January 22, 2016

Reason for the Shortage

- Sandoz said the shortage is due to a delay in obtaining raw materials.
- There are no other manufacturers of reserpine tablets.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=975>

Vancomycin Hydrochloride Injection

January 25, 2016

Reason for the Shortage

- Hospira has vancomycin on shortage due to increased demand.¹
- Fresenius Kabi has vancomycin injection on shortage due to increased demand.²
- Mylan Institutional cannot provide a reason for the shortage.
- Baxter is allocating vancomycin.⁴
- Sagent had vancomycin injection on allocation due to increased demand.⁵

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=132>

Hydroxyamphetamine Hydrobromide and Tropicamide Ophthalmic Solution

January 25, 2016

Reason for the Shortage

- Akorn has Paremyd on shortage due to manufacturing delays.
- No clinical trial data were found to support the use of Paremyd in the diagnosis of Horner Syndrome.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1193>

Cytarabine Injection

January 25, 2016

Reason for the Shortage

- Fresenius Kabi had cytarabine on shortage due to increased demand.¹
- Mylan Institutional cannot provide a reason for the shortage.²
- West-Ward discontinued cytarabine injection in September 2014.³
- Hospira has all cytarabine injection available.⁴

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=413>

Cefpodoxime

January 25, 2016

Reason for the Shortage

- Aurobindo could not provide a reason for the shortage.
- Pfizer has discontinued Vantin.
- Ranbaxy has an import ban on all solid medications including cefpodoxime.
- Sandoz could not provide a reason for the shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=793>

Calcium Gluconate Injection

January 25, 2016

Reason for the Shortage

- American Regent has calcium gluconate on shortage due to manufacturing delays.
- Fresenius Kabi has replaced calcium gluconate glass vials with plastic vials.
- American Regent has issued a statement that all lots of calcium gluconate may contain glass particles and filters must be used. Do not use if there are visible glass particles and filter all other product.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=48>

Benzotropine Injection

January 25, 2016

Reason for the Shortage

- American Regent discontinued benztropine injection in May 2015.
- Fresenius Kabi recalled benztropine injection due to potential for glass particles in the vials. The product is on long-term back order.
- Nexus divested benztropine injection to Fresenius Kabi in 2012.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1042>

23.4% Sodium Chloride Concentrated Solution for Injection

January 25, 2016

Reason for the Shortage

- Fresenius Kabi has sodium chloride concentrated solution on shortage due to increased demand.
- Hospira has 23.4% sodium chloride solutions for injection on shortage due to increased demand.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1194>

Phenytoin Injection

January 26, 2016

Reason for the Shortage

- Hospira has phenytoin sodium injection on shortage due to manufacturing delay.
- X-Gen is no longer marketing phenytoin sodium injection.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=740>

Multiple Vitamins for Infusion

January 26, 2016

Reason for the Shortage

- Hospira states the shortage is due to manufacturing delays.
- Baxter has all presentations fully available at this time.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=831>

Morphine PCA Vials

January 26, 2016

Reason for the Shortage

- Hospira has morphine PCA vials on shortage due to quality assurance issues.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1220>

Dexamethasone 0.1% Ophthalmic Drops

January 26, 2016

Reason for the Shortage

- Valeant could not provide a reason for the shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1205>

Sufentanil Injection

January 27, 2016

Reason for the Shortage

- West-Ward has sufentanil on shortage due to manufacturing delays.¹
- Hospira has sufentanil on shortage due to manufacturing delays.²
- Akorn cannot provide a reason for the shortage.³

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=823>

Sodium Chloride 0.9% Injection Bags

January 27, 2016

Reason for the Shortage

- Baxter has 0.9% sodium chloride on shortage due to increased demand.¹
- BBraun has 0.9% sodium chloride available for current customers.²
- Hospira cites increased demand as the reason for the shortage.³
- In cooperation with the FDA, Fresenius Kabi is providing 0.9% sodium chloride to the US market to help alleviate the national shortage. This 0.9% sodium chloride is manufactured in an FDA-approved facility in Norway by Fresenius Kabi AG. There will be presentations available with Australian/English labels and the package insert is the same for all imported presentations.^{4,5}
- Baxter has received FDA approval for 0.9% sodium chloride in Viaflo containers manufactured in an FDA-approved facility in Spain.⁶

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=993>

Ranitidine Injection

January 27, 2016

Reason for the Shortage

- West-Ward discontinued ranitidine injection in September 2014.¹
- Covis had Zantac on shortage due to capacity issues at the manufacturer.²
- IGI laboratories acquired Zantac injection from Covis in October 2015.³
- Zydus has ranitidine injection available.⁴
- Oral ranitidine products are not affected by this shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=820>

Potassium Chloride Injection

January 27, 2016

Reason for the Shortage

- Baxter has a consistent supply of potassium chloride injection.
- Fresenius Kabi has potassium chloride injection available.
- Hospira has a consistent supply of potassium chloride injection.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=696>

Levetiracetam Injection

January 27, 2016

Reason for the Shortage

- American Regent states the reason for the shortage is manufacturing delay.
- Caraco has temporarily discontinued levetiracetam.
- Fresenius states the reason for the shortage is manufacturing delay.
- Hospira has product available.
- Sagent has product available.
- X-Gen states the reason for the shortage is change in manufacturing site.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1183>

Leuprolide Acetate 14-Day Kit

January 27, 2016

Reason for the Shortage

- Caraco states the reason for the shortage is increased demand.
- Sandoz states the reason for the shortage was increased demand.
- Teva states the shortage is due to manufacturing delays.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=737>

Leflunomide Tablets

January 27, 2016

Reason for the Shortage

- Apotex has temporarily discontinued leflunomide and cannot state if they will bring the product back to market.
- Heritage states the shortage is due to a delay in obtaining active ingredient.
- Sanofi-Aventis could not provide a reason for the shortage

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=711>

Dextrose 5% Injection Large Volume Bags

January 27, 2016

Reason for the Shortage

- Baxter states the shortage is due to increased demand.¹
- BBraun has 5% dextrose available for current customers.²
- Hospira states the shortage is due to increased demand and manufacturing delays.³

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1081>

Clindamycin Injection

January 27, 2016

Reason for the Shortage

- Akorn cannot provide a reason for the shortage.
- Pfizer states the Cleocin Add-Vantage vials are on shortage due to manufacturing delays.

- Hospira divested clindamycin injection to Alvogen in September 2015. Alvogen will sell Hospira labeled product until supplies are gone and then will sell Alvogen labeled product.
- Sandoz had clindamycin injection on shortage due to increased demand.
- Sagent has clindamycin injection on shortage due to manufacturing

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1029>

Cardioplegic Solution for Cardiac Perfusion

January 27, 2016

Reason for the Shortage

- Baxter states they are experiencing an increased demand.
- Hospira states the reason for the shortage is manufacturing delay.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1172>

Aminocaproic Acid Injection

January 27, 2016

Reason for the Shortage

- American Regent is not manufacturing aminocaproic acid injection at this time.
- Hospira has aminocaproic acid on shortage due to manufacturing delays.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=789>

Methylprednisolone Sodium Succinate Injection

January 28, 2016

Reason for the Shortage

- Fresenius Kabi states the reason for the shortage is increased demand.
- Pfizer states the reason for the shortage is manufacturing delay.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1077>

Lactated Ringer's Injection Bags

January 28, 2016

Reason for the Shortage

- Baxter is experiencing increased demand.¹
- BBraun has lactated ringer's available for current customers.²
- Hospira cited increased demand as the reason for the shortage.³

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1078>

Fluorouracil Injection

January 28, 2016

Reason for the Shortage

- Accord cannot provide a reason for the shortage.
- Fresenius Kabi states the reason for the shortage is increased demand.
- Teva states the reason for the shortage is increased demand.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=798>

Ceftazidime Injection

January 28, 2016

Reason for the Shortage

- IGI Laboratories changed its name to Teligent in late-October 2015.
- Covis divested Fortaz injection to IGI Laboratories in October 2015.
- Hospira has Tazicef on shortage due to increased demand.
- Sagent has ceftazidime injection on shortage due to manufacturing delays.
- Sandoz discontinued ceftazidime 1 gram and 2 gram vials in 2015.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=869>

Carboplatin Solution for Injection

January 28, 2016

Reason for the Shortage

- Bedford discontinued carboplatin in May, 2011 to concentrate on the manufacturing of other products.¹

- Fresenius Kabi has carboplatin on shortage due to increased demand for the product.²
- Hospira has carboplatin injection available.³
- Mylan Institutional cannot provide a reason for the shortage.⁴
- Sagent states the reason for the shortage is increased demand for the product.⁵
- Sandoz has discontinued carboplatin injection.⁶
- Teva states the reason for the shortage is increased demand for the

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1005>

Calcitriol Injection

January 28, 2016

Reason for the Shortage

- Akorn cannot provide a reason for the shortage.
- American Regent has had calcitriol injection unavailable since 2011.
- Calcitriol capsule and oral solution presentations are available from multiple manufacturers.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=940>

Atropine Sulfate Ophthalmic Solution

January 28, 2016

Reason for the Shortage

- Alcon has discontinued Isopto Atropine.
- Akorn received FDA approval for atropine sulfate 1% ophthalmic solution in July 2014; this new product launched in January 2015.
- Sandoz has discontinued atropine sulfate ophthalmic solution.
- Valeant discontinued their atropine sulfate 1% ophthalmic solution products in 2015.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1146>

Sodium Bicarbonate Injection

January 29, 2016

Reason for the Shortage

- Amphastar has sodium bicarbonate on shortage due to increased demand and has a new NDC number for the product.

- Fresenius Kabi is not currently manufacturing sodium bicarbonate 4.2% 5 mL vials.
- Hospira has sodium bicarbonate on shortage due to manufacturing delays.
- Hospira is the sole supplier of the 4.2% 10 mL syringes used in pediatric patients.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=788>

Morphine Injections

January 29, 2016

Reason for the Shortage

- Astramorph injection has been unavailable since 2012. Fresenius Kabi changed manufacturing sites and cannot estimate if Astramorph will return.
- Hospira states the shortage is due to manufacturing delays.
- West-Ward launched several new morphine sulfate products in late-September 2015.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=664>

Etomidate Injection

January 29, 2016

Reason for the Shortage

- American Regent has etomidate injection on shortage due to manufacturing delays.
- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- Hospira has Amidate on shortage due to manufacturing delays.
- Par Sterile Products discontinued etomidate in early 2015.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=419>

Estradiol Valerate Injection

January 29, 2016

Reason for the Shortage

- Par states the reason for the shortage is manufacturing delay.
- Perrigo states the reason for the shortage was manufacturing issue.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1186>

Dipyridamole Injection

January 29, 2016

Reason for the Shortage

- West-Ward could not provide a reason for the shortage.
- Teva's dipyridamole injection has been unavailable since 2010 and the company has no current plans to return the product to market.
- There are no other manufacturers of dipyridamole injection.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=465>

Dextrose (50%) Injection

January 29, 2016

Reason for the Shortage

- Amphastar has 50% dextrose injection on shortage due to increased demand.
- Hospira has 50% dextrose injection on shortage due to increased demand and manufacturing delays.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1012>

Dexamethasone Sodium Phosphate

January 29, 2016

Reason for the Shortage

- American Regent has dexamethasone sodium phosphate on shortage due to manufacturing delays.
- Fresenius Kabi states the dexamethasone sodium phosphate shortage was due to supply and demand issues.
- West-Ward had dexamethasone sodium phosphate injection on shortage due to increased demand.
- Mylan Institutional states the shortage is due to increased demand.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=751>

Atropine Sulfate Injection

January 29, 2016

Reason for the Shortage

- Amphastar had atropine on shortage due to increased demand.
- Hospira states the shortage is due to manufacturing delays.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=814>

Testosterone Cypionate Intramuscular Injection

February 1, 2016

Reason for the Shortage

- Actavis discontinued testosterone cypionate injection in 2015.
- Paddock had testosterone on shortage due to increased demand and shipping delays from their contract manufacturer.
- West-Ward had testosterone cypionate on shortage due to manufacturing delays.
- Sandoz discontinued testosterone cypionate 200 mg/mL 1 mL and 10 mL vials in September 2011. Sandoz discontinued final presentation in first half of 2012.
- Sun Pharma did not provide a reason for the shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=638>

Mannitol Injection

February 1, 2016

Reason for the Shortage

- American Regent has mannitol injection on shortage due to manufacturing delays.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=863>

Leucovorin Calcium Injection

February 1, 2016

Reason for the Shortage

- Fresenius Kabi has leucovorin on shortage due to increase demand.
- Teva had leucovorin on allocation due to increased demand.

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired leucovorin calcium injection from Bedford in July 2014. West-Ward is not actively marketing leucovorin calcium injection at this time.
- Sagent has leucovorin on shortage due to manufacturing delay.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=488>

Famotidine Injection

February 1, 2016

Reason for the Shortage

- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.¹
- West-Ward states the shortage was due to manufacturing delays.²
- Oral famotidine products are not affected by this shortage.
- Pfizer launched famotidine injections in March, 2012.³
- Mylan Institutional acquired famotidine injections from Pfizer on December 6, 2013.⁴
- Baxter has famotidine premixed bags available.⁶
- Fresenius Kabi has famotidine injection available.⁵

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=810>

Calcium Chloride Injection

February 1, 2016

Reason for the Shortage

- American Regent has calcium chloride on shortage due to manufacturing delays.
- Amphastar had calcium chloride on shortage due to increased demand.
- Hospira has calcium chloride on shortage due to manufacturing delay.
- Mylan Institutional has withdrawn calcium chloride syringes from the market. The company recalled the syringes in April 2015 due to incompatibility of the syringes and some needless adaptors.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=941>

Tamsulosin Hydrochloride Capsules

February 2, 2016

Reason for the Shortage

- Boehringer Ingelheim had tamsulosin capsules on shortage due to production delays.
- Actavis and Zydus state the reason for the shortage was increased demand.
- Aurobindo is not marketing the 100 count size.
- Caraco cannot provide a reason for the shortage.
- Teva discontinued tamsulosin 0.4 mg capsules in April 2014.
- Par discontinued tamsulosin 0.4 mg capsules.
- Sandoz has tamsulosin on shortage due to increased demand for the product.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1112>

Oxytocin Injection

February 2, 2016

Reason for the Shortage

- Fresenius Kabi states the shortage was due to increased demand.
- Par Sterile Products (formerly JHP) discontinued generic oxytocin injection in July 2014. Par Sterile Products discontinued Pitocin 10 unit/mL 50 mL vials in September 2015.
- West-Ward cannot provide a reason for the shortage.
- West-Ward has oxytocin on shortage due to manufacturing delays.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=876>

Milrinone Injection

February 2, 2016

Reason for the Shortage

- Fresenius Kabi states the reason for the shortage is increased demand for the product.
- Hospira has milrinone injection on shortage due to increased demand.
- West-Ward states the shortage is due to manufacturing delays.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=741>

Furosemide Injection

February 2, 2016

Reason for the Shortage

- Fresenius Kabi has furosemide injection available.¹
- American Regent has furosemide injection on shortage due to manufacturing delays.^{2,3}
- Hospira has furosemide injection available.^{4,5}
- Wockhardt has discontinued all furosemide injection presentations.⁶
- Claris could not provide a reason for the shortage

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=636>

Dexrazoxane Injection

February 2, 2016

Reason for the Shortage

- Biocodex USA acquired Totect from Apricus Pharmaceuticals in April 2013.
- Mylan Institutional could not provide a reason for the shortage.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired dexrazoxane injection from Bedford in July 2014. West-Ward is not actively marketing dexrazoxane injection at this time.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=415>

Cefepime Injection

February 2, 2016

Reason for the Shortage

- Apotex could not provide a reason for the shortage.
- BBraun has cefepime on allocation due to increased demand.
- Baxter has cefepime on shortage due to increased demand.
- Fresenius Kabi has cefepime injection on shortage due to manufacturing delays.
- Sagent has cefepime injection on shortage due to manufacturing delays.
- Sandoz discontinued cefepime injection in December 2015.
- WG Critical Care has cefepime injection on shortage due to increased demand.
- Hospira has Maxipime on shortage due to manufacturing delays.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1176>

Ampicillin Sulbactam

February 2, 2016

Reason for the Shortage

- Hospira states that ampicillin sulbactam vials are on back order due to manufacturing delay.
- Sagent has ampicillin sulbactam vials on allocation due to increased demand for the product.
- WG Critical Care states the shortage is due to increased demand.
- Pfizer and Sandoz cannot provide a reason for the shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=805>

Yellow Fever Vaccine Injection

February 3, 2016

Reason for the Shortage

- Sanofi Pasteur could not provide a reason for the shortage of YF-Vax.¹
- There are no other suppliers of yellow fever vaccine.
- Additional information is available

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=383>

Tobramycin Injection

February 3, 2016

Reason for the Shortage

- Fresenius Kabi had tobramycin solution for injection on shortage due to increased demand.
- Hospira has tobramycin on shortage due to manufacturing delays.
- Mylan Institutional could not provide a reason for the shortage.
- Teva has tobramycin solution for injection on shortage due to manufacturing delays.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=701>

Tigecycline Injection

February 3, 2016

Reason for the Shortage

- Pfizer has Tygacil on shortage due to manufacturing delays.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1218>

Propranolol Injection

February 3, 2016

Reason for the Shortage

- Ben Venue closed its plant in Bedford, Ohio in July 2014.
- Fresenius Kabi has propranolol injection on back order due to shortage of raw materials.
- Sandoz cannot provide a reason for the shortage.
- West-Ward has propranolol injection available.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1091>

Piroxicam Capsules

February 3, 2016

Reason for the Shortage

- Teva could not provide a reason for the shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=610>

Nicardipine Hydrochloride Injection

February 3, 2016

Reason for the Shortage

- American Regent has never started manufacturing nicardipine injection.
- Caraco has temporarily discontinued nicardipine injection and it is unclear if product will return.
- Chiesi acquired Cornerstone Therapeutics and changed the company's name in 2014. Cardene ampules were discontinued in March 2014.
- Mylan Institutional has had nicardipine injection temporarily unavailable since 2013 and it is unclear if product will return.

- Sandoz has had nicardipine injection temporarily unavailable since 2013 and it is unclear if product will return.
- Wockhardt has nicardipine on shortage due to an FDA import alert. It is unclear if product will return.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=31>

Mitoxantrone Hydrochloride Injection

February 3, 2016

Reason for the Shortage

- Hospira has mitoxantrone injection on shortage due to manufacturing delays.
- Teva has mitoxantrone injection on allocation due to current market conditions.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1212>

Methylphenidate Transdermal

February 3, 2016

Reason for the Shortage

- Noven has Daytrana patches on shortage due to shipping delays.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1216>

Imipenem Cilastatin Injection

February 3, 2016

Reason for the Shortage

- Fresenius has imipenem and cilastatin sodium injection on shortage due to increased demand.
- Hospira has imipenem and cilastatin sodium injection on shortage due to manufacturing delays.
- Merck has Primaxin vials on shortage due to increased demand. Merck has discontinued Primaxin ADD-Vantage vials.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1182>

Haloperidol Lactate Injection

February 3, 2016

Reason for the Shortage

- Patriot Pharmaceuticals could not provide a reason for the shortage.
- Sagent could not provide a reason for the shortage.
- Teva has haloperidol lactate on shortage due to manufacturing delays.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including haloperidol lactate injection. West-Ward is not actively marketing haloperidol lactate at this time.
- Janssen could not provide a reason for the shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=527>

Haemophilus B Conjugate Vaccine

February 3, 2016

Reason for the Shortage

- GlaxoSmithKline cannot provide a reason for the shortage of Hiberix.¹
- Sanofi Pasteur has ActHIB in short supply due to the shortage of other combination vaccines (eg, Pentacel).^{2,3}
- Merck has PedvaxHIB (Haemophilus b meningococcal protein conjugate vaccine) available.⁴

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1052>

Cisplatin Injection

February 3, 2016

Reason for the Shortage

- Fresenius Kabi has cisplatin available.¹
- Mylan Institutional could not provide a reason for the shortage.²
- Teva was allocating cisplatin to prevent stockpiling.³
- WG Critical Care could not provide a reason for the shortage.⁴

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=57>

BCG Vaccine Live Intravesical

February 3, 2016

Reason for the Shortage

- Sanofi Pasteur states the reason for the shortage is manufacturing delay.¹
- Merck states the reason for the shortage was increased demand. Merck has Tice BCG readily available.²

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=915>

Ampicillin Injection

February 3, 2016

Reason for the Shortage

- Fresenius states the reason for the shortage is increased demand.
- Sagent states the reason for the shortage is manufacturing delay.
- Sandoz cannot provide a reason for the shortage.
- WG Critical Care states the reason for the shortage is increased demand.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1226>

Piperacillin Tazobactam Injection

February 4, 2016

Reason for the Shortage

- Apotex has piperacillin/tazobactam on shortage due to regulatory delays.
- AuroMedics and Sandoz could not provide a reason for the shortage.
- Baxter has Zosyn frozen premixes on allocation due to increased demand.
- Fresenius Kabi has piperacillin/tazobactam on shortage due to increased demand.
- Sagent has piperacillin/tazobactam on shortage due to increased demand.
- Pfizer has Zosyn on shortage due to manufacturing delays. Pfizer estimates there will be supply shortages through December 2015 for the single dose vials and 1st quarter 2017 for the bulk vials.
- Sandoz discontinued piperacillin/tazobactam in late 2015.
- WG Critical Care states the reason for the shortage is increased demand.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1075>

Ondansetron Injection

February 4, 2016

Reason for the Shortage

- AuroMedics did not provide a reason for the shortage.
- Fresenius Kabi had ondansetron injection on back order due to increased demand.
- Heritage has new NDC numbers for ondansetron injection.
- Hospira has ondansetron injection on shortage due to increased demand.
- Sagent had ondansetron on back order due to increased demand.
- The Medicines Company will no longer be supplying ondansetron.
- West-Ward had ondansetron on back order due to increased demand.
- Wockhardt has ondansetron injection on an FDA import alert.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1040>

Iron Dextran Injection

February 4, 2016

Reason for the Shortage

- Actavis had INFeD on shortage due to manufacturing delays.
- American Regent's Dexferrum injection has been unavailable since 2013.
- Other parenteral iron products are not affected by this shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1069>

Eptifibatide Injection

February 4, 2016

Reason for the Shortage

- Merck states the reason for the shortage is manufacturing delay.
- AuroMedics launched eptifibatide injection in December 2015.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1210>

Diltiazem Injection

February 4, 2016

Reason for the Shortage

- Akorn states the reason for the shortage is increased demand due to market conditions.
- Hospira states the reasons for the shortage are manufacturing delays and increases in demand.
- West-Ward had diltiazem injection on shortage due to manufacturing delays caused by increased demand due to current market conditions.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=217>

Desmopressin Injection

February 4, 2016

Reason for the Shortage

- Teva and Hospira have desmopressin injection on shortage due to manufacturing delays.
- Ferring divested generic desmopressin to Amring Pharmaceuticals in January 2016.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1010>

Albuterol Sulfate Metered Dose Inhalers

February 4, 2016

Reason for the Shortage

- GlaxoSmithKline could not provide a reason for the shortage.
- Teva had ProAir on allocation due to limited supplies.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1217>

Zolpidem Tartrate Immediate Release Tablets

February 5, 2016

Reason for the Shortage

- Aurobindo could not provide a reason for the shortage.
- Major could not provide a reason for the shortage.
- Mylan could not provide a reason for the shortage.

- Torrent was unable to provide availability information.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1219>

Theophylline Extended-Release Tablets

February 5, 2016

Reason for the Shortage

- Major has theophylline extended-release tablets on shortage due to increased demand.
- Teva cannot provide a reason for the shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1221>

Synthetic Conjugated Estrogen

February 5, 2016

Reason for the Shortage

- Teva discontinued Cenestin in late-August 2014.
- Premarin is not affected by this shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1087>

Pantoprazole Injection

February 5, 2016

Reason for the Shortage

- Pfizer has Protonix on shortage due to increased demand.
- Pfizer is the sole supplier of pantoprazole injection.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1153>

Metoprolol Injection

February 5, 2016

Reason for the Shortage

- American Regent has metoprolol injection on shortage due to manufacturing delays.¹
- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.^{2,3}
- Claris has metoprolol injection on allocation.⁴
- Fresenius Kabi states the shortage is due to increased demand for the product.⁵
- Hospira states the shortage is due to increased demand.⁶
- Novartis discontinued Lopressor injection in mid-2015.⁷
- Sagent states the shortage is due to increased demand for the product.⁸
- Sandoz cannot provide a reason for the shortage.⁹
- West-Ward has metoprolol injection on shortage due to increased demand.¹⁰

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=813>

Ketorolac Tromethamine Injection

February 5, 2016

Reason for the Shortage

- BD Rx has ketorolac injection available.¹
- Fresenius Kabi has ketorolac injection available.²
- Hospira has ketorolac on shortage due to manufacturing delays for quality improvement activities and increased demand for the product.³
- Hospira issued a voluntary recall of several presentations of ketorolac in January 2015 due to potential for particulate matter.
- Sagent states the reason for the shortage is demand exceeding supply.⁴
- West-Ward has ketorolac injection on shortage due to manufacturing delays.⁵
- Ben Venue closed its plant in Bedford, Ohio in July 2014.⁶
- FDA imposed an import ban in mid-2013 on several Wockhardt products including ketorolac.⁷
- Sprix Nasal Spray is not affected by this shortage.⁸

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=593>

Benzonatate Capsules

February 5, 2016

Reason for the Shortage

- Amneal and Ascend Laboratories cannot provide a reason for the shortage.
- Caraco discontinued benzonatate capsules in mid-2015.
- Zydus states the reason for the shortage is manufacturing delay.
- Pfizer had Tessalon Perles on shortage due to supply and demand issues.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1155>

Sodium Acetate Injection

February 8, 2016

Reason for the Shortage

- American Regent has sodium acetate injection on back order due to manufacturing delays.
- Fresenius Kabi only has short-dated product available.
- Hospira has sodium acetate injection on back order due to increased demand.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=762>

Epinephrine Injection

February 8, 2016

Reason for the Shortage

- American Regent discontinued both epinephrine presentations in early 2015.
- Amphastar states the shortage is due to increased demand.
- BPI Labs received FDA approval for epinephrine injection in 2014 and the company launched product in February 2015.
- Hospira has epinephrine syringes on shortage due to manufacturing delays.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=685>

Cefazolin Injection

February 8, 2016

Reason for the Shortage

- BBraun has cefazolin on shortage due to increased demand.
- Fresenius Kabi has cefazolin available.
- WG Critical Care has cefazolin available.
- Sandoz has cefazolin available.
- Hospira has cefazolin available.
- Sagent has cefazolin on shortage due to increased demand.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=987>

Amino Acid Products

February 8, 2016

Reason for the Shortage

- Baxter was experiencing increased demand.
- BBraun was experiencing increased demand.
- Hospira has amino acid products on back order due to manufacturing delays.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=671>

Thrombin Topical Solution (Bovine)

February 10, 2016

Reason for the Shortage

- Pfizer states the reason for the shortage is manufacturing delay.
- Recombinant thrombin topical solution products (Recothrom) are available and not affected by this shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1199>

Poliovirus Vaccine Inactivated

February 10, 2016

Reason for the Shortage

- Sanofi Pasteur has IPOL vaccine on allocation due to the shortage of other combination vaccines (e.g., Pentacel).^{1,2}

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1228>

Phenazopyridine Hydrochloride

February 10, 2016

Reason for the Shortage

- Amneal Pharmaceuticals, Avkare, SDA Laboratories discontinued phenazopyridine tablets.
- Gemini Laboratories has new NDC numbers for Pyridium products.
- Marlex could not provide a reason for the shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1144>

Mupirocin Calcium 2% Nasal Ointment

February 10, 2016

Reason for the Shortage

- GlaxoSmithKline states the shortage was due to manufacturing issues.¹
- Mupirocin ointment 22 gram tubes are not affected by this shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1094>

Meropenem Injection

February 10, 2016

Reason for the Shortage

- BBraun had meropenem on shortage due to increased demand.
- Fresenius Kabi states the reason for the shortage is increased demand.
- Hospira has meropenem available.
- Sandoz discontinued meropenem injection in January 2015.
- AstraZeneca has Merrem on shortage due to increase demand.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=969>

lothalamate Meglumine 17.2%

February 10, 2016

Reason for the Shortage

- Guerbet (formerly a Mallinckrodt product) states the reason for the shortage is increased demand

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1227>

Diphtheria, Tetanus Toxoid, and Acellular Pertussis and Inactivated Poliovirus and Haemophilus B Conjugate Vaccine (DTaP - IPV/Hib)

February 10, 2016

Reason for the Shortage

- Sanofi Pasteur states the reason for the shortage is manufacturing delay

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=921>

Digoxin Injection

February 10, 2016

Reason for the Shortage

- West-Ward states the shortage is due to manufacturing delays.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=748>

Chloroquine Tablets

February 10, 2016

Reason for the Shortage

- Global Pharmaceuticals discontinued chloroquine tablets in 2014.
- Rising discontinued chloroquine tablets in February 2015.
- Ranbaxy has chloroquine tablets on shortage due to third party supply issues.
- West-Ward has chloroquine tablets on shortage due to manufacturing delays.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1178>

Chloramphenicol Sodium Succinate Injection

February 10, 2016

Reason for the Shortage

- Fresenius Kabi has chloramphenicol injection on back order due to a raw material shortage.
- Fresenius Kabi is the sole supplier of chloramphenicol injection.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1068>

14.6% Sodium Chloride Concentrated Solution for Injection

February 10, 2016

Reason for the Shortage

- Hospira has 14.6% sodium chloride solutions for injection on shortage due to manufacturing delays

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1195>

Tretinoin Oral Capsules

February 16, 2016

Reason for the Shortage

- Par was not able to provide a reason for the shortage.
- Teva was not able to provide a reason for the shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=838>

Propranolol Hydrochloride Tablets

February 16, 2016

Reason for the Shortage

- Actavis cannot provide a reason for the shortage.

- Heritage is not marketing propranolol tablets at this time.
- Northstar discontinued all propranolol tablets in February 2015.
- Mylan Institutional discontinued propranolol unit-dose tablets. The 10 mg tablets were discontinued in March 2013, the 20 mg tablets were discontinued in May 2014, and the 40 mg tablets were discontinued in January 2015.
- Qualitest refuses to provide product availability as the company considers it proprietary information.
- Teva could not provide a reason for the shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1189>

Promethazine Injection

February 16, 2016

Reason for the Shortage

- Teva states the shortage is due to manufacturing delays.
- West-Ward states the shortage was due to manufacturing delays.
- Hospira states the shortage is due to manufacturing delays.
- X-Gen is in the process of changing NDC numbers for promethazine injection and awaiting FDA approval for two new presentations.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=654>

Prochlorperazine Edisylate Injection

February 16, 2016

Reason for the Shortage

- Heritage Pharmaceuticals states the reason for the shortage was manufacturing delay.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1063>

L-Cysteine Hydrochloride Injection

February 16, 2016

Reason for the Shortage

- American Regent has L-cysteine hydrochloride injection on back order due to manufacturing delays.

- Sandoz had L-cysteine in short supply due to requirements related to complying with good manufacturing practices.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=632>

Chlorpromazine Injection

February 16, 2016

Reason for the Shortage

- West-Ward has chlorpromazine injection on shortage due to manufacturing delays.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1188>

Cefotaxime Injection

February 16, 2016

Reason for the Shortage

- Hospira has discontinued Claforan. Sanofi-Aventis manufactured Claforan for Hospira and is no longer making the product.
- Baxter discontinued Claforan in late-2015.
- West-Ward has cefotaxime on shortage due to increased demand.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=826>

Carvedilol Tablets

February 16, 2016

Reason for the Shortage

- Glenmark cannot provide a reason for the shortage.
- Mylan cannot provide a reason for the shortage.
- Sun Pharma cannot provide a reason for the shortage.
- Teva cannot provide a reason for the shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1208>

Anagrelide Capsules

February 16, 2016

Reason for the Shortage

- Mylan Pharmaceuticals discontinued anagrelide capsules in 2015.
- Teva cannot provide a reason for the shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1156>

Potassium Acetate Injection

February 17, 2016

Reason for the Shortage

- American Regent has potassium acetate on shortage due to manufacturing delays.
- Hospira has potassium acetate on shortage due to increased demand.
- Exela received FDA approval for potassium acetate injection in late-December 2015.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=668>

Ofloxacin Otic Solution

February 17, 2016

Reason for the Shortage

- Apotex discontinued ofloxacin otic solution in early-2015.
- Sandoz discontinued ofloxacin otic solution in mid-2015.
- Valeant cannot provide a reason for the shortage.

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1187>

Ethiodized Oil

February 17, 2016

Reason for the Shortage

- Guerbet states their Lipiodol product is in short supply due to manufacturing problems at Jubliant HollisterStier, the manufacturing site in Canada that supplies Lipiodol for Guerbet. The company estimates the shortage will last at least one year.^{1,2}

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=618>

Diphtheria, Tetanus Toxoid, and Acellular Pertussis Vaccine (DTaP)

February 17, 2016

Reason for the Shortage

- Sanofi Pasteur has Daptacel in short supply due to the shortage of other combination vaccines (eg, Pentacel).^{1,2}
- GlaxoSmithKline has Infanrix available

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=922>

Dextran Low Molecular Weight (Dextran 40), 10% Injection

February 17, 2016

Reason for the Shortage

- Hospira states the reason for the shortage is manufacturing delay and increased demand

Article Link:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1108>

* Please refer to ASHP website for more information

NEW DRUGS COMING TO MARKET

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
NuplazidTM (pimavanserin)	Acadia	Oral	For the treatment of psychosis associated with Parkinson's disease	Selective serotonin inverse agonist	5/01/2016
Avelumab	Pfizer	injection	None-small cell lung cancer, gastric cancer, ovarian cancer, urothelial cancer (in collaboration with Merck KgaA)	Monoclonal PD-L1 antibody of isotype IgG1	Unknown
Ertugliflozin	Pfizer	Oral	Type 2 diabetes (in collaboration with Merck)	SGLT2I in combination with other antidiabetic agents	Unknown
Ibrance (palbociclib)	Pfizer	Injection	Recurrent advanced breast cancer, high risk early breast cancer, early breast cancer In adjuvant setting	CDK inhibitor	4/13/2016
Somatropin	Pfizer	Subcutaneous	Adult growth hormone deficiency (in collaboration with OPKO)	Growth hormone	Unknown
Bococizumab	Pfizer	Subcutaneous	Hyperlipidemia	PCSK9I	Late 2016
Rivipansel	Pfizer	Injection	Sickle Cell Disease	Glycomimetic inhibitor	Unknow (orphan status)
Tanezumab	Pfizer	Injection	OA signs and symptoms, chronic low back pain, cancer pain	Nerve growth factor inhibitor	Unkown
Trumenba	Pfizer	Injection	B meningococcal vaccine	Vaccine	Unknown
Vyndaqel	Pfizer	Oral	Hereditart amyloidosis	Kinectoc stabilization of the transthyretin protein	Approved in UK and Japan

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
Bridion®	Merck	Injection	Neuromuscular blockade reversal	Selective relaxant binding agent	Approved 12/15/2015
Omarigliptin	Merck	Oral	Diabetes	DPP4 inhibitor	Unknown
Odanacatib	Merck	Oral	Osteoporosis	Cathepsin K inhibitor	Unknown
Etrolizumab	Genentech	injection	Inflammatory bowel disease	Beta 7 integrin inhibitor	Unknown
Lebrikizumab	Genentech	Subcutaneous	Severe asthma	IL-13 inhibitor	Unknown (orphan status)