September 2014

Drug Information Update

DRUG INFORMATION UPDATE

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NEW GENERICS TO MARKET

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME	APPROVAL DATE
DEXMEDETOMIDINE HCL	200MCG/2ML	Par Pharm & Mylan Institu	PRECEDEX	8/19/2014
GUAIFENESIN/DM/PSEUDOEPHEDRINE 34975	187 mg-10 mg-30 mg/5 mL	Kramer-novis**not listed in Argus under generic name	TRISPEC PSE	8/26/2014
TESTOSTERONE	10 MG (2%) GEL MD PMP	Qualitest	FORTESTA	8/28/2014
IBANDRONATE SODIUM	3 MG/3 ML SYRINGE	Sagent Pharmace & Mylan Institu	BONIVA	9/3/2014
ENTECAVIR	0.5 MG TABLET 1 MG TABLET	TEVA USA & PAR PHARMACEUTICAL	BARACLUDE	9/4/2014
HYDROCORT/LIDOCAINE IN COLEUS	2%-2%-1% KIT	Avion pharmaceutical	ANA-LEX	9/4/2014
SULFACT SOD/SULUR/AVOB/OTN/OCT	9 %-4.5 % CMB CLN CR	Biocomp Pharma	SUMADAN XLT	9/10/2014
CEFDITOREN PIVOXIL	200 MG TABLET 400 MG TABLET	Pharma RomLev Inc.	SPECTRACEF	200 - 9/18/2014 400 - 3/11/2013
ROPIVACAINE HCL	2 MG/ML VIAL 7.5 MG/ML VIAL	Sagent Pharmace	NAROPIN	9/24/2014

NEW DRUG ENTITIES

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
PEDIATRIC VITAMIN PREPARATIONS	COMPLETE FORMULATION PEDIATRIC	PEDI MULTIVIT #77/VIT D3/VIT K	750-500/.5	New Combination
BETA-ADRENERGIC AGENTS	STRIVERDI RESPIMAT	OLODATEROL HCL	2.5 MCG	New Entity
INFLUENZA VIRUS VACCINES	SINGLE USE EZ FLU 2014-2015	FLU VACC TS 14-15 (18+)CELL/PF	45MCG/.5ML	New Entity
TOPICAL ANTIFUNGALS	KERYDIN	TAVABOROLE	5%	New Entity
ANTI-ARTHRITIC, FOLATE ANTAGONIST AGENTS	RASUVO	METHOTREXATE/PF	7.5MG/0.15	New Strength
ANTI-ARTHRITIC, FOLATE ANTAGONIST AGENTS	RASUVO	METHOTREXATE/PF	10MG/0.2ML	New Strength
ANTI-ARTHRITIC, FOLATE ANTAGONIST AGENTS	RASUVO	METHOTREXATE/PF	12.5/0.25	New Strength
ANTI-ARTHRITIC, FOLATE ANTAGONIST AGENTS	RASUVO	METHOTREXATE/PF	15MG/0.3ML	New Strength
ANTI-ARTHRITIC, FOLATE ANTAGONIST AGENTS	RASUVO	METHOTREXATE/PF	17.5/0.35	New Strength
ANTI-ARTHRITIC, FOLATE ANTAGONIST AGENTS	RASUVO	METHOTREXATE/PF	22.5/0.45	New Strength
ANTI-ARTHRITIC, FOLATE ANTAGONIST AGENTS	RASUVO	METHOTREXATE/PF	25MG/0.5ML	New Strength
ANTI-ARTHRITIC, FOLATE ANTAGONIST AGENTS	RASUVO	METHOTREXATE/PF	27.5/0.55	New Strength
ANTI-ARTHRITIC, FOLATE ANTAGONIST AGENTS	RASUVO	METHOTREXATE/PF	30MG/0.6ML	New Strength
TETRACYCLINES	BENOXYLDOXY 30	DOXYCYCLINE/BENZOYL PEROXIDE	100MG-4.4%	New Combination
ARV COMB-NRTIS & INTEGRASE INHIBITOR	TRIUMEQ	ABACAVIR/DOLUTEGRAVIR/LAMIVUDI	600-50-300	New Combination
DRUGS TO TX GAUCHER DX-TYPE 1, SUBSTRATE REDUCING	CERDELGA	ELIGLUSTAT TARTRATE	84 MG	New Entity
ACNE AGENTS,SYSTEMIC	ABSORICA	ISOTRETINOIN	25 MG	New Strength
ACNE AGENTS,SYSTEMIC	ABSORICA	ISOTRETINOIN	35 MG	New Strength

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
ANTIHEMOPHILIC FACTORS	ALPHANATE	ANTIHEMOPHILIC FACTOR/VWF	2000 (800)	New Strength
C1 ESTERASE INHIBITORS	RUCONEST	C1 ESTERASE INHIBITOR, RECOMB	2100 UNIT	New Strength
INFLUENZA VIRUS VACCINES	FLUBLOK 2014-2015	FLU VAC TV 2014(18-49YR)RCM/PF	135MCG/0.5	New Entity
ANTISERA	OCTAGAM	IMMUNE GLOBULIN,G(IGG)/MALTOSE	10%	New Strength
LIPOGLYCOPEPTIDE ANTIBIOTICS	ORBACTIV	ORITAVANCIN DIPHOSPHATE	400 MG	New Entity
PULM.ANTI-HTN,SEL.C-GMP PHOSPHODIESTERASE T5 INHIB	REVATIO	SILDENAFIL CITRATE	10 MG/ML	New Strength and Dosage Form
DIETARY SUPPLEMENT, MISCELLANEOUS	PEPTAMEN JUNIOR WITH PREBIO1	NUTRITIONAL SUPP/INULIN/FOS	0.03G-1/ML	New Combination
NUTRITIONAL THERAPY, MED COND SPECIAL FORMULATION	CAMINO PRO 15 PE	NUTRIT.THERAPY, MSUD WITH IRON	15-140/140	New Combination
NUTRITIONAL THERAPY, MED COND SPECIAL FORMULATION	TYR ANAMIX NEXT	NUT TX FOR TYROSINEMIA W-IRON	28 G-385	New Combination
ANTINEOPLASTIC,ANTI-PROGRAMMED DEATH-1 (PD-1) MAB	KEYTRUDA	PEMBROLIZUMAB	50 MG	New Entity
PARENTERAL AMINO ACID SOLUTIONS AND COMBINATIONS	KABIVEN	AA 3.31 %/D9.8W/FAT/ELECT #10	3.31%-9.8%	New Combination
PARENTERAL AMINO ACID SOLUTIONS AND COMBINATIONS	PERIKABIVEN	AA 2.36%/D6.8W/FAT/ELECT CMB#9	2.36%-6.8%	New Combination
ANALGESICS, NARCOTICS	BUTRANS	BUPRENORPHINE	7.5 MCG/HR	New Strength
ANTI-OBESITY - OPIOID ANTAG/NOREPI & DA REUP INHIB	CONTRAVE ER	NALTREXONE HCL/BUPROPION HCL	8 MG-90 MG	New Entity
GROWTH HORMONE RECEPTOR ANTAGONISTS	SOMAVERT	PEGVISOMANT	25 MG	New Strength
GROWTH HORMONE RECEPTOR ANTAGONISTS	SOMAVERT	PEGVISOMANT	30 MG	New Strength
ANTISERA	HYQVIA	IGG/HYALURONIDASE,RECOMBINANT	2.5G/25ML	New Strength
ANTISERA	HYQVIA	IGG/HYALURONIDASE,RECOMBINANT	5 G/50 ML	New Strength
ANTISERA	HYQVIA	IGG/HYALURONIDASE,RECOMBINANT	10 G/100ML	New Strength
ANTISERA	HYQVIA	IGG/HYALURONIDASE,RECOMBI	20 G/200ML	New Strength

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
		NANT		
ANTISERA	HYQVIA	IGG/HYALURONIDASE,RECOMBINANT	30 G/300ML	New Strength
CHEMOTHERAPEUTICS, ANTIBACTERIAL, MISC.	UTA	METHEN/SOD PHOS/METH BLUE/HYOS	120-40.8MG	New Strength and Dosage Form
IRON REPLACEMENT	PERFECT IRON	IRON,CARBONYL	25 MG	None

NEW INDICATIONS (EXISTING DRUGS)

VIMPAT®

September 1, 2014

New indication for VIMPAT® (lacosamide): UCB's anti-epileptic drug approved by FDA as monotherapy in the treatment of patients with partial-onset seizures

Brussels (Belgium)– UCB announced today that the U.S. Food and Drug Administration (FDA) has approved a supplemental new drug application (sNDA) for VIMPAT® (lacosamide) C-V as monotherapy in the treatment of partial-onset seizures in patients with epilepsy aged 17 years and older.1 This is a new indication for VIMPAT® which is already approved in the U.S. as adjunctive treatment for partial-onset seizures in patients in this age group.1 This new indication means that adults with partial-onset seizures can be initiated on VIMPAT® monotherapy, and patients already on an anti-epileptic drug can be converted to VIMPAT® monotherapy.

Article link: http://www.ucb.presscentre.com/News/New-indication-for-VIMPAT-lacosamide-UCB-s-anti-epileptic-drug-approved-by-FDA-as-monotherapy-in-4a0.aspx

Source: presscentre.com

XTANDI®

September 10, 2014

U.S. FDA Approves New Indication for the Use of XTANDI® (Enzalutamide) Capsules for Patients With Metastatic Castration-Resistant Prostate Cancer

Approval Based on Improved Overall Survival, Delayed Time to Radiographic Progression and an Overall Positive Benefit-Risk Profile

SAN FRANCISCO, CA and TOKYO, JAPAN -- Medivation, Inc. and Astellas Pharma Inc. announced today that the U.S. Food and Drug Administration (FDA) approved a new indication for the use of XTANDI® (enzalutamide) capsules to treat patients with metastatic castration-resistant prostate cancer (CRPC). This new approved use follows a priority review of the supplemental New Drug Application (sNDA) that was based on results of the Phase 3 PREVAIL trial.

Article link: http://investors.medivation.com/releasedetail.cfm?ReleaseID=870267

Source: medivation.com

OTEZLA®

September 23, 2014

Oral OTEZLA® (apremilast) Approved by the U.S. Food and Drug Administration for the Treatment of Patients with Moderate to Severe Plaque Psoriasis

In phase III studies, OTEZLA resulted in significant and clinically meaningful improvements in plaque psoriasis

OTEZLA demonstrated a consistent safety and tolerability profile across clinical trials

SUMMIT, N.J.--(BUSINESS WIRE)-- Celgene Corporation (NASDAQ: CELG) today announced that the U.S. Food and Drug Administration (FDA) has approved OTEZLA® (apremilast), the Company's oral, selective inhibitor of phosphodiesterase 4 (PDE4), for the treatment of patients with moderate to severe plaque psoriasis for whom phototherapy or systemic therapy is appropriate. OTEZLA is the first and only PDE4 inhibitor approved for the treatment of plaque psoriasis. Psoriasis, a chronic inflammatory disease of the skin resulting from an uncontrolled immune response, affects more than 125 million people worldwide.
Article link: http://ir.celgene.com/releasedetail.cfm?ReleaseID=872240
Source: Celgene Corporation

HUMIRA®

September 25, 2014
Abbvie's Humira® (adalimumab) receives U.S. FDA Approval for the treatment of pediatric patients with moderately to severely active Chron's disease

NORTH CHICAGO, Ill., -- AbbVie announced today that the U.S. Food and Drug Administration (FDA) has approved HUMIRA® (adalimumab) for reducing signs and symptoms, and achieving and maintaining clinical remission, in pediatric Crohn's disease patients 6 years of age and older when certain other treatments have not worked well enough. This FDA approval represents the eighth indication for HUMIRA in the United States and makes it the first and only biologic treatment approved for use in this patient population that can be administered at home.
Article link: http://abbvie.mediaroom.com/2014-09-25-AbbVies-HUMIRA-adalimumab-Receives-U-S-FDA-Approval-for-the-Treatment-of-Pediatric-Patients-with-Moderately-to-Severely-Active-Crohns-Disease
Source: AbbVie.com

FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

Amgen Issues voluntary recall of Aranesp (darbepoetin alfa) (500 mcg) prefilled syringes in several countries outside of the United States due to the presence of visible particulates

August 13, 2014

ISSUE: Amgen initiated a voluntary recall on June 26, 2014 for nine packaged lots of Aranesp® (darbepoetin alfa) (500 mcg) prefilled syringes from non-U.S. distributors, wholesalers and a number of hospital pharmacies due to the potential presence of cellulose and/or polyester particles observed in a small number of syringes during a routine quality examination. Lots 1042847, 1044141A, 1044141C, 1044141D, 1046891A, 1046891B, 1047394A, 1047622A, and 1047996A are being recalled as a precautionary measure. To date, there have been no complaints or adverse events reported that can be attributed to the presence of these particles. Evaluations by Amgen found a very low potential to impact patients who may have received the affected product.

The U.S. Food and Drug Administration (FDA) has determined that health implications related to particles, depending on the route of administration, would vary depending on the amount of particulate matter injected into the patient, the size of the particles, the patient's underlying medical condition, and the presence of a right-to-left cardiac shunt. The presence of particulate foreign matter may elicit inflammatory and allergic responses, both chronic and acute, and may be life-threatening.

BACKGROUND: In the U.S., Aranesp is indicated for the treatment of anemia associated with chronic renal failure, including patients on dialysis and patients not on dialysis or in patients with non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy. The potentially impacted product is Aranesp 500mcg prefilled syringes which were distributed outside of the United States.

RECOMMENDATION: A single lot of Aranesp was packaged for different countries into nine packaged lots (lot numbers: 1042847, 1044141A, 1044141C, 1044141D, 1046891A, 1046891B, 1047394A, 1047622A, and 1047996A). Aranesp distributed in the U.S. is not impacted by this recall nor is product supply impacted. The impacted syringes were distributed in Belgium, Denmark, Finland, France, Ireland, Italy, Kuwait, Luxemburg, Russia, Saudi Arabia, Slovenia, Sweden, Switzerland and UK. Notifications to the appropriate regulatory authorities have been completed.

Consumers in the U.S. who have questions regarding this recall can contact Amgen at 1-800-77-AMGEN to arrange for the prompt return of the product (open 24 hours per day, 7 days per week).

Source: U.S. Food and Drug Administration (FDA)
Article Link: http://www.fda.gov/Safety/Recalls/ucm410011.htm

Baxter Voluntarily Initiates U.S. Recall of Two Lots of Peritoneal Dialysis Solution Due to Presence of Particulate Matter

August 13, 2014

ISSUE: Baxter International Inc. announced today it is voluntarily initiating a recall in the United States of two lots of DIANEAL Low Calcium (2.5mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose 5000mL (Ambu-Flex II) to the hospital/user level. The recall is being initiated due to the presence of oxidized stainless steel, garment fiber, and PVC particulate matter identified during the manufacturing process.

To date, no adverse events or related product complaints have been associated with the recalled products, which were distributed to dialysis centers, facilities, distributors, and patients in the United States.

Intraperitoneal administration of a product with particulate matter may cause local inflammation with foreign body reaction or result in adhesion formation. The particulate matter could potentially serve as a focal point for infection should any pre-existing peritonitis exist, and may lead to a fatal outcome.

BACKGROUND: DIANEAL is a peritoneal dialysis (PD) solution for use in chronic renal failure patients being maintained on peritoneal dialysis therapy. PD therapy is performed by using the body's peritoneal membrane as a filter, while special solution and osmotic pressure help remove extra fluids and clean the blood. This process takes the place of what healthy kidneys do for the body.

This recall affects the following lots of DIANEAL Low Calcium (2.5 mEq/L) Peritoneal Dialysis Solution with 2.5% Dextrose 5000 mL (Ambu-Flex II container):

Product Code	NDC Number	Lot #	Expiration Date
L5B5202	0941-0457-05	C940700	May 31, 2016
L5B5202	0941-0457-05	C940841	May 31, 2016

The number of individual units within these two lots represents less than one percent of Baxter's average annual units produced globally. Unaffected lot numbers can continue to be used according to the instructions for use.

RECOMMENDATION: Baxter notified customers by recall letter to instruct them to locate and remove any affected product from their facility. All patients who received product from the affected lots also were contacted by recall letter and provided instructions to arrange for product return. Dialysis centers, facilities, distributors, and patients should stop use and return to place of purchase. The affected lots were distributed to customers between May 30, 2014 and July 9, 2014.

Healthcare providers who received affected product should return it to Baxter for credit by contacting Baxter Healthcare Center for Service at 1-888-229-0001, Monday through Friday, between the hours of 7:00 a.m. and 6:00 p.m., Central Time. Unaffected lots of product are available for replacement.

Consumers with questions regarding this recall or requiring replacement product can call Baxter Home Care Services at 1-800-284-4060, Monday through Friday, between the hours of 7:00 a.m. and 6:00 p.m. Central Time. Patients should contact their physician or PD nurse if they have experienced any problems that may be related to taking or using this drug product.

According to the DIANEAL PD Solution product labeling, the container should be inspected visually for signs of leakage prior to use. Solutions that are cloudy, discolored, contain visible particulate matter, or show evidence of leakage should not be used.

Article link: http://www.fda.gov/Safety/Recalls/ucm410010.htm
Source website: http://www.fda.gov

Martin Avenue Pharmacy, Inc. Issues a Voluntary Multi-State Recall of All Compounded Sterile Preparations Due to a Lack of Assurance of Sterility

08/27/2014

ISSUE: Naperville, Illinois, Martin Avenue Pharmacy, Inc. is conducting a voluntary recall of all in-date compounded sterile preparations. The recall is being initiated in connection with a recent FDA inspection due to observations associated with certain quality control procedures that present a risk to sterility assurance.

If the sterility of a compounded preparation is compromised, a patient is at risk for infection. To date, Martin Avenue Pharmacy, Inc. has received no reports of suspected infection or other injury, illness or complaints associated with the use of its compounded sterile preparations. However, in an abundance of caution, and in the interest of patient safety, Martin Avenue Pharmacy, Inc. has proactively decided to voluntarily proceed with this recall process and to cease production of compounded sterile preparations until further notice. Martin Avenue Pharmacy, Inc. is committed to compounding quality and patient safety.

BACKGROUND: Martin Avenue Pharmacy, Inc. supplied compounded sterile preparations to the offices of licensed medical professionals and individual patients by prescription until 08/20/14 in multiple states including IL, WI, OH, MI, FL, AL, and TX.

RECOMMENDATION: Martin Avenue Pharmacy, Inc. is notifying its customers of this recall by fax, mail, phone or email with instruction on how to return recalled compounded sterile preparations to the pharmacy. Patients and healthcare providers that have product which is being recalled should stop using the products, and follow the instructions in the recall notice. To identify which sterile products and lots are being recalled, visit http://www.martinavenue.com/voluntaryrecall/.

Consumers or health care providers with questions regarding this recall may contact Martin Avenue Pharmacy, Inc. by phone at (630) 355-6400 or toll free (888) 355-6492, Monday through Friday, 9:00 a.m. to 7:00 p.m. Central Time or by e-mail at info@martinavenue.com. Be advised, this recall does not pertain to any non-sterile compounded medications prepared by the pharmacy.

Article link: http://www.fda.gov/Safety/Recalls/ucm412431.htm
Source website: http://www.fda.gov/

Solace International, Inc. Issues Voluntary Nationwide Recall of Dermatend Original and Dermatend Ultra Due to Safety Concerns

August 28, 2014

ISSUE: Reno, Nevada, Solace International, Inc. is voluntarily recalling all lots of Dermatend Original and Dermatend Ultra, in all sizes and dosage form, to the distributor/wholesaler level. A mole should be removed under the supervision of a dermatologist. Dermatend is not FDA approved, thus has not been shown to be safe and effective for the uses suggested in the labeling. Using these Dermatend products instead of seeking medical attention could result in delayed diagnosis of conditions such as cancer.

BACKGROUND: Currently, the Dermatend Original and Dermatend Ultra products are used to remove moles, warts and skin tags. Dermatend Original and Dermatend Ultra are packaged in a flexible plastic tubes labeled with the product name in blue letters. All units and lots are affected by the recall.

RECOMMENDATION: Solace International, Inc. is notifying its distributors/wholesalers by certified letter and is arranging for the return of all recalled products. Distributors/wholesalers that have Dermatend Original and Dermatend Ultra product, which is being recalled, should return all units and cases to Solace International, Inc. Consumers who purchased Dermatend Original and Dermatend Ultra to remove moles and warts should immediately discontinue use and consult their physician.

Consumers with questions regarding this recall can contact Solace International, Inc. at 775-323-1413 or info@dermatend.com, Monday through Friday from 8:00 a.m. to 5:00 p.m. PST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product.

Article link: http://www.fda.gov/Safety/Recalls/ucm412302.htm
Source website: http://www.fda.gov/

The MedWatch August 2014 Drug Safety Labeling Changes posting includes 35 products with safety labeling changes to the following sections: BOXED WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, PATIENT PACKAGE INSERT/MEDICATION GUIDE, PATIENT INFORMATION, AND PATIENT COUNSELING INFORMATION

August 2014

The "Summary Page" provides a listing of product names and safety labeling sections revised:

Eliquis (apixaban) tablets
Estring (estradiol vaginal ring)
Zohydro ER (hydrocodone bitartrate)
Adenoscan (adenosine) injection
Axert (almotriptan malate) tablets
Elelyso (taliglucerase alfa) for injection
Inlyta (axitinib) tablets
Keppra XR (levetiracetam) extended-release tablets
Nicorette (nicotine polacrilex) gum
Omnitrope (somatropin [rDNA origin] injection)
Radiogardase (Prussian Blue Insoluble)
Requip SL (ropinirole) tablet
Vectibix (panitumumab) injection
Zemplar (paricalcitol) capsules
Zyban (buproprion hydrochloride) sustained-release tablets
Farxiga (dapagliflozin) tablets
Ifex (Ifosfamide) for injection
Intelence (etravirine) tablets
Juxtapid (lomitapide) capsules
Pradaxa (dabigatran etexilate mesylate) capsules
Sylatron (peginterferon alfa-2b) for injection
Stavzor (valproic acid) delayed release capsules
Vimpat (lacosamide) tablet, injection, and oral solution

Avastin (bevacizumab) solution for IV
Emend (aprepitant) capsules
Emend (fosaprepitant dimeglumine) for injection
Halaven (eribulin mesylate) for injection
Keppra (levetiracetam) tablets and oral solution
Keppra (levetiracetam) injection
Zostavax (Zoster Vaccine Live)
Actoplus MET (pioglitazone and metformin hydrochloride) tablets
Zorvolex (diclofenac) capsules

Article link: http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm413266.htm
Source website: http://www.fda.gov/

Pharmacy Creations Issues Voluntary Recall of Four Product Lots With Limited Distribution in Florida, New Jersey, New York, and Puerto Rico Due to Potential Non-Sterility

September 4, 2014

ISSUE: Pharmacy Creations has voluntarily recalled four product lots (see below) following testing results conducted by Front Range, Inc., its former independent testing laboratory, that indicated that the product lots may have the potential of not being sterile. Pharmacy Creations no longer uses Front Range, Inc. for testing of any kind for any of its formulations.
Although we cannot be certain that the product subject to the recall is contaminated, to the extent it was, there are serious health implications for the use of contaminated product in all patients which could include development of a life-threatening infection. **To date there have been NO reported adverse events associated with the use of the product.**
BACKGROUND: The prescription preparations listed below were distributed in Florida, New Jersey, New York, and Puerto Rico between March 4, 2014 and June 18, 2014 and were mailed directly to patients and physicians.

Product Name	Strength	Package Size	Lot Number	Expiry
Ascorbic Acid	500 mg/mL	50 mL vial	05082014@7	11/4/2014
Glutathione	100 mg/mL	30 mL vial	05122014@4	9/9/2014
Magnesium Chloride	200 mg/mL	50 mL vial	05202014@7	11/19/2014

Tropi/Cyclo/Phenyl/Tobra/Flurb (1/1/10/0.3/0.3)% 3 mL vial 05202014@3 11/16/2014

RECOMMENDATION: We are voluntarily recalling the products as a precautionary measure, out of an abundance of caution and in order to ensure the public health and the safety of our patients.
Pharmacy Creations has notified all affected customers and has arranged for the return of the recalled product lots. Physicians and patients that have products which are being recalled should stop use and return to place of purchase.
Customers with questions regarding this recall can contact Pharmacy Creations by mail at 540 Route 10 West Randolph, NJ 07869 or call (858) 366-8389, Monday through Friday, 8 A.M. to 5 P.M, Eastern Standard Time. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these drug products.

Article link: http://www.fda.gov/Safety/Recalls/ucm413052.htm
Source website: http://www.fda.gov/

Hospira Issues a Voluntary Nationwide Recall of One Lot of Heparin Sodium, 1,000 USP Heparin Units/500 mL (2 USP Heparin Units/mL), in 0.9% Sodium Chloride Injection, 500 mL, Due to Particulate Matter

September 11, 2014

ISSUE: Hospira, Inc. announced today it is initiating a voluntary nationwide user-level recall of one lot of Heparin Sodium, 1,000 USP Heparin Units/500 mL (2 USP Heparin Units/mL), in 0.9% Sodium Chloride Injection, 500 mL, NDC 0409-7620-03 Lot 41-046-JT with expiration date of 01NOV 2015. This action is due to one confirmed customer report of particulate in a single unit. The foreign particle was confirmed by Hospira as human hair, sealed between the tube and the film at the round seal of the unused Administrative Port on the non-print side of the container.

In the unlikely event that the particulate breaks and pieces are able to pass through the intravenous catheter, injected particulate material may result in local inflammation, phlebitis, and/or low-level allergic response. Capillaries which may be as small as the size of a red blood cell, approximately seven microns in diameter, may become occluded. Patients with preexisting condition of trauma or other medical condition that adversely affects the microvascular blood supply are at an increased risk.
BACKGROUND: Heparin Sodium Injection in 0.9% Sodium Chloride at a concentration of 2 units/mL is indicated as an anticoagulant to maintain catheter patency. To date, Hospira has not received reports of any adverse events associated with this issue for this lot. The root cause has not been determined and is under investigation.
RECOMMENDATION: The affected lot was distributed nationwide between June 2014 and August 2014 to wholesalers/distributors, hospitals and pharmacies.

Anyone with an existing inventory should stop use and distribution and quarantine the product immediately. In addition, customers should inform potential users of this product in their organizations of this notification. Hospira will be notifying its direct distributors/customers via a recall letter and will arrange for impacted product to be returned to Stericycle. For additional assistance, call Stericycle at 1-855-201-4337 between the hours of 8am to 5pm ET, Monday through Friday.

Article link: http://www.fda.gov/Safety/Recalls/ucm414201.htm
Source website: http://www.fda.gov/

Haparin Sodium, 1,000 USP Heparin Units/500 mL (2 USP Heparin Units/mL), In 0.9 percent Sodium chloride injection, 500 mL by Hospira: Recall—Particulate Matter

September 12, 2014

ISSUE: Hospira, Inc. announced a voluntary nationwide user-level recall of one lot of Heparin Sodium, 1,000 USP Heparin Units/500 mL (2 USP Heparin Units/mL), in 0.9% Sodium Chloride Injection, 500 mL, NDC 0409-7620-03 Lot 41-046-JT with expiration date of 01NOV 2015. This action is due to one confirmed customer report of particulate in a single unit. The foreign particle was confirmed by Hospira as human hair, sealed between the tube and the film at the round seal of the unused Administrative Port on the non-print side of the container. Injected particulate material may result in local inflammation, phlebitis, and/or low-level allergic response. Capillaries which may be as small as the size of a red blood cell, approximately seven microns in diameter, may become occluded. Patients with preexisting condition of trauma or other medical condition that adversely affects the microvascular blood supply are at an increased risk.
BACKGROUND: The affected lot was distributed nationwide between June 2014 and August 2014 to wholesalers/distributors, hospitals and pharmacies.
RECOMMENDATION: Anyone with an existing inventory should stop use and distribution and quarantine the product immediately. In addition, customers should inform potential users of this product in their organizations of this notification. Hospira will be notifying its direct distributors/customers via a recall letter and will arrange for impacted product to be returned to Stericycle. For additional assistance, call Stericycle at 1-855-201-4337 between the hours of 8am to 5pm ET, Monday through Friday.
SOURCE: US Food and Drug Administration

Baxter Initiates U.S. Voluntary Recall of One Lot of Potassium Chloride Injection Due to Shipping Carton Mislabeling

September 16, 2014

ISSUE: Baxter International Inc. announced today it is voluntarily recalling one lot of Potassium Chloride Injection 10mEq per 100mL, product code 2B0826 to the hospital/pharmacy/nurse level. The recall is being initiated due to a labeling error on the shipping cartons in a single lot,

which was identified by three customers. Shipping cartons labeled for this specific lot number of Potassium Chloride Injection may contain units of Gentamicin Sulfate Injection, 80 mg in 100 mL, product code 2B0862.

BACKGROUND: Potassium Chloride is indicated for treatment of potassium deficiency and administered intravenously. Gentamicin Sulfate is an antibacterial drug for intravenous administration.

As both products are packaged in 100mL containers, have similar code numbers and red labeling on the front panel, there is a potential risk of medication error or delay in therapy for patients that require high concentration potassium chloride.

The affected lot of Potassium Chloride Injection was distributed to customers in the United States between May 26, 2014, and August 8, 2014.

This recall affects the following lot of Potassium Chloride Injection 10mEq per 100mL:

Product Code	Description	Lot #	NDC #
2B0826	Potassium Chloride Injection 10mEq per 100mL	P318220	0338-0709-48

RECOMMENDATION: As part of standard clinical practice, it is recommended that healthcare professionals carefully review the product label before administering. There have been no reported adverse events associated with this situation to date.

Consumers with questions regarding this recall can call Baxter at 1-800-422-9837, Monday through Friday, between the hours of 8:00 a.m. and 5:00 p.m. Central Time, or e-mail Baxter at onebaxter@baxter.com. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using this drug product.

Article link: http://www.fda.gov/Safety/Recalls/ucm414842.htm
Source website: http://www.fda.gov/

STUDIES and RECENT TOPICS

Oral contraceptive equal to antibiotics for acne care

August 27, 2014

Review shows antibiotics superior at three months; equivalent reduction in acne lesions at six months. At six months, oral contraceptive pills (OCPs) are comparable to systemic antibiotics for acne management, according to a review published in the September issue of the Journal of the American Academy of Dermatology.

Article link: http://www.physiciansbriefing.com/Article.asp?AID=691008

Source: physiciansbriefing.com

More dose escalation and cost with infliximab, compared with other TNF inhibitors in RA

August 28, 2014

Infliximab is associated with high rates of dose escalation and a larger overall cost, compared with adalimumab and etanercept in patients with rheumatoid arthritis, without any additional gains in effectiveness, according to analysis of data from 563 patients in the Veterans Affairs Rheumatoid Arthritis registry.

Article link: http://www.rheumatologynews.com/home/article/more-dose-escalation-and-cost-with-infliximab-compared-with-other-tnf-inhibitors-in-ra/08e2f857f4106259cf97d6cec2183571.html

Source website: rheumatologynews.com

Arthritis patients failing to take expensive medication, according to research

August 28, 2014

Large numbers of people with severe rheumatoid arthritis are failing to take expensive medication as prescribed, according to a new multi-centre study led by researchers in Manchester.

Article link: http://www.manchester.ac.uk/discover/news/article/?id=12673

Source: Manchester.ac.uk

Amgen seeks U.S. approval of new cholesterol-fighting drug

August 28, 2014

Amgen Inc said on Thursday it applied to U.S. health regulators to sell its cholesterol fighter, evolocumab, becoming the first company to seek approval of a medicine from a closely watched new class of potent heart drugs.

Article link: http://news.yahoo.com/amgen-submits-u-application-sell-cholesterol-fighting-drug-134605179--finance.html

Source: yahoo.com

'Doctor-shopping' for painkillers common after broken-bone surgery, study finds

August 29, 2014

About one in five patients operated on for broken bones or other orthopedic trauma shops around for additional painkillers after surgery, a new study finds. Less-educated patients and patients who had used narcotic painkillers previously were several times more likely to be "doctor shoppers," said study lead author Dr. Brent Morris, a shoulder and neck surgeon in Lexington, Ky. Overall, he said, the study suggests that doctors aren't talking to one another about the painkiller needs of their patients.
Article link: http://consumer.healthday.com/general-health-information-16/doctor-news-206/doctor-shopping-for-painkillers-common-after-broken-bone-surgery-study-says-690767.html
Source: healthday.com

Fears of addiction keep cancer patients from getting pain relief

August 29, 2014

Fears of opioid abuse and addiction might be keeping patients with advanced cancer from getting enough pain medicine, researchers say. "At the end of life, we should feel comfortable providing whatever necessary to control pain," said Joel Hyatt, assistant regional director at Kaiser Permanente. Concerns about overdose and addiction, he told Reuters Health, should not prevent terminally ill patients from obtaining relief.
Article link: http://www.reuters.com/article/2014/08/29/us-cancer-pain-addiction-idUSKBN0GT27H20140829
Source: reuters.com

Germany's Bayer to launch three new Xarelto trials

August 29, 2014

Germany's Bayer unveiled plans to launch three new studies to expand the uses of its anticlotting drug Xarelto, one of its top five new medicines. Xarelto, which competes with the Eliquis pill developed by Bristol-Myers Squibb and Pfizer in stroke prevention, reached sales of $1.7 billion in the 12 months to June. Analysts estimate annual sales could rise to more than $9.5 billion by 2020.
Article link: http://www.reuters.com/article/2014/08/29/us-bayer-xarelto-idUSKBN0GT1UI20140829
Source: reuters.com

Cholesterol drug halves heart attack and stroke in early test

August 31, 2014

BARCELONA — An experimental cholesterol-lowering drug from Sanofi and Regeneron Pharmaceuticals cut roughly in half the number of heart attacks and strokes in a clinical trial, researchers reported on Sunday.
Article link: http://www.nytimes.com/2014/09/01/business/international/cholesterol-drug-halves-heart-attack-and-stroke-in-early-test.html?_r=0
Source: nytimes.com

ESC: Darapladib fails in ACS trial
August 31, 2014

Inhibiting an enzyme involved in inflammation has once again failed to reduce cardiovascular events, this time in patients who had been hospitalized with an acute coronary syndrome (ACS) event, researchers reported here.
Article link: http://www.medpagetoday.com/MeetingCoverage/ESC/47430
Source: medpagetoday.com

Five ways ACA and employers shift costs this open enrollment season
September 1, 2014

As the Affordable Care Act and moves by employers and private insurers emphasize lower cost medical care and increased quality, consumers need to closely examine their open enrollment information this fall for myriad changes.
Article link: http://www.forbes.com/sites/brucejapsen/2014/09/01/five-open-enrollment-tips-to-cope-with-obamacare-employer-cost-shifting/
Source: forbes.com

Possible risks of S.S.R.I antidepressants to newborns
September 1, 2014

Pregnant women often go to great lengths to give their babies a healthy start in life. They quit smoking, skip the chardonnay, switch to decaf, forgo aspirin. They say no to swordfish and politely decline Brie. Yet they rarely wean themselves from popular selective serotonin reuptake inhibitor antidepressants like Prozac, Celexa and Zoloft despite an increasing number of studies linking prenatal exposure to birth defects, complications after birth and even developmental delays and autism.
Article link: http://well.blogs.nytimes.com/2014/09/01/possible-risks-of-s-s-r-i-antidepressants-to-newborns/
Source: nytimes.com

Pricing is key for new heart drugs challenging cheap generics
September 1, 2014

BARCELONA - Doctors looking at highly encouraging clinical trial results for new heart drugs at the world's largest cardiology meeting this week are missing one piece of data that will be critical to their success - the price.
Article link: http://www.reuters.com/article/2014/09/01/us-health-heart-costs-analysis-idUSKBN0GW2QJ20140901
Source: reuters.com

Cipla targets U.S. with Glaxo's Advair, Anti-AIDS drugs
September 1, 2014

Cipla Ltd. shot to prominence a decade ago by selling AIDS drugs for $1 a day in Africa. Now the Indian generics maker is seeking a bigger slice of the U.S. market with cheaper medicines for asthma and HIV.
Article link: http://www.bloomberg.com/news/2014-08-31/cipla-targets-u-s-with-glaxo-s-advair-anti-aids-drugs.html?cmpid=yhoo
Source: bloomberg.com

Actavis faces shortage of slow-release Alzheimer's drug
September 2, 2014

Actavis Plc is struggling to meet demand for its Alzheimer's drug Namenda after promoting a slow-release version of the drug ahead of a patent expiration for the traditional pill. "We're working as fast as we can to fix supply for the XR version," said David Belian, an Actavis spokesman, referring to the extended release version of Namenda.
Article link: http://www.bloomberg.com/news/2014-09-02/actavis-faces-shortage-of-slow-release-alzheimer-s-drug.html
Source: bloomberg.com

What doctors are saying about those new cholesterol meds
September 2, 2014

Over the past week, a horse race accelerated among drug makers looking to dominate the next generation of cholesterol-lowering medicines in development for people who can't take statins. Amgen filed for FDA approval for its PCSK9 inhibitor, while Sanofi and Regeneron Pharmaceuticals , which are working together, released encouraging study results.
Article link: http://blogs.wsj.com/pharmalot/2014/09/02/what-doctors-are-saying-about-those-new-cholesterol-meds/
Source: wsj.com

ADHD medications won't stunt kids' growth, study finds
September 2, 2014

Stimulant medications -- such as Adderall, Ritalin and Concerta -- used to treat attentiondeficit/ hyperactivity disorder (ADHD) in children, won't stunt their growth, a new study suggests. "Stimulant medication did not affect children's final height as adults," said study researcher Dr. Slavica Katusic, an associate professor of pediatrics at the Mayo Clinic in Rochester, Minn.
Article link: http://consumer.healthday.com/kids-health-information-23/adderall-news-796/adhd-meds-won-t-stunt-kids-growth-691234.html
Source: healthday.com

Novartis' game changer: When failure turns to success
September 2, 2014

Here's what two frequent skeptics have to say about the results of Novartis' new heart failure drug that were presented over the weekend. Stephen Nissen, chair of cardiology at the Cleveland Clinic and probably best known for highlighting safety problems with Merck's painkiller Vioxx, calls it "the first new heart failure drug in decades." Sanjay Kaul of Cedars- Sinai Health System, a stickler for procedure and nuance in the design of clinical trials, says that unless there are problems that only the Food and Drug Administration can uncover, it's "a major win."
Article link: http://www.forbes.com/sites/matthewherper/2014/09/02/novartis-game-changer-when-failure-turns-to-success/
Source: forbes.com

Google joins AbbVie in $1.5 billion aging disease effort
September 3, 2014

AbbVie Inc., the drugmaker spun off from Abbott Laboratories last year, and Google's Calico will spend as much as $1.5 billion to tackle age-related diseases, including cancer and neurodegenerative disorders.
Article link: http://www.bloomberg.com/news/2014-09-03/google-joins-abbvie-in-1-5-billion-aging-disease-effort.html
Source: bloomberg.com

Newer drug helps myeloma patients who can't have transplant
September 3, 2014

A cancer drug that targets the immune system may help improve the outlook for older adults with multiple myeloma, though a stem cell transplant remains the standard of care for relatively younger patients. Those are some of the findings from two studies in the Sept. 4 issue of the New England Journal of Medicine.
Article link: http://consumer.healthday.com/senior-citizen-information-31/misc-aging-news-10/newer-drug-helps-myeloma-patients-who-can-t-have-transplant-691388.html
Source:healthday.com

U.S. healthcare spending growth to slow further: government report
September 3, 2014

U.S. healthcare spending is expected to grow more slowly in the coming decade as a sluggish economic recovery and higher cost sharing in private insurance plans limit demand for services, a government report released on Wednesday said.
Article link: http://www.reuters.com/article/2014/09/03/us-usa-healthcare-spending-idUSKBN0GY2I620140903
Source: reuters.com

Little evidence to support testosterone drugs
September 3, 2014

The Food and Drug Administration says there is little evidence that testosterone-boosting drugs taken by millions of American men are beneficial, though the agency is also unconvinced by studies suggesting the hormone carries serious risks.
Article link: http://www.washingtontimes.com/news/2014/sep/3/fda-little-evidence-to-support-testosterone-drugs/
Source: washingtontimes.com

Treat-to-target with Actemra succeeds in RA
September 3, 2014

A "treat-to-target" strategy with the monoclonal antibody tocilizumab (Actemra) in patients with rheumatoid arthritis -- with clinical remission as the target -- allowed many to remain in remission while off the drug, and some were able to stop all treatments for short periods, European researchers reported.
Article link: http://www.medpagetoday.com/Rheumatology/Arthritis/47490
Source: medpagetoday.com

Study links potassium to fewer strokes in older women
September 4, 2014

Could eating foods rich in potassium, such as bananas and potatoes, help lower the risk of stroke and an earlier death for older women? Possibly, suggest the findings from a new study. But the research is too preliminary to confirm that potassium alone -- and not a better overall diet -- actually plays a major role in helping women avoid strokes and live longer.
Article link: http://consumer.healthday.com/vitamins-and-nutrition-information-27/food-and-nutrition-news-316/study-links-potassium-to-fewer-strokes-in-older-women-691401.html
Source: healthday.com

More evidence ties some bone-building drugs to rare fractures
September 4, 2014

Taking osteoporosis drugs called bisphosphonates to help prevent fractures may carry a slight risk for unusual breaks in the thigh bone, Swedish researchers report. For those who took bisphosphonates for four to five years, the so-called "relative risk" was 100 times higher than among people who didn't use the medications. But the researchers explained that the absolute risk of having such a fracture was small, and would affect only one in 1,000 people.
Article link: http://consumer.healthday.com/bone-and-joint-information-4/bone-joint-and-tendon-news-72/more-evidence-tying-bone-drugs-to-fractures-691386.html
Source: healthday.com

ESC: Patients stick to polypill
September 4, 2014

A series of trials has pinpointed factors that contribute to medication nonadherence, and has shown that a polypill can increase compliance among patients who've had a heart attack, researchers reported here.
In the FOCUS (Fixed-Dose Combination Drug for Secondary Cardiovascular Prevention) series of studies, post-MI patients who were taking the polypill -- a combination of aspirin, a statin, and an ACE inhibitor -- had significantly greater medication adherence than those taking the three pills separately, according to Valentin Fuster, MD, PhD, of Mount Sinai Hospital in New York, and colleagues.
Article link: http://www.medpagetoday.com/MeetingCoverage/ESC/47509
Source: medpagetoday.com

10 percent of Americans admit to illicit drug use
September 4, 2014

Marijuana tops list of substances, federal report says nearly 10 percent of Americans aged 12 and older were illicit drug users in 2013, and almost 20 million said they used marijuana, making it the most widely used drug, U.S. health officials reported Thursday. Two states, Colorado and Washington, permit the recreational use of marijuana.
Article link: http://consumer.healthday.com/general-health-information-16/drug-abuse-news-210/10-percent-of-americans-admit-to-illicit-drug-use-691385.html
Source: healthday.com

The FDA has approved how many novel drugs so far this year?
September 5, 2014

For those who like to track the progress at FDA, here is a significant and up-to-date metric.
So far this year, the agency has approved 27 novel new medicines, a tally that includes biologics and which matches the 27 such medicines approved for all of 2013. At this rate, the FDA may come close to matching the 39 novel new medicines approved in 2012.

Article link: http://blogs.wsj.com/pharmalot/2014/09/05/the-fda-has-approved-how-many-novel-new-drugs-so-far-this-year/
Source: wsj.com

New single-dose influenza drug appears safe, effective

September 6, 2014

An analysis of phase 2 and phase 3 clinical trials shows that a single injected dose of the neuraminidase inhibitor (NAI) peramivir is safe and effective at alleviating influenza symptoms, including fever and viral shedding, when administered within 48 hours of the onset of symptoms. Researchers report their findings today at the 54th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), an infectious diseases meeting of the American Society for Microbiology (ASM).
Article link: http://www.sciencedaily.com/releases/2014/09/140906173236.htm
Source: sciencedaily.com

Novartis COPD drug Ultibro beats Seretide on flare-ups

September 7, 2014

Novartis has presented data showing that its chronic obstructive pulmonary disease drug Ultibro was superior in reducing flare-ups compared to GlaxoSmithKline's blockbuster Seretide. Findings from the head-to-head LANTERN study were presented at the European Respiratory Society congress in Munich demonstrated that once-daily Ultibro Breezhaler (indacaterol/glycopyrronium) was superior in reducing exacerbations and improving lung function compared to twice-daily Seretide Accuhaler (salmeterol/fluticasone). Specifically, it reduced the rate of moderate-to-severe exacerbations by 31% compared to Seretide in moderate-to-severe COPD patients with a history of one exacerbation or none in the previous year.
Article link: http://www.pharmatimes.com/Article/14-09-07/Novartis_COPD_drug_Ultibro_beats_Seretide_on_flare-ups.aspx
Source: pharmatimes.com

AstraZeneca drug misses goal in sever COPD but improves lung function

September 8, 2014

An experimental drug from AstraZeneca - part of a new wave of injectable respiratory drugs designed for people who do not respond adequately to traditional inhalers - has shown mixed results in chronic lung disease. Data published in The Lancet on Monday and being presented at the European Respiratory Society congress in Munich showed benralizumab missed its primary goal in a mid-stage Phase IIa study in chronic obstructive pulmonary disease (COPD).
Article link: http://www.reuters.com/article/2014/09/08/us-health-respiratory-astrazeneca-idUSKBN0H30G520140908
Source: reuters.com

Give Aspirin to All Pregnant Women at Risk of Preeclampsia: U.S. Experts

September 8, 2014

Women at high risk for the pregnancy complication known as preeclampsia should take lowdose aspirin daily after 12 weeks of pregnancy, a panel of U.S. health experts recommends. The recommendation came after the U.S. Preventive Services Task Force (USPSTF) reviewed previous research and found that a daily low-dose aspirin could reduce the risk of preeclampsia by 24 percent in women with a high risk of developing the condition.
Article link: http://consumer.healthday.com/general-health-information-16/aspirin-news-46/give-aspirin-to-all-pregnant-women-at-risk-of-preeclampsia-u-s-experts-691493.html
Source: healthday.com

New Guidelines for Treating Advanced Prostate Cancer

September 8, 2014

Men newly diagnosed with prostate cancer often turn first to testosterone-depleting therapies, since male hormones help prostate tumors grow. But, those therapies almost always fail over time as the tumor develops resistance, according to oncologists.
Article link: http://consumer.healthday.com/cancer-information-5/prostate-cancer-news-106/experts-issue-guidelines-on-treating-advanced-prostate-cancer-691448.html
Source: healthday.com

Feds: 'Sham' lawsuits stopped generic drug

September 8, 2014

The Federal Trade Commission filed a lawsuit on Monday alleging that several pharmaceutical giants struck illegal deals to keep the generic version of a billion-dollar drug off the market. The FTC claims that the drug makers AbbVie Inc and its partner, Besins Healthcare Inc., made “sham” legal challenges to halt the production of a lower-priced version of a testosterone replacement drug called AndroGel.
Article link: http://thehill.com/policy/healthcare/216993-feds-accuse-drug-makers-of-sham-lawsuits
Source: thehill.com

D.E.A. to Allow Return of Unused Pills to Pharmacies

September 8, 2014

Concerned by rising rates of prescription drug abuse, the Drug Enforcement Administration announced Monday that it would permit consumers to return unused prescription medications like opioid painkillers to pharmacies.
Article link: http://www.nytimes.com/2014/09/09/health/unused-pills-return-to-pharmacies.html?_r=0

Source: nytimes.com

Doctors' Magical Thinking About Conflicts of Interest

September 8, 2014

When the Food and Drug Administration creates an advisory committee to help it decide whether to approve drugs, it often asks academic physicians to serve on the committee as external experts. This is supposed to help the committee render judgments that are unbiased and scientific.
Article link: http://www.nytimes.com/2014/09/09/upshot/doctors-magical-thinking-about-conflicts-of-interest.html
Source: nytimes.com

Most Dementia Patients Get Drugs of Questionable Benefit

September 8, 2014

More than half of patients with advanced dementia regularly are given drugs of questionable benefit at a monthly cost of about $272, researchers said. The report, published today by the journal JAMA Internal Medicine, reviewed treatments for 5,406 nursing home residents, based on standards set by a medical panel.
Article link: http://www.bloomberg.com/news/2014-09-08/most-dementia-patients-get-drugs-of-questionable-benefit.html
Source: bloomberg.com

Osteoporosis Drugs Work, But Review Finds No Clear Winner

September 8, 2014

Many osteoporosis drugs cut women's risk of suffering a bone fracture, though it's not clear whether any one medication works better than others, a new research review finds. Reporting Sept. 8 in Annals of Internal Medicine, researchers said that for women with the bone-thinning disease osteoporosis, various drugs cut the risk of a spine fracture by 40 to 60 percent, compared to a placebo.
Article link: http://consumer.healthday.com/bone-and-joint-information-4/actonel-news-794/osteoporosis-drugs-work-but-review-finds-no-clear-winner-691528.html
Source: healthday.com

Novo Weight-Loss Drug May Crack Market Others Have Missed

September 9, 2014

A weight-loss drug from Novo Nordisk A/S helped people get thinner, U.S. regulators said today, as the Danish drugmaker became the latest to push a pharmaceutical remedy for America's obesity woes.

Article link: http://www.bloomberg.com/news/2014-09-09/more-obesity-drugs-seek-to-enter-still-struggling-market.html
Source: bloomberg.com

UPDATE 1-FDA staff: Novo Nordisk drug liraglutide effective for obesity

September 9, 2014

Novo Nordisk's drug liraglutide appears effective in treating obesity, though safety questions remain, according to a preliminary assessment by reviewers at the U.S. Food and Drug Administration. The report, posted on the agency's website on Tuesday, noted an imbalance in the number of breast malignancies in women who took the drug, but said the available data neither supports nor denies the potential role of the drug in cancer promotion or progression.
Article link: http://www.reuters.com/article/2014/09/09/novo-nordisk-liraglutide-idUSL1N0RA0UD20140909
Source: reuters.com

Single-Pill HIV Therapy Proves Less Toxic

September 9, 2014

An investigational single-pill regimen for HIV -- the first to be based on a protease inhibitor -- was less toxic than a similar regimen using separate drugs, researchers said here. In a phase II, placebo-controlled, randomized trial, the single-pill regimen also yielded the same efficacy as the multi-pill regimen over 48 weeks of treatment, according to Anthony Mills, MD, of the Southern California Men's Medical Group in Los Angeles.
Article link: http://www.medpagetoday.com/MeetingCoverage/ICAAC/47571
Source: medpagetoday.com

Another Insulin Closer to FDA Assessment

September 9, 2014

Once-daily insulin peglispro proved non-inferior to insulin glargine (Lantus) in two of the late-stage trials in the IMAGINE program, drugmaker Eli Lilly announced. The novel basal insulin lowered HbA1c better than the diabetes blockbuster at both 6 months and 1 year, in the IMAGINE-1 and IMAGINE-3 trials, respectively, Lilly said -- although the company did not release exact figures.
Article link: http://www.medpagetoday.com/Endocrinology/Diabetes/47556
Source: medpagetoday.com

Polypills on FDA Docket: One Pill Panacea?

September 9, 2014

Will fixed-dose polypills safely and effectively reduce the risk of heart attack and stroke as well as individual doses of the same medications? That is the question that the FDA addresses this week in back-to-back advisory committee reviews of two investigational polypills.
Article link: http://www.medpagetoday.com/PublicHealthPolicy/FDAGeneral/47558
Source: medpagetoday.com

Anxiety Medications May Be Tied to Alzheimer's Risk
September 9, 2014

Older adults who habitually use sedatives for anxiety or insomnia may have a heightenedrisk of developing Alzheimer's disease, a new study suggests. The drugs in question are benzodiazepines, a widely prescribed group of sedatives that include lorazepam (Ativan), diazepam (Valium) and alprazolam (Xanax). Older adults commonly take the drugs for anxiety or insomnia, often long-term, according to background information in the study.
Article link: http://consumer.healthday.com/cognitive-health-information-26/alzheimer-s-news-20/anxiety-medications-tied-to-alzheimer-s-risk-691577.html
Source: healthday.com

FDA comes out with 'Purple Book' to catalog biologics and biosimilars
September 10, 2014

In a move that heralds greater momentum toward regulating biosimilars, the Food and Drug Administration has published its first-ever "Purple Book" – a list of all FDA-licensed biologics and the biosimilars that can be used in their stead.
Article link: http://medcitynews.com/2014/09/fda-comes-purple-book-catalog-biologics-biosimilars/
Source: medcitynews.com

FDA Staff: NPS Drug Effective; No Significant Safety Imbalance
September 10, 2014

NPS Pharmaceuticals Inc's hormone replacement therapy Natpara reduced the need for calcium and vitamin D supplements in clinical trials, though some data was excluded due to manufacturing violations, according to a preliminary review by the U.S. Food and Drug Administration.
Article link: http://www.businessinsider.com/r-fda-staff-nps-drug-effective-no-significant-safety-imbalance-2014-9
Source: businessinsider.com

Generic Drugs Saved Americans How Much Money?
September 11, 2014

The prices for some generic drugs may have risen precipitously in recent months, but a new report from the trade group representing generic drug makers boasts that these medicines saved Americans nearly $239 billion last year, a 14% increase from the year before.
Article link: http://blogs.wsj.com/pharmalot/2014/09/11/generic-drugs-saved-americans-how-much-money/
Source: wsj.com

Novo's Weight-Loss Shot Wins Backing of U.S. Advisers
September 11, 2014

Novo Nordisk A/S won the backing of U.S. advisers for its weight-loss injection, bringing the company closer to expanding the use of a medicine originally approved fordiabetes. Novo's Saxenda should be approved based on an assessment of its risks and benefits, a Food and Drug Administration advisory panel voted 14-1 today at a meeting. The Bagsvaerd, Denmark-based company sells the active ingredient, liraglutide, in a lower dose as Victoza for Type 2 diabetes.
Article link: http://www.bloomberg.com/news/2014-09-11/novo-s-weight-loss-shot-wins-backing-of-u-s-advisers.html
Source:bloomberg.com

Price Tag on Old Insulin Skyrockets
September 11, 2014

Retired nurse Mary Smith was having trouble controlling her type-2 diabetes on her regular insulin regimen, so her doctor decided to put her on something stronger. Amber Taylor, MD, director of The Diabetes Center at Mercy Medical Center in Baltimore, wrote Smith a prescription for Humulin U-500 insulin, a much more concentrated form of the drug. It could deliver far more active ingredient at far less overall volume, which was important since Smith's insulin doses were getting high.
Article link: http://www.medpagetoday.com/Endocrinology/Diabetes/47603
Source: medpagetoday.com

UPDATE 1-Lilly stomach cancer drug prolongs life in colon cancer study
September 12, 2014

Eli Lilly and Co's Cyramza stomach-cancer drug prolonged survival of patients with advanced colon cancer in a late-stage study, the U.S. drugmaker said on Friday. Based on favorable data from the Phase III study, Lilly said it would ask regulators in the first half of 2015 to approve Cyramza in patients with colorectal cancer that has spread to other parts of the body. It plans to present detailed results from the trial at a scientific meeting next year.
Article link: http://www.reuters.com/article/2014/09/12/eli-lilly-study-idUSL3N0RD4B020140912
Source: reuters.com

Generic Copaxone for MS Passes Clinical Test

September 12, 2014

A copycat version of the multiple sclerosis (MS) drug Copaxone, known generically as glatiramer acetate, performed similarly to the original product in a large head-to-head clinical trial, paving the way for it to win regulatory approval as a generic drug.
Article link: http://www.medpagetoday.com/MeetingCoverage/ECTRIMS/47630
Source: medpagetoday.com

Gilead to raise price for new hepatitis C drug above $84,000

September 12, 2014

The next generation version of Gilead Sciences Inc's $84,000 hepatitis C drug, already under fire for its record-breaking costs, is going to be even more expensive.
Article link: http://finance.yahoo.com/news/gilead-raise-price-hepatitis-c-224613245.html
Source: yahoo.com

$250 Billion in Biotech Drug Savings on Brink of Arrival

September 13, 2014

At least 14 expensive biotechnology medicines that have never before faced generic rivals in the U.S. are being targeted by drugmakers who want to sell imitations at cheaper prices, according to regulators. For years, patients have been able to buy less expensive copies of existing chemical drugs - - ranging from Lipitor for cholesterol to the antidepressant Prozac -- once their patents ended. That saved the nation $239 billion last year alone, according to the Generic Pharmaceutical Association.
Article link: http://www.bloomberg.com/news/2014-09-12/-250-billion-in-biotech-drug-savings-on-brink-of-arrival.html
Source: bloomberg.com

Fears Rise of Medication Misuse by the Elderly

September 14, 2014

With the Senior Population Growing, Experts on Addiction and Geriatric Care Raise the Alarm Prescription-drug abuse and misuse by seniors doesn't get much attention. But with the senior population steadily growing, it's getting harder to ignore.
Article link: http://online.wsj.com/articles/fears-rise-of-medication-misuse-by-the-elderly-1410724822
Source: wsj.com

Some Cancer Experts See 'Overdiagnosis,' Question Emphasis on Early Detection
September 14, 2014

Early detection has long been seen as a powerful weapon in the battle against cancer. But some experts now see it as double-edged sword. While it's clear that early-stage cancers are more treatable than late-stage ones, some leading cancer experts say that zealous screening and advanced diagnostic tools are finding ever-smaller abnormalities in prostate, breast, thyroid and other tissues. Many are being labeled cancer or precancer and treated aggressively, even though they may never have caused harm.
Article link: http://online.wsj.com/articles/some-cancer-experts-see-overdiagnosis-and-question-emphasis-on-early-detection-1410724838?mod=WSJ_hpp_MIDDLE_Video_second
Source: wsj.com

Novel MS Tx Appears Free of Cardiac Side Effects
September 14, 2014

An investigational oral drug for multiple sclerosis (MS) with the same mechanism as the approved product fingolimod (Gilenya) was highly effective in a phase II trial with seemingly fewer side effects than the earlier drug, researchers said here.
Article link: http://www.medpagetoday.com/MeetingCoverage/ECTRIMS/47647
Source: medpagetoday.com

Kids' poisonings linked to anti-addiction medicine
September 15, 2014

An anti-addiction drug used to fight the nation's heroin and painkiller abuse epidemics poses a threat to young children who accidentally swallow relatives' prescriptions, a federal study says. Some children have died.
Article link: http://www.ajc.com/ap/ap/top-news/kids-poisonings-linked-to-anti-addiction-medicine/nhMnn/
Source: ajc.com

Select Drugs Cause Most Childhood Poisonings
September 15, 2014

Almost all prescription medicines in the United States come in bottles with child-resistant caps. Still, more than 9,000 children younger than 6 are hospitalized annually for the accidental ingestion of prescription drugs; three-quarters of these are 1- and 2-year-olds, a new study reports.
Article link: http://well.blogs.nytimes.com/2014/09/15/select-drugs-cause-most-childhood-poisonings/?_php=true&_type=blogs&_php=true&_type=blogs&_r=1
Source: nytimes.com

Gilead licenses hepatitis C drug to Cipla, Ranbaxy, 5 others
September 15, 2014

U.S. drugmaker Gilead Sciences Inc said on Monday it has licensed its hepatitis C drug to seven companies including Cipla Ltd and Ranbaxy Laboratories Ltd to make it available in 91 developing countries including India.
Article link: http://www.reuters.com/article/2014/09/15/gilead-sciences-india-idUSL3N0RG2M920140915
Source: reuters.com

Older Patients More Likely to Fill Prescriptions for Generic Statins: Study
September 15, 2014

Patients prescribed cholesterol-lowering drugs are more likely to fill their prescriptions and gain health benefits if the medications are cheaper generic brands, new research suggests. At issue are the cholesterol-lowering drugs known as statins. Well-known brands include Crestor, Zocor and Lipitor. Generic statins are also available. The drugs are designed to lower the risk of heart problems due to clogged arteries.
Article link: http://consumer.healthday.com/general-health-information-16/misc-drugs-news-218/patients-more-likely-to-fill-prescriptions-for-cheaper-cholesterol-lowering-drugs-691690.html
Source:healthday.com

FDA shouldn't fall for latest ruse to derail biosimilars competition
September 15, 2014

Headlines about the rising cost of healthcare in the United States are a dime a dozen these days. But imagine how much worse off we would be without low-cost generic drugs, which save consumers $3 billion a week. That's exactly the overpriced nightmare we could face if the Food and Drug Administration (FDA) does not take the right approach in regulating the latest advanced pharmaceutical therapies.

Article link: http://thehill.com/blogs/congress-blog/healthcare/217580-fda-shouldnt-fall-for-latest-ruse-to-derail-biosimilars
Source:thehill.com

Kids Prescribed Antibiotics Twice as Often as Needed, Study Finds
September 15, 2014

Pediatricians prescribe antibiotics about twice as often as they're actually needed for children with ear and throat infections, a new study indicates. More than 11 million antibiotic prescriptions written each year for children and teens may be unnecessary, according to

researchers from University of Washington and Seattle Children's Hospital. This excess antibiotic use not only fails to eradicate children's viral illnesses, researchers said, but supports the dangerous evolution of bacteria toward antibiotic resistance.
Article link: http://consumer.healthday.com/infectious-disease-information-21/antibiotics-news-30/antibiotics-prescribed-twice-as-often-as-needed-in-children-study-says-691686.html
Source: healthday.com

GLP-1 Plus Insulin Betters Glycemic Control
September 15, 2014

The combination of GLP-1 agonists and basal insulin beat other type 2 diabetes treatments at lowering HbA1c and improving glycemic control, researchers found in a review and metaanalysis. In a pooled analysis of 15 studies, there was a significantly greater mean reduction in HbA1c (-0.44%) against all other comparators, Ravi Retnakaran, MD, of Mount Sinai Hospital in Toronto, and colleagues reported online in The Lancet.
Article link: http://www.medpagetoday.com/Endocrinology/Diabetes/47661
Source: medpagetoday.com

Avanir's drug reduces Alzheimer's related agitation in trial
September 15, 2014

Avanir Pharmaceuticals Inc said its drug was more effective in reducing agitation associated with Alzheimer's, compared with a placebo, sending the company's shares up 55 percent to an over eight-year high. The company said based on the mid-stage trial data it planned to request a meeting with both the U.S. Food and Drug Administration and the European Medicines Agency.
Article link: http://www.reuters.com/article/2014/09/15/us-avanir-study-idUSKBN0HA1FG20140915
Source: reuters.com

TCT: No Harm, No Foul With Triple Therapy
September 15, 2014

Limiting the length of triple therapy for stent patients who require anticoagulation does not increase the benefit or reduce the risk in this population, researchers reported. The ISAR-TRIPLE investigators compared a 6-week regimen of warfarin, aspirin, and clopidogrel to a 6-month regimen and at 9 months found the the incidence of major adverse cardiovascular events (MACE) plus major bleeding was 9.8% in the 6-week group and 8.8% in the 6-month arm.
Article link: http://www.medpagetoday.com/MeetingCoverage/TCT/47672
Source: medpagetoday.com

Shire eating disorder drug gets U.S. priority review

September 15, 2014

Shire's hyperactivity drug Vyvanse will get a priority review in the United States as a potential treatment for binge eating disorder, showing a willingness by U.S. regulators to consider novel ways to fight eating problems.
Article link: http://www.reuters.com/article/2014/09/15/shire-abbvie-eating-idUSL6N0RG38V20140915
Source: reuters.com

Deaths From Narcotic Painkillers Quadrupled in Past Decade: CDC

September 16, 2014

The number of Americans dying from accidental overdoses of narcotic painkillers jumped significantly from 1999 to 2011, federal health officials reported Tuesday. Deaths from overdoses of drugs such as hydrocodone (Vicodin), morphine and oxycodone (Oxycontin) climbed from 1.4 per 100,000 people to 5.4 per 100,000, according to the U.S. Centers for Disease Control and Prevention.
Article link: http://consumer.healthday.com/mental-health-information-25/addiction-news-6/deaths-from-narcotic-painkillers-quadrupled-in-past-decade-cdc-691788.html
Source: healthday.com

American waistlines still expanding, study says

September 16, 2014

The average waistline of Americans increased by more than an inch over the past decade, according to a study from U.S. health researchers. Along with the increase in waist circumference measurements, the number of Americans with abdominal obesity increased by about eight percentage points between 1999-2000 and 2011-2012, researchers from the Centers of Disease Control and Prevention (CDC) found.
Article link: http://www.reuters.com/article/2014/09/16/us-waist-fat-usa-idUSKBN0HB2IP20140916
Source: reuters.com

Combo Therapy Best for COPD: Study

September 16, 2014

A combination drug therapy aimed at opening the airways and reducing inflammation appears to be the best treatment for older adults with chronic obstructive pulmonary disease (COPD), especially those with asthma, a new study finds.
Article link: http://consumer.healthday.com/respiratory-and-allergy-information-2/asthma-news-47/combo-therapy-best-for-copd-study-691771.html
Source: healthday.com

BMS striving to push Opdivo past Keytruda

September 16, 2014

Timing may not be everything. While Merck's Keytruda was the first PD-1 inhibitor to debut in the US, one analyst says that Bristol-Myers Squibb could wind up the long-term winner in this category. The FDA approved Keytruda (pembrolizumab) on September 4 for second-line use in patients with unresectable or metastatic melanoma, but before Keytruda could land on US shores a week later, BMS and its partner company Ono Pharmaceuticals had already begun launching Opdivo in Japan, making it the first of the new—and highly touted—class of cancer drugs to be made available.

Article link: http://www.mmm-online.com/bms-striving-to-push-opdivo-past-keytruda/article/371903/

Source: mmm-online.com

Sanofi Wants to Add Oral GLP-1 to Diabetes Offering

September 17, 2014

Sanofi wants to add an oral diabetes drug that mimics a hormone known as GLP-1 as the French drugmaker seeks to lower its reliance on the blockbuster Lantus insulin, set to lose patent protection soon.

Article link: http://www.bloomberg.com/news/2014-09-17/sanofi-wants-to-add-oral-glp-1-to-diabetes-offer-chancel-says.html

Source: bloomberg.com

FDA Panel Says Testosterone Drugs Need More Study and Reduced Use

September 18, 2014

In a move that may dampen the sale of testosterone treatments, an FDA advisory panel yesterday recommended that drug makers study the risk of heart attacks associated with these widely advertised products. And the panel also wants prescribing information to include language that the drugs have not been proven to reverse common effects of aging, such as low libido, fatigue and muscle loss.

Article link: http://blogs.wsj.com/pharmalot/2014/09/18/fda-panel-says-testosterone-drugs-need-more-study-and-reduced-use/

Source: wsj.com

FDA backs ED upstart Stendra as a fast-acting alternative to Viagra

September 18, 2014

It's no picnic competing with a cultural phenom. Auxilium and Vivus know this well: Their new erectile dysfunction pill Stendra has to go up against Pfizer's Viagra. Competition from Eli Lilly's blockbuster Cialis doesn't help, either.

Article link: http://www.fiercepharma.com/story/fda-backs-ed-upstart-stendra-fast-acting-alternative-viagra/2014-09-18
Source: fiercepharma.com

Novo's Ryzodeg effective in type 2 diabetes treatment: study

September 18, 2014

Novo Nordisk's type 2 diabetes treatment Ryzodeg has proved effective in providing good blood sugar control with fewer injections than a so-called basal-bolus treatment, according to new data from a late-stage study. Ryzodeg combines Tresiba, Novo Nordisk's great hope for future growth, with insulin aspart, a man-made form of insulin, also known as NovoRapid, in a single pen injector.
Article link: http://www.reuters.com/article/2014/09/18/us-novo-nordisk-study-idUSKBN0HD10M20140918
Source: reuters.com

One Dose of Antidepressant Changes Brain Connections, Study Says

September 18, 2014

Just a single dose of a common antidepressant can quickly alter the way brain cells communicate with one another, early research suggests. The findings, reported online Sept. 18 in Current Biology, are a step toward better understanding the brain's response to widely prescribed antidepressants. Experts said the hope is to eventually be able to predict which people with depression are likely to benefit from a drug -- and which people would fare better with a different option.
Article link: http://consumer.healthday.com/mental-health-information-25/antidepressants-news-723/one-dose-of-antidepressant-changes-brain-connections-study-says-691856.html
Source: healthday.com

The new $84,000 hepatitis C treatment is losing momentum, for now

September 18, 2014

After recording the best launch of any drug in history, it looks like the pace is starting to slow down for Gilead Sciences' Sovaldi — the new $84,000 hepatitis C cure that's sparking a new focus on specialty drug costs.
Article link: http://www.washingtonpost.com/blogs/wonkblog/wp/2014/09/18/the-new-84000-hepatitis-c-treatment-is-losing-momentum-for-now/
Source: washingtonpost.com

Multiple Benefits With New Diabetes Drugs
September 18, 2014

The newest class of diabetes medications, the SGLT2 inhibitors, were good at controlling HbA1c and offered additional benefits of weight loss and reductions in blood pressure, researchers said here.
Article link: http://www.medpagetoday.com/MeetingCoverage/EASD/47722
Source: medpagetoday.com

Sedentary lifestyle linked to depression
September 18, 2014

A new analysis of previous studies ties too much sitting at the computer or lying around watching TV to a greater risk of depression. Based on dozens of studies covering hundreds of thousands of participants, Chinese researchers found that sedentary behavior was linked to a 25 percent higher likelihood of being depressed compared to people who were not sedentary.
Article link: http://www.reuters.com/article/2014/09/18/us-health-depression-sedentary-idUSKBN0HD2K120140918
Source: reuters.com

Regeneron says allergy drug may be darling of its pipeline
September 19, 2014

Regeneron Pharmaceuticals Inc has quickly become one of the world's biggest biotech companies thanks to its Eylea treatment for macular degeneration, but its little known experimental allergy drug could become equally successful, senior company executives said in interviews.
Article link: http://www.reuters.com/article/2014/09/19/us-regeneron-allergies-idUSKBN0HE29G20140919
Source: reuters.com

Legislation Would Prevent Drug Makers From Thwarting Generic Rivals.
September 19, 2014

A bill has been introduced in Congressmen that would end a practice that generic drug makers say is used by their brand-name rivals to thwart competition. Known as the Fair Access for Safe and Timely Generics Act, the bill arrives amid accusations that brand-name drug makers exploit an FDA program known as Risk Evaluation and Mitigation Strategies, or REMS, which are designed to boost patient safety.
Article link: http://blogs.wsj.com/pharmalot/2014/09/19/legislation-would-prevent-drug-makers-from-thwarting-generic-rivals/
Source: wsj.com

Prescription drug abuse epidemic demands mandatory physician education

September 22, 2014

Our nation's growing concern and response to the epidemic of opioid misuse and abuse continues to drive action from public health and public policy leaders. Attorney General Eric Holder recently announced a new regulation to greatly expand the drug-take-back program to make it easier to return unused prescription drugs and controlled substances. New DEA rules for the safe and secure disposal of prescription drugs take effect in October. And public health officials from three of the largest metropolitan health departments this week briefed Capitol Hill on their front-line efforts to battle opioid abuse.
Article link: http://thehill.com/blogs/congress-blog/healthcare/218368-prescription-drug-abuse-epidemic-demands-mandatory-physician
Source: thehill.com

Epirus tests generic version of Remicade as it awaits clarity from FDA on biosimilars

September 23, 2014

As U.S. regulators try to catch up to the rest of the world in regulating generic version of so-called biologic drugs, Boston-based Epirus today reported trial data suggesting that it has a drug that is interchangeable with the rheumatoid arthritis medication, Remicade.
Article link: http://www.bizjournals.com/boston/blog/bioflash/2014/09/epirus-tests-generic-version-of-remicade-as-it.html?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+vertical_38+%28Health+Care+Regulation+Industry+News%29
Source: bizjournals.com

Gilead's HIV drug shows potential in two mid-stage studies

September 24, 2014

Gilead Sciences Inc said its HIV tablet containing tenofovir alafenamide was found better than its approved drug, Stribild, in two mid-stage studies. The company's shares rose 1.3 percent to $106.77 in early trading on the Nasdaq on Wednesday.
Article link: http://www.reuters.com/article/2014/09/24/us-gilead-sciences-hivdrug-idUSKCN0HJ1H520140924
Source: reuters.com

Smoke This: Pfizer Wants Serious Warnings Removed From Chantix

September 24, 2014

In a boost to Pfizer, the FDA has updated labeling on its Chantix smoking cessation pill to indicate the drug may not carry the risks of suicidal behavior, a controversial issue that

prompted the agency to include a serious warning in the labeling in 2009. The changes are being made to reflect the results of various studies.
Article link: http://blogs.wsj.com/pharmalot/2014/09/24/smoke-this-pfizer-wants-serious-warnings-removed-from-chantix/?mod=WSJBlog
Source: wsj.com

Actavis to keep selling Alzheimer's drug in U.S. for 60 days

September 24, 2014

Actavis has reached an agreement with New York's attorney general to keep selling a top Alzheimer's drug for 60 days so U.S. patients will not be forced to switch to a newer, more expensive form of the drug with additional patent protection.
Article link: http://www.reuters.com/article/2014/09/24/actavis-lawsuit-idUSL2N0RP27J20140924
Source: reuters.com

Novartis reports positive trials for arthritis drug

September 25, 2014

Swiss drugmaker Novartis said two late-stage trials showed its drug secukinumab improved symptoms of psoriatic arthritis, a type of arthritis associated with the skin disease psoriasis that causes joint pain, stiffness and swelling.
Article link: http://www.reuters.com/article/2014/09/25/us-novartis-study-idUSKCN0HK0KM20140925
Source: reuters.com

RECALLS*

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
Drugs	DOBUTamine Injection, USP, 250 mg per 20 mL, 20 mL Single-dose Fliptop Vial, Rx only, Manufactured for Hospira Inc., Lake Forest, IL 60045 USA. NDC 0409-2344-02	Lot # 27-352-DK; Exp 03/15	Class I	Presence of Particulate Matter: Discolored solution due to a chip in the glass at the neck of the vial, also glass particulate was found within the solution.	Hospira Inc.
Drugs	Propofol Injectable Emulsion, 1%, 200 mg/20 mL (10 mg/mL), For I.V. Administration, Rx Only, 20 mL vial, Contains Benzyl Alcohol, Hospira, Inc., Lake Forest, IL 60045 USA, NDC 0409-4699-30	Lot #s: 29-614-DJ, 29-615-DJ, 29-616-DJ, 29-617-DJ, 29-628-DJ, 29-629-DJ, 29-630-DJ, Exp 05/01/2015	Class I	Presence of Particulate Matter: A glass defect was found on the interior neck of the vial during a retain sample inspection where the glass vial contained visible embedded metallic particulate and free floating metallic particulates were also found in solution.	Hospira Inc.
Drugs	0.9 % Sodium Chloride Injection, USP, 1000 mL in VIAFLEX Plastic Container, Baxter Healthcare Corporation, Deerfield, IL 60015	Lot C931923, exp 8/31/2015	Class I	Presence of Particulate Matter; blue polyisoprene shavings found inside the bag port tubes	Baxter Healthcare Corp
Drugs	Ascorbic Acid 500 mg/mL Sterile Injection, 50 mL Multi-dose Vial, Rx only, Pharmacy Creations, Randolph, NJ 07869.	Lot: 06062014@8, Do Not Use Beyond 12/03/2014	Class I	Non-Sterility: Pharmacy Creations is recalling Ascorbic Acid 500 mg/mL 50 mL vials due to mold contamination.	Pharmacy Creations
Drugs	MINERAL IV Injection, compounded by Abrams Royal Pharmacy, Inc., Dallas, TX	Lot number 11142013@74	Class I	Non-Sterility; analytical results found product to contain Sphingomonas	Abrams Royal Pharamacy

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
				paucimobilis	
Drugs	Midazolam HCl 2 mg/ml in 0.9% Sodium Chloride in 30 mL PVC Vial, Rx Only. Pharmakon Pharmaceuticals, Inc., 14450 Getz Rd., Noblesville IN 46060 NDC#: 45183-0234-68.	Lot #: E21294K3C Exp Date: 6/29/2014	Class I	Incorrect/ Undeclared Excipient: Contains undeclared benzyl alcohol.	Pharmakon Pharmaceuticals
Drugs	Midazolam HCl 1 mg/ml in 0.9% Sodium Chloride in 50 mL and 100 mL IV bag, Rx Only. Labeled A) 50 mL, Pharmakon Pharmaceuticals, Inc., 14450 Getz Rd., Noblesville, IN 46060. NDC#: 45183-0989-41. B) 100 mL, Pharmakon Pharmaceuticals, 14450 Getz Rd., Noblesville, IN 888-660-6715. NDC#: 45183-0796-48.	A) Lot #: E21294DK1C; Exp Date: 05/22/2014 B) Lot #: E21294DK3C; Exp Date: 06/08/2014	Class I	Incorrect/ Undeclared Excipient: Contains undeclared benzyl alcohol.	Pharmakon Pharmaceuticals
Drugs	Atropine Sulfate 0.4 mg/ml Injection, USP, Total Dosage 0.8 mg per 2 mL, 3 mL pre-filled syringe, Rx Only. Pharmakon Pharmaceuticals, Inc., 14450 Getz Road, Noblesville, IN. NDC: 45183-0105-78.	Lot #: E0333282R; Exp: 7/13/2014	Class I	Incorrect/ Undeclared Excipient: Contains undeclared benzyl alcohol.	Pharmakon Pharmaceuticals
Drugs	PEDIATRIC CARDIOPLEGIA, 255 mL, Rx Only, Central Admixture Pharmacy Services, Inc., Livonia, MI 48150	Lot # 13-920741-0-1 EXP 21 JUN 2014	Class I	Non Sterility; microbial contamination identified as Aspergillus species	Central Admixture Pharmacy Services, Inc.
Drugs	del Nido Cardioplegia with Lidocaine 1052.8 ml, Rx Only, Central Admixture Pharmacy Services, Inc., Livonia, MI	Lot# 13-920742-0-1 EXP 21 JUN 2014 and Lot# 13-920452-0-1 through 13-	Class I	Non Sterility; microbial contamination identified as Aspergillus species	Central Admixture Pharmacy Services, Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	48150	920452-0-30, EXP 21 JUN 2014			
Drugs	adenosine 90 mg in 0.9% sodium chloride/90 mL, Rx Only, Central Admixture Pharmacy Services, Inc., Livonia, MI 48150	Lot# 13-920757-0-1 through Lot# 13-920757-0-5 (5 total doses) EXP 06 JUL 2014	Class I	Non Sterility; microbial contamination identified as Aspergillus species	Central Admixture Pharmacy Services, Inc.
Drugs	LOW Potassium Cardioplegia 792 mL, Rx Only, Central Admixture Pharmacy Services, Inc., Livonia, MI 48150	Lot # 13-920739-01 through Lot # 13-920739-04 (4 total doses) EXP 21 Jun 2014	Class I	Non Sterility; microbial contamination identified as Aspergillus species	Central Admixture Pharmacy Services, Inc.
Drugs	AFRICAN BLACK ANT, 2800 mg, 6 capsules per box, produced by: Qinghan Hongwei Bioengineering Company, No. 158, Renmin Road, Xining City.	2006-000926	Class I	Nova Products, Inc. of Aston, Pennsylvania is voluntarily recalling AFRICAN BLACK ANT because FDA laboratory analysis determined they contain undeclared amounts of sildenafil an active ingredient of FDA-approved drugs used to treat erectile dysfunction.	Nova Products, Inc.
Drugs	Black Ant, 4600 mg, four capsules per box, , Manufacturer Timpo Bioengineering Co., Ltd, USA.,	2006-3627878	Class I	Nova Products, Inc. of Aston, Pennsylvania is voluntarily recalling Black Ant because FDA laboratory analysis determined they contain undeclared amounts of sildenafil an active ingredient of FDA-approved drugs used to treat erectile dysfunction.	Nova Products, Inc.
Drugs	XZEN GOLD,750 mg, six	Lot# 130310GL	Class I	Nova Products, Inc.	Nova Products,

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	capsules per bottle, Distributed by: XZEN, City of Los Angeles, CA 90012			of Aston, Pennsylvania is voluntarily recalling XZEN GOLD because FDA laboratory analysis determined they contain undeclared amounts of sildenafil and tadalafil, active ingredients of FDA-approved drugs used to treat erectile dysfunction.	Inc.
Drugs	XZEN PLATINUM, 750 mg, 1 capsule per blister pack, Distributed by: XZEN, City of Los Angeles, CA 90012	Lot# 130520PL	Class I	Nova Products, Inc. of Aston, Pennsylvania is voluntarily recalling XZEN PLATINUM because FDA laboratory analysis determined they contain undeclared amounts of sildenafil and tadalafil, active ingredients of FDA-approved drugs used to treat erectile dysfunction.	Nova Products, Inc.
Drugs	Xzen 1200, 750 mg, six capsules per bottle, Distributed by: xzen, City of Los Angeles, CA 90012	Lot# 13051012	Class I	Nova Products, Inc. of Aston, Pennsylvania is voluntarily recalling Xzen 1200 because FDA laboratory analysis determined they contain undeclared amounts of sildenafil and tadalafil, active ingredients of FDA-approved drugs used to treat erectile dysfunction.	Nova Products, Inc.
Drugs	Xzone 1200, 750 mg, one	Lot# 13071012	Class I	Nova Products, Inc.	Nova Products,

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	capsule per blister pack, Distributed by: xzone, Orlando, FL 32789			of Aston, Pennsylvania is voluntarily recalling XZone 1200because FDA laboratory analysis determined that they contain undeclared amounts of sildenafil and tadalafil, active ingredients of FDA-approved drugs used to treat erectile dysfunction.	Inc.
Drugs	XZONE GOLD, 750 mg, one capsule blister pack, Distributed by: XZONE, Orlando, FL 32789	lot# 131110GL	Class I	Nova Products, Inc. of Aston, Pennsylvania is voluntarily recalling XZONE GOLD because FDA laboratory analysis determined that they contain undeclared amounts of sildenafil and tadalafil, active ingredients of FDA-approved drugs used to treat erectile dysfunction.	Nova Products, Inc.
Drugs	MOJO RISEN ,670 mg, 2 capsule per pouch, Distributed by: Mojo Risen, LLC, Springville, UT 84663	Lot# 10081359	Class I	Nova Products, Inc. of Aston, Pennsylvania is voluntarily recalling MOJO RISEN, because FDA laboratory analysis determined that they contain undeclared amounts of sildenafil an active ingredient of FDA-approved drugs used to treat erectile dysfunction.	Nova Products, Inc.
Drugs	COUMADIN FOR INJECTION (Warfarin	Lot 00201125, Exp. 09/14;	Class I	Presence of Particulate Matter:	Bristol-Meyers Squibb

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	Sodium for Injection, USP 5 mg Single-Use Vial Rx Only Distributed by Bristol Meyers Squibb Company, Princeton, NJ 08543 USA NDC 0590-0324-96	00201126 Exp.11/14; 00201127, Exp.12/14; 00201228 Exp.06/15; 00201229 Exp. 07/15; 00201230, Exp. 09/15		particulate matter identified as metallic-like and non-metallic cellulose fiber particles found in retain vials	
Drugs	THINOGENICS, WEIGHT LOSS MADE EASY! DIETARY SUPPLEMENT, 30 CAPSULES, 30 Count Bottles, THINOGENICS LLC, Nashville, TN 37203 USA.	None Available. All lots distributed prior to 02/06/2014 are being recalled.	Class I	Marketed Without an Approved NDA/ANDA: Product contains undeclared sibutramine.	Nature's Universe
Drugs	0.9% Sodium Chloride Injection USP, packaged in a) 50 mL VIAFLEX Container bags, NDC 0338-0049-41, Product Code 2B1306; and b) 100 mL VIAFLEX Container bags, NDC 0338-0049-18, Product Code 2B1302, Rx only, Baxter Healthcare Corporation, Deerfield, IL 60015 USA.	Lot #: a) P309187, Exp 10/14; b) P298190, Exp 08/14	Class I	Presence of Particulate Matter: particulate matter identified as fibers and/or plastics.	Baxter Healthcare Corp.
Drugs	0.9% Sodium Chloride Injection USP MINI-BAG Plus Container, 100 mL VIAFLEX Single Dose Container bags, Rx only, Baxter Healthcare Corporation, Deerfield, IL 60015 USA, NDC 0338-0553-18, Product Code 2B0043.	Lot #: P308650, Exp 10/14	Class I	Presence of Particulate Matter: particulate matter identified as fibers and/or plastics.	Baxter Healthcare Corp.
Drugs	Potassium Chloride Injection, 20 mEq per 50 mL, 50 mL Sterile Single Dose Container bag, Rx only, Baxter Healthcare	Lot #: P309476, Exp 10/14	Class I	Presence of Particulate Matter: particulate matter identified as fibers and/or plastics.	Baxter Healthcare Corp.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	Corporation, Deerfield, IL 60015, NDC 0338-0703-41, Product Code 2B0822.				
Drugs	Ibuprofen Tablets, USP, 600 mg, 100 tablets per carton (10 x 10), Rx Only, Packaged and Distributed by: American Health Packaging, Columbus, OH 43217, NDC 68084-0703-01	Lot #142588, Exp 01/2016	Class I	Labeling: Label Mix-Up: Some cartons of AHP Ibuprofen Tablets, USP, 600mg, lot #142588 that contain blister cards filled with Ibuprofen tablets, 600mg drug product, were found to be mis-labeled with blister card print identifying the product as AHP Oxcarbazepine Tablets, 300mg, lot #142544	American Health Packaging
Drugs	Oxcarbazepine Tablets, 300 mg, 100 tablets per carton (10 x 10), Rx Only, Packaged and Distributed by: American Health Packaging, Columbus, OH 43217, NDC 62584-143-01	Lot #142544, Exp 02/2016	Class I	Labeling: Label Mix-Up: Some cartons of AHP Ibuprofen Tablets, USP, 600mg, lot #142588 that contain blister cards filled with Ibuprofen tablets, 600mg drug product, were found to be mis-labeled with blister card print identifying the product as AHP Oxcarbazepine Tablets, 300mg, lot #142544.	American Health Packaging
Drugs	ePHEDrine Sulfate Injection, USP 25 mg/5 mL (5 mg/mL) Single Use 5 mL Syringe, For IV, IM, or SC injection, Preservative Free, For Office/Hospital Use Only, Protect from Light, 62295-3084-05, US	Lot# 20142104@30 USE BY: 10/18/2014	Class II	Labeling: Label Error on Declared Strength; The outer light protective bags, where the ephedrine sulfate injection syringes are stored, were mislabeled with 25 mg/mL in big font	US Compounding Inc

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	Compounding Pharmacy, Conway, AR 800-718-3588			and 5 mg/mL in small font, however, the actual syringes were correctly labeled as 25 mg/5 mL.	
Drugs	Doctor's Best Red Yeast Rice 1200, 600 mg Capsules, 120-count bottle. UPC 753950001183, Manufactured for Doctor's Best San Clemente, CA 92673	Lot # 3121005; Exp 02/17	Class II	Marketed Without an Approved NDA/ANDA: FDA analysis discovered undeclared lovastatin, making this an unapproved new drug.	Doctor's Best, Inc.
Drugs	CYTARAbine for Injection USP, lyophiled in glass vials, 1 gram per vial, Rx only, Distributed by Bedford Laboratories, Bedford, OH 44146, Manufactured by Ben Venue Labs, Inc., Bedford, OH 44146, NDC 55390-808-01	Lot # 0161-13-2167551; Exp. 07/14 Lot # 0161-13-2176919; Exp. 08/14	Class II	Lack of Assurance of Sterility: Crimp defects during visual inspection could affect container closure integrity.	Ben Venue Laboratories Inc
Drugs	PROPRANOLOL HYDROCHLORIDE INJECTION, USP 1 mg/mL, 1 mL Single Dose Vial, Rx only, APP Pharmaceuticals, LLC Schaumburg, IL 60173, NDC 63323-604-01	Lot 6007698, Exp. 03/16	Class II	CGMP Deviations: Citations given to API supplier by the Italian Health Agency AIFA for several critical deficiencies which caused a recall of the API lot used to manufacture Propanolo HCl Injection.	Fresenius Kabi USA, LLC
Drugs	Wockhardt Metoprolol Succinate Extended-Release Tablets, USP 200 mg, a) 100-count bottle (NDC 64679-737-02), b) 500-count bottle (NDC 64679-737-03) Rx only, Manufactured by: Wockhardt Limited Mumbai, India	Lot # a) LN11005, Exp 04/15; LN11006; Exp 04/15; b) LN10979; Exp. 04/15, LN10980; Exp. 04/15	Class II	Failed Dissolution Specifications: Dissolution failures found during testing of control samples at the four hour time point.	Wockhardt Usa Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	Distributed by: Wockhardt USA LLC 20 Waterview Boulevard. Parsippany, NJ 07054 USA				
Drugs	ProSol - sulfite-free (Amino Acid) Injection, 20%, 2000 mL VIAFLEX container bag, Rx only, Baxter Healthcare Corporation, Clinitec Nutrition Division, Deerfield, IL 60015 USA, Product Code 2B6186, NDC 0338-0499-06.	Lot #: P306225, Exp 08/14	Class II	Presence of Particulate Matter: identification of particulates in a retention sample that have been identified as a mixture of the amino acid leucine and inorganic material (containing iron, silicone and chlorine).	Baxter Healthcare Corp
Drugs	fentaNYL 1500 mcg/30 mL (50 mcg/mL) in prefilled syringe, COMPOUNDED DRUG For Institutional or Office Use Only--Not for Resale Federal Law Prohibits Dispensing without Prescription Healix Infusion Therapy, Inc. (866) 298-4826 1075 West Park One Drive, Suite 200, Sugar Land, Texas, 77478 NDC 75901-8008-90	Lot 7088-0 Exp. 07/14	Class II	Lack of Assurance of Sterility: Firm received fentanyl from a supplier who recalled it because fliptop vial crimps were loose or missing.	Healix Infusion Therapy, Inc.
Drugs	fentaNYL 2500 mcg/250 mL (10 mcg/mL) in 0.9% Sodium Chloride in flexable bag, COMPOUNDED DRUG For Institutional or Office Use Only--Not for Resale Federal Law Prohibits Dispensing without Prescription Healix Infusion Therapy, Inc. (866) 298-4826 1075	Lots 7230-0, 7269-0 Exp. 08/14	Class II	Lack of Assurance of Sterility: Firm received fentanyl from a supplier who recalled it because fliptop vial crimps were loose or missing.	Healix Infusion Therapy, Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	West Park One Drive, Suite 200, Sugar Land, Texas, 77478, NDC 75901-8002-04				
Drugs	fentaNYL 200 mcg/100 mL (2 mcg/mL) and Ropivacaine 0.2% in 0.9% Sodium Chloride 100mL, in flexable bag, COMPOUNDED DRUG For Institutional or Office Use Only--Not for Resale Federal Law Prohibits Dispensing without Prescription Healix Infusion Therapy, Inc., at 866-299-4826, 1075 West Park One Drive, Suite 200, Sugar Land, Texas, 77478, NDC 75901-8007-02	Lot 7250-0 Exp. 08/14	Class II	Lack of Assurance of Sterility: Firm received fentanyl from a supplier who recalled it because fliptop vial crimps were loose or missing.	Healix Infusion Therapy, Inc.
Drugs	fentaNYL 2750 mcg/55 mL (50 mcg/mL) in prefilled syringe, COMPOUNDED DRUG, For Institutional or Office Use Only--Not for Resale Federal Law Prohibits Dispensing without Prescription Healix Infusion Therapy, Inc. (866) 298-4826 1075 West Park One Drive, Suite 200, Sugar Land, Texas, 77478 NDC 75901-8008-33	Lots 7083-0, 7202-0, 7222-0 Exp. 08/14	Class II	Lack of Assurance of Sterility: Firm received fentanyl from a supplier who recalled it because fliptop vial crimps were loose or missing.	Healix Infusion Therapy, Inc.
Drugs	fentaNYL 5000 mcg/250 mL (20 mcg/mL) in 0.9% Sodium Chloride in a flexable bag, COMPOUNDED DRUG For Institutional or Office Use Only--Not for Resale, Federal Law Prohibits Dispensing without	Lot 7257-0 Exp. 08/14	Class II	Lack of Assurance of Sterility: Firm received fentanyl from a supplier who recalled it because fliptop vial crimps were loose or missing.	Healix Infusion Therapy, Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	Prescription Healix Infusion Therapy, Inc. (866) 298-4826 1075 West Park One Drive, Suite 200, Sugar Land, Texas, 77478, NDC 75901-8015-04				
Drugs	All Unexpired Sterile Drug Products, compounded by Abrams Royal Pharmacy Inc., Dallas, TX	All unexpired lots of sterile drug products	Class II	Lack of Assurance of Sterility	Abrams Royal Pharamacy
Drugs	VIVITROL (naltrexone for extended-release injectable suspension); 380 mg vial NDC 65757-300-01; RX Only Manufactured and marketed by Alkermes, Inc., Waltham, MA 02451.	Batch Number: 412-3732AA; expiration date 07/2016 (NDC# 65757-302-02; Kit Pacaging Lot Number: 2013-021; expiration date 07/2016 (NDC# 65757-300-01.	Class II	Customer complaints for failure to deliver the dose.	Alkermes, Inc.
Drugs	Glycopyrrolate 0.2 mg/ml, 5 mL pre-filled syringe, Rx Only. Pharmakon Pharmaceuticals, Inc., 14450 Getz Rd., Noblesville, IN 46060, NDC#: 45183-0965-70.	Lot #: E131210.212 Exp: 07/14/2014	Class II	Incorrect/ Undeclared Excipient: Contains undeclared benzyl alcohol.	Pharmakon Pharmaceuticals
Drugs	Paroxetine HCL Controlled-Release Tablets 12.5 mg, 30-count bottle, Rx only, Manufactured by GlaxoSmithKline, RTP, NC 27709, Manufactured for Apotex Corp., Weston, FL 33328, NDC 60505-3673-3	Lot # 2A001, Exp. 01/15 Lot # 2A002, Exp. 01/15 Lot # 2C003, Exp. 03/15 Lot # 2F005, Exp. 06/15 Lot # 2G006, Exp. 07/15	Class II	Chemical Contamination: Product were manufactured with active pharmaceutical ingredient (API) batches contaminated with residual materials and solvents.	Apotex Inc.
Drugs	PAXIL (Paroxetine HCL) Oral Suspension 10 mg/5	Lot # 2A001, Exp. 01/15; Lot	Class II	Chemical Contamination:	Apotex Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	mL - 250 mL bottle, Rx Only, Manufactured by GlaxoSmithKline, RTP, NC 27709. Distributed by Apotex Corp., Westin, FL 33326, NDC 60505-0402-5	# 2C002, Exp. 03/15		Product were manufactured with active pharmaceutical ingredient (API) batches contaminated with residual materials and solvents.	
Drugs	Paroxetine HCL Controlled-Release Tablets 25 mg, 30-count bottle, Rx only, Manufactured by GlaxoSmithKline, RTP, NC 27709, Manufactured for Apotex Corp., Weston, FL 33328, NDC 60505-3674-3	Lot # 2A002, Exp. 01/15 Lot # 2A003, Exp. 01/15 Lot # 2C004, Exp. 03/15 Lot # 2C005, Exp. 03/15 Lot # 2E008, Exp. 05/15 Lot # 2F009, Exp. 06/15 Lot # 2F010, Exp. 06/15 Lot # 2H011, Exp. 08/15 Lot # 2H012, Exp. 08/15 Lot # 2H013, Exp. 0815	Class II	Chemical Contamination: Product were manufactured with active pharmaceutical ingredient (API) batches contaminated with residual materials and solvents.	Apotex Inc.
Drugs	Paroxetine HCL Controlled-Release Tablets 37.5 mg, 30-count bottle, Rx only, Manufactured by GlaxoSmithKline, RTP, NC 27709, Manufactured for Apotex Corp., Weston, FL 33328, NDC 60505-3675-3	Lot # 2C002, Exp. 03/15 Lot # 2H004, Exp. 08/15 Lot # 2H006, Exp. 08/15	Class II	Chemical Contamination: Product were manufactured with active pharmaceutical ingredient (API) batches contaminated with residual materials and solvents.	Apotex Inc.
Drugs	PAXIL CR (Paroxetine HCL) Controlled-Release Tablets 25 mg, 30-count bottle, Rx only, Manufactured by	Lot # 2F004, Exp. 06/15	Class II	Chemical Contamination: Product were manufactured with active	Apotex Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	GlaxoSmithKline, RTP, NC 27709, Manufactured for Apotex Corp., Weston, FL 33328, NDC 60505-3669-3			pharmaceutical ingredient (API) batches contaminated with residual materials and solvents.	
Drugs	PAXIL CR (Paroxetine HCL) Controlled-Release Tablets 37.5 mg, 30-count bottle, Rx only, Manufactured by GlaxoSmithKline, RTP, NC 27709, Manufactured for Apotex Corp., Weston, FL 33328, NDC 60505-3670-3	Lot # 2E001; Exp. 05/15	Class II	Chemical Contamination: Product were manufactured with active pharmaceutical ingredient (API) batches contaminated with residual materials and solvents.	Apotex Inc.
Drugs	PAXIL (Paroxetine HCL) Tablets 10 mg, 30-count bottle, Rx only, Manufactured by GlaxoSmithKline, RTP, NC 27709, Manufactured for Apotex Corp., Weston, FL 33328, NDC 60505-3663-3	Lot # 2ZP7113, Exp. 08/15	Class II	Chemical Contamination: Product were manufactured with active pharmaceutical ingredient (API) batches contaminated with residual materials and solvents.	Apotex Inc.
Drugs	PAXIL (Paroxetine HCL) Tablets 20 mg, 30-count bottle, Rx only, Manufactured by GlaxoSmithKline, RTP, NC 27709, Manufactured for Apotex Corp., Weston, FL 33328, NDC 60505-3664-3	Lot # 2ZP5499, Exp. 02/15	Class II	Chemical Contamination: Product were manufactured with active pharmaceutical ingredient (API) batches contaminated with residual materials and solvents.	Apotex Inc.
Drugs	PAXIL (Paroxetine HCL) Tablets 40 mg, 30-count bottle, Rx only, Manufactured by GlaxoSmithKline, RTP, NC	Lot # 2ZP3908, Exp. 05/15	Class II	Chemical Contamination: Product were manufactured with active	Apotex Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	27709, Manufactured for Apotex Corp., Weston, FL 33328, NDC 60505-3666-3			pharmaceutical ingredient (API) batches contaminated with residual materials and solvents.	
Drugs	Comfort Shield Barrier Cream Cloths with dimethicone a) 8 count NDC 53462-915-80, b) 24 count NDC 53462-915-60, OTC, SAGE PRODUCTS INC., 3909 Three Oaks Road, Cary, IL 60013	Lot: 44385; Exp.06/16; Lot: 44669; Exp.12/15	Class II	Microbial Contamination of Non-Sterile Products: Comfort Shield Barrier Cream Cloth packages tested positive for bacterial contamination.	Sage Products Inc
Drugs	OXYCODONE and ACETAMINOPHEN, USP 10 mg/325 mg, CII, 100 TABLETS, Rx only, Manufactured for: QUALITEST PHARMACEUTICALS, HUNTSVILLE, AL 35811, NDC 0603-4982-21	T062A14A, Exp 12/15	Class II	Failed Tablet/Capsule Specifications: Broken tablets found in sealed bottles.	Qualitest Pharmaceuticals
Drugs	0.9% Sodium Chloride Injection, USP, 500 mL, VIAFLEX Plastic Container, Baxter Healthcare Corporation, Deerfield, IL NDC 0338-0049-03	Lot #C926642, Product Code: 2B1323N	Class II	Lack of Assurance of Sterility; complaints of mold in the overpouch	Baxter Healthcare Corp.
Drugs	NORepinephrine 4 mg in 250 mL Sodium Chloride0.9%, For IV Use Only, Flexible Bag, Rx only, UNIQUE PHARMACEUTICALS, Inc.Temple, TX USA 76502	Lot # 00083844 Exp. 07/13	Class II	Lack of Assurance of Sterility: A mold like substance was discovered on the surface of an unopened bag of Sodium Chloride 0.9% while prepping the bag for production.	Unique Pharmaceutical, Ltd
Drugs	Dermatend Original, mole, wart and skin tag remover, For external	All lots	Class II	Labeling: Labeling Bears Unapproved Claims; Dermatend is	Solace International Inc

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	use only, Ingredient: Distilled Water, Sanguinaria Canadensis, Vegetable Glycerin, Butter of Zinc, Germall Plus, 0.17 OZ (5g) container, Solace International, Inc., Reno, NV 89509, USA			not FDA approved and therefore has not been shown to be safe and effective for the uses suggested in the labeling.	
Drugs	Dermatend Ultra, mole, wart and skin tag remover, For external use only, Ingredient: Distilled Water, Sanguinaria Canadensis, Vegetable Glycerin, Butter of Zinc, Germall Plus, 0.34 OZ (10g) container, Solace International, Inc., Reno, NV 89509, USA	All lots	Class II	Labeling: Labeling Bears Unapproved Claims; Dermatend is not FDA approved and therefore has not been shown to be safe and effective for the uses suggested in the labeling.	Solace International Inc
Drugs	Bupivacaine HCl Inj., USP, 0.5% (5 mg/mL), 30 mL Single-dose Preservative-Free, For Nerve Block, Caudal, and Epidural Anesthesia, Not for Spinal Anesthesia, Rx Only, Hospira, Inc., Lake Forest, IL 60045 USA, NDC 0409-1162-02	LOT 37-268-DK; Exp: 1JAN2016	Class II	Presence of Particulate Matter: A confirmed customer complaint reported the presence of a brown, rust-colored particle embedded at the bottom of the glass vial.	Hospira Inc.
Drugs	Tolterodine Tartrate Tablets, 1 mg, 60 Tablet Bottles, Rx only. Mylan Pharmaceuticals Inc., Morgantown, WV 26505. NDC: 0378-5445-91.	Lot # 2004069, Expiry: 09/2014; Lot #: 2004070, Expiry: 09/2014.	Class III	Failed Impurities/Degradation Specifications; Out of specification for lactol and total impurities.	Mylan Pharmaceuticals Inc.
Drugs	Triveen - PRx RNF Capsules, 30-count bottles, Rx only; Manufactured for: Trigen Laboratories, Inc., Sayreville, NJ 08872, NDC 13811-558-30, UPC 3	Lot #: 505024006, 505024007, Exp 03/15; 505024008; 505024009, Exp 06/15;	Class III	Labeling: Not Elsewhere Classified: Label indicates that the product contains Vitamin B12 (12 micrograms) on the Supplement Facts	Trigen Laboratories, Inc.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	13811 55830 2.	505024010, Exp 08/15; 505024011, Exp 09/15; and 505024012, Exp 10/15		panel, however, the formulation of this product does not contain Vitamin B12.	
Drugs	Famotidine for Oral Suspension, USP 40 mg/5 mL, Rx Only, Cherry-Banana-Mint Flavored, Not for Injection, Manufactured by: Novel Laboratories, Inc., Somerset, NJ 08873. Distributed by: Gavis Pharmaceuticals, LLC, Somerset, NJ 08873, NDC 43386-500-11.	Lot #'s M13075A, M13076A, M13076B, M13077A, M13077B all with expiry dated 2/2015 and M13490A with expiry date 3/2016.	Class III	Failed Impurity/Degradation Specification; 12-month stability time point	Novel Laboratories, Inc.
Drugs	Nicotine Polacrilex Lozenge, 2 mg Mint Mini. 27 Ct Tubes, Over the Counter. Perrigo, 502 Eastern Ave, Plant #6, Allegan, MI 49010. Labeled: A) CareOne, 81 and 108 Ct Cartons, Distributed by: Foodhold U.S.A., LLD, Landover, MD 20785, NDC: 41520-734-02, 41520-734-03, B) CVS Pharmacy, 81 Ct Cartons, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895, NDC: 59779-734-02, C) equate, 27, 108, and 135 Ct Cartons, Distributed by: Wal-Mart Stores, Inc., Bentonville, AR 72716, NDC: 49035-734-01, 49035-734-03, 49035-734-04, D) Kroger, 81 Ct Cartons, Distributed by: The Kroger Co., Cincinnati,	Cartons of 27 ct Tubes: Lot #: 2MV1074, Expiry: 09/14; ... More	Class III	Failed Dissolution Specifications and Failed Tablet Specifications: High 30 minute dissolution test and presence of broken lozenges.	Perrigo Holland Inc

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	Ohio 45202, NDC: 30142-734-02, E) Rite Aid, 81 and 108 Ct Cartons, Distributed by: Rite Aid, 30 Hunter Lane, Camp Hill, PA 17011, NDC: 11822-0734-3, 11822-0734-2, F) TopCare, 81 Ct Cartons, Distributed by Topco Associates LLC., Elk Grove Villiage, IL 60007, NDC: 36800-734-60 G) Walgreens, 81 and 135 Ct Cartons, Distributed by: Walgreen Co., 200 Wilmot Rd., Deerfield, IL 60015, NDC: 0363-0734-02, 0363-0374-04, H) 20 Ct Stretchcard, Target Corporation, Minneapolis, MN 55403. NDC: 11673-734-02.				
Drugs	CHIROTHIN Dietary Supplement, 2 Fl Oz (60 ml), OTC. Manufactured for ChiroNeutraceutical, 877-377-7636, Chesterfield, MO 63005.	Lot #: 072010-22, Exp: 12/2013; Lot #: 072010-23, Exp: 01/2014; Lot ... More	Class III	Marketed without an Approved NDA/ANDA; Product contains unapproved hHCG.	ChiroNutraceutical LLC
Drugs	Warfarin Sodium Tablets, USP Crystalline, 2 mg, 100 and 1000 Tablet Bottles, Rx Only. Mfd. by: Taro Pharmaceutical Industries, Ltd., Haifa Bay, Israel 26110. Dist. by: Taro Pharmaceuticals U.S.A., Inc., Hawthorne, NY 10532. 100 Tablet Bottle NDC: 51672-4028-1, 1000 Tablet Bottle NDC: 51672-4028-3.	Lot #: 149400, Expiry: January 2016; Lot #: 149649, Expiry: January 2016.	Class III	Failed Content Uniformity Specifications.	Taro Pharmaceuticals U.S.A., Inc.
Drugs	Candesartan Cilexetil and Hydrochlorothiazide Tablets 32 mg/12.5 mg, 90 count bottles, Rx only,	Lot # KK6086, exp 03/2015, UPC 360505375998.	Class III	Failed Impurity/Degradation Specification; high out of specification	Apotex Corp.

Product Type	Product Description	Code info.	Class	Reason for Recall	Recalling firm
	Manufactured by: Apotex Research Pvt. Ltd. Bangalore - 560 099, India NDC 60505-3759-9			for CAD II degradant	

*Please refer to FDA website for further information

http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm

CURRENT DRUG SHORTAGES‡

Selenium Injection
August 25, 2014

Reason for the Shortage

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

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=784
Source link: http://www.ashp.org

Dextran Low Molecular Weight (Dextran 40), 10% Injection
August 25, 2014

Reason for the Shortage

- Hospira states the reason for the shortage is manufacturing delay.

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

Source link: http://www.ashp.org

Copper Injection
August 25, 2014

Reason for the Shortage

- American reagent has cupric sulfate on shortage due to manufacturing delays.
- Hospira had cupric chloride on shortage due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=946
Source link: http://www.ashp.org

Ammonium Molybdate Injection
August 25, 2014

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
Source link: http://www.ashp.org

Rabies Immune Globulin
August 26, 2014

Reason for the Shortage

- Sanofi Pasteur states the reason for the shortage is increased demand and manufacturing delay.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=331
Source link: http://www.ashp.org

Multiple Vitamins for Infusion
August 26, 2014

Reason for the Shortage

- Hospira states the shortage is due to manufacturing delays.
- Baxter states the reason for the shortage is manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=831
Source link: http://www.ashp.org

Epinephrine Injection
August 26, 2014

Reason for the Shortage

- American Regent has epinephrine on shortage due to manufacturing delays.
- Hospira had epinephrine syringes on shortage due to manufacturing delays.
- Amphastar states the shortage is due to increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=685
Source link: http://www.ashp.org

Mercaptopurine Tablets
August 27, 2014

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=997
Source link: http://www.ashp.org

Iron Dextran Injection
August 27, 2014

Reason for the Shortage

- American Regent cannot provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1069
Source link: http://www.ashp.org

Hydrocortisone Sodium Succinate Injection
August 27, 2014

Reason for the Shortage

- Hospira has A-Hydrocort on shortage due to requirements related to good manufacturing practices.
- Pfizer had Solu-Cortef on shortage due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=925
Source link: http://www.ashp.org

Chloramphenicol Sodium Succinate Injection
August 27, 2014

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
Source link: http://www.ashp.org

Acetazolamide Injection
August 27, 2014

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired acetazolamide injection from Bedford in July 2014. West-Ward is not actively marketing acetazolamide injection at this time.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=463
Source link: http://www.ashp.org

Vinblastine Injection
May 07, 2014

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired vinblastine injection from Bedford in July 2014. West-Ward is not actively marketing vinblastine injection at this time.
- Fresenius Kabi (formerly APP) had their product in short supply due to increased demand for the product and a manufacturing delay.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=883
Source link: http://www.ashp.org

Vasopressin Injection
August 28, 2014

Reason for the Shortage

- American Regent had temporarily suspended manufacture of most drug products including vasopressin injection in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- American Regent recalled 17 lots of vasopressin in August, 2011 due to potential for decreased potency.
- JHP had Pitressin on shortage due to increased demand for the product.
- Fresenius Kabi (formerly APP) had vasopressin on shortage due to increased demand for the product.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=795
Source link: http://www.ashp.org

Synthetic conjugated estrogen
August 28, 2014

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
Source link: http://www.ashp.org

Propranolol Injection
August 28, 2014

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 had propranolol injection on shortage due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1091
Source link: http://www.ashp.org

Levocarnitine Injection
August 28, 2014

Reason for the Shortage

- American Regent has levocarnitine injection on back order due to manufacturing delays.
- Teva could not provide a reason for the shortage.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including levocarnitine injection. West-Ward is not actively marketing levocarnitine injection.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=968
Source link: http://www.ashp.org

Labetalol Injection

August 28, 2014

Reason for the Shortage

- Hospira had labetalol on shortage due to manufacturing delays and increased demand.
- Apotex discontinued their 4 mL vials (NDC 60505-0717-00) in February, 2010. The company could not provide a reason for the discontinuation.
- Sagent suspended production on labetalol 5 mg/mL 20 mL vials in July 2013.
- Sagent suspended production on labetalol 5 mg/mL 20 mL vials in July 2013 and 40 mL vials in February 2014.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including labetalol injection. West-Ward is not actively marketing labetalol injection.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=397
Source link: http://www.ashp.org

Fluconazole Injection

August 28, 2014

Reason for the Shortage

- Teva has fluconazole injection on shortage due to manufacturing delays.

- Pfizer had fluconazole injection on shortage due to manufacturing delays related to labeling changes.
- West-Ward has fluconazole injection on shortage due to manufacturing delays.
- Ben Venue has stopped production in its plant in Bedford, Ohio and closed in July 2014.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=644
Source link: http://www.ashp.org

Lactated Ringer's Injection Bags
August 29, 2014

Reason for the Shortage

- Baxter has lactated ringer's on shortage due to increased demand.
- BBraun has lactated ringer's on allocation due to increased demand.
- Hospira cites increased demand as the reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1078
Source link: http://www.ashp.org

Ketamine Injection
August 29, 2014

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including ketamine injection.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=592
Source link: http://www.ashp.org

Doxycycline capsules and tablets
August 29, 2014

Reason for the Shortage

- Actavis states the reason for the shortage is supply and demand.
- Teva discontinued their doxycycline presentations in May 2013.

- Major discontinued most doxycycline presentations in February 2013. The company could not provide a reason for the discontinuation.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=977
Source link: http://www.ashp.org

Doxorubicin Liposomal Injection
August 29, 2014

Reason for the Shortage

- Janssen Products, LP states the shortage is due to manufacturing issues. Janssen Products, LP has updates with information about the shortage on the Doxil website that is updated regularly.
- Janssen is working to transition Doxil manufacturing to additional suppliers. A temporary solution to this shortage was to use areas of the Ben Venue Laboratories facility available for production and other partners to complete the manufacturing process. FDA exercised regulatory discretion and approved an additional lot of 2 mg/mL 10 mL (20 mg) vials.
- Ben Venue has stopped production in its plant in Bedford, Ohio and will close in early 2014. Ben Venue supplies multiple sterile injectable products for Bedford Laboratories. Supplies of product that has already been manufactured will continue to be released until inventory is depleted. Bedford Laboratories has a small number of products manufactured elsewhere that are not affected by this closure.
- Ben Venue has stopped production in its plant in Bedford, Ohio and closed in 2014.
- Caraco launched generic doxorubicin liposomal injection in mid-March 2013 and can supply the market with their presentations.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=806
Source link: http://www.ashp.org

Dexmethylphenidate Hydrochloride
August 29, 2014

Reason for the Shortage

- Teva and Mylan cannot provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1079
Source link: http://www.ashp.org

Desmopressin Injection
August 29, 2014

Reason for the Shortage

- Teva and Hospira have desmopressin injection on shortage due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1010
Source link: http://www.ashp.org

Cytarabine Injection
August 29, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) has cytarabine on shortage due to increased demand.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including cytarabine injection.
- Mylan Institutional acquired cytarabine injection from Pfizer on December 6, 2013.
- Mylan discontinued cytarabine 20 mg/mL 25 mL vials in 2014.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=413
Source link: http://www.ashp.org

Azathioprine tablets
August 29, 2014

Reason for the Shortage

- Roxane and Zydus cannot provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1123
Source link: http://www.ashp.org

Amifostine Injection
August 29, 2014

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired amifostine injection from Bedford in July 2014. West-Ward is actively marketing amifostine injection.
- Caraco could not provide a reason for the shortage.
- Medimmune discontinued brand name Ethyol 500 mg injection in August, 2009.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=980
Source link: http://www.ashp.org

Trenexamic Acid Injection
September 3, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) has tranexamic acid injection on shortage due to increased demand for the product.
- X-Gen had tranexamic acid on shortage due to increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1049
Source link: http://www.ashp.org

Papverine Injection
September 3, 2014

Reason for the Shortage

- Bedford and Sandoz have discontinued their papaverine presentations.
- American Regent has papaverine on shortage due to manufacturing delays.
- American Regent is the sole supplier of papaverine.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=781
Source link: http://www.ashp.org

Olanzapine Injection

September 3, 2014

Reason for the Shortage

- American Regent states the reason for the shortage is manufacturing delay.
- Sandoz states the reason for the shortage is increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1093
Source link: http://www.ashp.org

Doxycyline hyclate Injection
September 3, 2014

Reason for the Shortage

- Mylan Institutional states the shortage is due to supplier availability.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including doxycycline injection.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=431
Source link: http://www.ashp.org

Defeoxamine Mesylate Injection
September 3, 2014

Reason for the Shortage

- Fresenius Kabi states the shortage is due to increased demand.
- Hospira has deferoxamine on shortage due to manufacturing delays.
- Teva discontinued all deferoxamine presentations in 2013.
- Watson discontinued all deferoxamine presentations.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired deferoxamine injection from Bedford in July 2014. West-Ward is not actively marketing deferoxamine injection at this time.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1008
Source link: http://www.ashp.org

Cefotaxime Injection

September 3, 2014

Reason for the Shortage

- Fresenius Kabi discontinued all cefotaxime presentations in April 2011.
- Hospira has Claforan on shortage due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=826
Source link: http://www.ashp.org

Butorphanol Injection

September 3, 2014

Reason for the Shortage

- Apotex discontinued butorphanol injection in 2008.
- Ben Venue closed its plant in Bedford, Ohio in July 2014.
- Hospira states the shortage was due to manufacturing delays.
- West-Ward discontinued butorphanol injection in early 2012.
- Sandoz discontinued Stadol injection in 2010.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=939
Source link: http://www.ashp.org

Atropine Sulfate Injection

September 3, 2014

Reason for the Shortage

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

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

Source link: http://www.ashp.org

Ascorbic Acid Injection
September 3, 2014

Reason for the Shortage

- American Regent has ascorbic acid injection on shortage due to manufacturing delays.
- Hospira has discontinued all presentations of Cenolate injection and all supplies were depleted as of early-February, 2010.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=934
Source link: http://www.ashp.org

Aminophylline Injection
September 3, 2014

Reason for the Shortage

- American Regent has aminophylline injection on shortage due to manufacturing delays.
- Hospira states that the shortage was due to manufacturing delays.
- Hospira discontinued aminophylline ampules in September, 2011.
- Theophylline injection is available from BBraun and may be affected by this shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=705
Source link: http://www.ashp.org

Allopurinol Injection
September 3, 2014

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including allopurinol injection.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=998
Source link: http://www.ashp.org

Sodium Chloride 0.45% Injection Bags
September 4, 2014

Reason for the Shortage

- Baxter has 0.45% sodium chloride on shortage due to increased demand.
- BBraun had 0.45% sodium chloride on allocation due to increased demand.
- Hospira cited increased demand as the reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1083
Source link: http://www.ashp.org

Dextrose 5% Injection Large Volume bags
September 4, 2014

Reason for the Shortage

- Baxter states the shortage is due to increased demand.
- BBraun had 5% dextrose on allocation due to increased demand.
- Hospira states the shortage is due to increased demand and manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1081
Source link: http://www.ashp.org

Dactinomycin Injection
September 4, 2014

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including dactinomycin injection. West-Ward is not actively marketing dactinomycin.
- Recordati acquired several products from Lundbeck in January 2013 including Cosmegen.
- Cosmegen can be ordered through wholesalers or ASD Healthcare at 1-800-746-6273.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1064
Source link: http://www.ashp.org

Ranitidine Injection
September 5, 2014

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired ranitidine injection from Bedford in July 2014. West-Ward is not actively marketing ranitidine injection.
- Covis has Zantac on shortage due to capacity issues at the manufacturer.
- Oral ranitidine products are not affected by this shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=820
Source link: http://www.ashp.org

Phytanadione (Vitamin K) Injection
September 5, 2014

Reason for the Shortage

- Amphastar has vitamin K injection on shortage due to increased demand for the product.
- Hospira had vitamin K injection on shortage due to increased demand for the product.
- Oral vitamin K is not affected by this shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=852
Source link: http://www.ashp.org

Pentostatin Injection
September 5, 2014

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including pentostatin injection. West-Ward is not actively marketing pentostatin.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=874

Source link: http://www.ashp.org

Naproxen Oral Suspension
September 5, 2014

Reason for the Shortage

- Roxane discontinued their naproxen oral suspension in June 2013.
- Genentech could not provide a reason for the shortage.
- Palmetto acquired naproxen 25 mg/mL oral suspension in June 2013.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1055
Source link: http://www.ashp.org

Digoxin Injection
September 5, 2014

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
Source link: http://www.ashp.org

Cisatracurium Injection
September 5, 2014

Reason for the Shortage

- Sandoz could not provide a reason for the shortage.
- Nimbex injection was on shortage due to increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1072
Source link: http://www.ashp.org

Vitamin E Aqueous Oral Solution
September 8, 2014

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.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=965
Source link: http://www.ashp.org

Sodium Chloride Concentrate Solution for Injection
September 8, 2014

Reason for the Shortage

- American Regent discontinued 23.4% sodium chloride 30 mL and 100 mL presentations in 2012.
- Baxter discontinued their sodium chloride 250 mL presentation in 2008.
- Fresenius Kabi (formerly APP) has sodium chloride concentrated solution on shortage due to increased demand. Fresenius Kabi discontinued 14.6% sodium chloride 20 mL vials in February 2013.
- Hospira has 14.6% and 23.4% sodium chloride solutions for injection on shortage due to manufacturing delays. Hospira discontinued sodium chloride 14.6% solution 250 mL vials in February 2011.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=724
Source link: http://www.ashp.org

Nitroglycerin Injection
September 8, 2014

Reason for the Shortage

- American Regent has recently upgraded their manufacturing plant. Product will become available in stages as production resumes.
- Hospira states the shortage is due to manufacturing delays.
- Hospira discontinued nitroglycerin in Dextrose 5%, 40 mg/100 mL, 500 mL glass bottles (NDC 00409-1484-03) in 2010.
- Baxter had nitroglycerin premixes on shortage due to a raw material supply issue.
- In cooperation with FDA, Arbor Pharmaceuticals is importing glyceryl trinitrate (Nitronal) injection to the US market to help alleviate the national shortage. This glyceryl trinitrate is manufactured in an FDA-approved facility in Germany by Pohl Boskamp. Glyceryl trinitrate is another name for nitroglycerin.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=786
Source link: http://www.ashp.org

Methylergonovine maleate
September 8, 2014

Reason for the Shortage

- Akorn could not provide a reason for the shortage of methylergonovine maleate injection.
- American Regent had methylergonovine maleate injection on back order due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=906
Source link: http://www.ashp.org

Lidocaine Topical 4% solution
September 8, 2014

Reason for the Shortage

- Hospira discontinued LTA Syringes kits on August 5, 2014 due to a business decision.
- Amphastar IMS has Laryng-O-Jets on shortage due to increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1128
Source link: http://www.ashp.org

Famotdine Injection
September 8, 2014

Reason for the Shortage

- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- West-Ward states the shortage is due to manufacturing delays.
- Oral famotidine products are not affected by this shortage.
- Pfizer launched famotidine injections in March, 2012.
- Mylan Institutional acquired famotidine injections from Pfizer on December 6, 2013.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=810
Source link: http://www.ashp.org

Dobutamine Injection
September 8, 2014

Reason for the Shortage

- Baxter had dobutamine on back order due to increased demand and manufacturing constraints.
- Hospira has dobutamine on shortage due to manufacturing delays.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including dobutamine injection.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=929
Source link: http://www.ashp.org

Citric acid and potassium citrate oral
September 8, 2014

Reason for the Shortage

- Cypress Pharmaceuticals has Cytra-K crystals on back order due to a raw material supply issue.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1080
Source link: http://www.ashp.org

Choline magnesium trisalicylate
September 8, 2014

Reason for the Shortage

- Caraco has discontinued their product. Product was recently seized by US Marshals due to good manufacturing practice violations (see news release for more information).
- Marlex could not provide a reason for their shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=556
Source link: http://www.ashp.org

Tiopronin tablets
September 10, 2014

Reason for the Shortage

- Mission Pharmacal had Thiola on shortage due to raw materials being discontinued.
- Thiola tablets are supplied by Mission Pharmacal and distributed by Retrophin.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1067
Source link: http://www.ashp.org

Ticarcillin Clavulanate
September 10, 2014

Reason for the Shortage

- GlaxoSmithKline could not provide a reason for the shortage.
- GlaxoSmithKline discontinued Timentin 3.1 gram ADD-Vantage vials in late-2012.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=802
Source link: http://www.ashp.org

Secretin Injection
September 10, 2014

Reason for the Shortage

- ChiRhoClin is qualifying a manufacturing site.
- ChiRhoClin is working with FDA to allow the release of ChiRhoStim lot # 0636149. This lot was produced at a new manufacturing site that has not been approved by FDA. Please see the Dear Health Care Provider letter.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=913
Source link: http://www.ashp.org

Lidocaine with Epinephrine Injection
September 10, 2014

Reason for the Shortage

- Hospira has lidocaine with epinephrine presentations on shortage due to manufacturing delays.
- Fresenius Kabi (formerly APP) has Xylocaine with epinephrine presentations on shortage due to increased demand for the product.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=860
Source link: http://www.ashp.org

Ezetimibe and Atorvastatin tablets
September 10, 2014

Reason for the Shortage

- In January 2014, Merck recalled all Liptruzet lots from wholesalers due to packaging defects in the outer laminate foil pouches.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1084
Source link: http://www.ashp.org

Cefpodoxime
September 10, 2014

Reason for the Shortage

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

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=793
Source link: http://www.ashp.org

Calcium acetate capsules
September 10, 2014

Reason for the Shortage

- Fresenius Medical cannot provide a reason for the shortage.
- Hawthorne states the reason for the shortage was manufacturing delay.
- Paddock discontinued calcium acetate tablets in February 2012.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1002
Source link: http://www.ashp.org

Sodium chloride 0.9% Injection bags
September 10, 2014

Reason for the Shortage

- Baxter has 0.9% sodium chloride on shortage due to increased demand.

- BBraun had 0.9% sodium chloride on allocation due to increased demand.
- Hospira cites increased demand as the reason for the shortage.
- 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 label and the package insert is the same for all imported presentations.
- In cooperation with the FDA, Baxter is providing imported 0.9% sodium chloride to the US market to help alleviate the national shortage. This 0.9% sodium chloride in Viaflo containers is manufactured in Spain by Baxter.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=993
Source link: http://www.ashp.org

Ocreotide Injection
September 11, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) reports that the shortage was due to increased demand for the product.
- Sandoz discontinued octreotide injection in 2nd quarter 2013.
- Sagent has octreotide on shortage due to increased demand for the product.
- Teva has octreotide on shortage due to manufacturing delays.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired octreotide injection from Bedford in July 2014. West-Ward is actively marketing octreotide injection.
- Wockhardt has octreotide on back order due to an import ban.
- Sandostatin LAR presentations from Novartis are not affected by this shortage

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=803
Source link: http://www.ashp.org

Leuprolide Acetate 14-day kit
September 11, 2014

Reason for the Shortage

- Sandoz states the shortage was due to increased demand.
- Sandoz relaunched Leuprolide 1 mg/0.2 mL 2.8 mL injection in late-January, 2013. The product has a new NDC number.
- Teva states the shortage is due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=737
Source link: http://www.ashp.org

Ethambutol tablets
September 11, 2014

Reason for the Shortage

- VersaPharm states the reason for the shortage is change in manufacturing facility.
- X-Gen could not provide a reason for the shortage.
- G&W Laboratories discontinued ethambutol tablets in mid-April 2013.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=982
Source link: http://www.ashp.org

Calcium chloride Injection
September 11, 2014

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 delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=941
Source link: http://www.ashp.org

Buprenorphine sublingual tablets
September 11, 2014

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=1030
Source link: http://www.ashp.org

Caffeine citrate injection and oral solution
September 12, 2014

Reason for the Shortage

- American Regent has caffeine citrate on shortage due to manufacturing delays.
- Paddock discontinued caffeine citrate injection and oral solution in May 2014.
- Sagent states the reason for the shortage is increased demand.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired Cafcit from Bedford in July 2014. West-Ward is actively marketing Cafcit injection.

.**Article link:**
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=862

Source link: http://www.ashp.org

Nicardipine hydrochloride
September 15, 2014

Reason for the Shortage

- Cornerstone Therapeutics discontinued Cardene ampules in March 2014. The company could not provide a reason for the discontinuation.
- Teva recalled 4 lots nicardipine injection because the product did not meet purity specifications. The recalled lots are 31302508B, 31302510B, 31302957B, 31303195B.
- Teva discontinued nicardipine injection in September, 2010.
- American Regent had temporarily suspended distribution of all drug products in April, 2011.
- American Regent resumed manufacturing in Shirely, New York in early-May, 2011.
- Mylan Institutional could not provide a reason for the shortage.
- Wockhardt has nicardipine on shortage due to an FDA import alert.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=31
Source link: http://www.ashp.org

Metoprolol Injection
September 15, 2014

Reason for the Shortage

- American Regent has metoprolol injection on shortage due to manufacturing delays.
- Fresenius Kabi, Hospira and Sagent state the shortage was due to increased demand for the product.
- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=813
Source link: http://www.ashp.org

Cidofovir Injection
September 15, 2014

Reason for the Shortage

- Gilead recalled one lot of Vistide on February 4, 2013, due to particulate matter in some vials.
- Gilead discontinued Vistide injection in July 2014.
- Mylan Institutional launched cidofovir injection in mid-March 2013.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=994
Source link: http://www.ashp.org

Cephalexin Oral Suspension
September 15, 2014

Reason for the Shortage

- Orchid/Karalax discontinued all cephalexin oral suspension products in the 3rd Quarter of 2013.
- Ranbaxy has an import ban on their cephalexin oral suspension products.

- Carlsbad Technology, Inc. discontinued all cephalexin oral suspension products in late-2012 due manufacturing cost and shortage or raw materials.
- Teva could not provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1043
Source link: http://www.ashp.org

Azithromycin Injection
September 15, 2014

Reason for the Shortage

- Fresenius Kabi could not provide a reason for the shortage.
- Hospira has azithromycin injection on shortage due to increased demand.
- Sagent has azithromycin injection on shortage due to increased demand.
- Pfizer discontinued Zithromax 500 mg vial with Vial-Mate Adaptor in January 2013.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=936
Source link: http://www.ashp.org

Amikacin Injection
September 15, 2014

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired amikacin injection from Bedford in July 2014.[1]
- Hospira discontinued amikacin in May, 2010 due to a raw material shortage.[2]
- Teva's product was unavailable due to manufacturing delays.[3]
- Sandoz discontinued Amikin injection in 2006.[4]
- Heritage launched amikacin injection in March 2014.[5]

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=501
Source link: http://www.ashp.org

Tolterodine Tartrate Extended Release Capsules
September 16, 2014

Reason for the Shortage

- Mylan discontinued tolterodine extended release 2 mg and 4 mg capsules in 90 count bottles in April 2014.
- Teva could not provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1114
Source link: http://www.ashp.org

Tesamorelin Injection
September 16, 2014

Reason for the Shortage

- EMD Serono had Egrifta 2 mg vials on shortage due to manufacturing delays.
- EMD Serono discontinued Egrifta 1 mg vials in May 2013.
- Theratechnologies acquired Egrifta from EMD Serono in the spring of 2014.
- Theratechnologies had Egrifta 2 mg vials on shortage due to manufacturing delays. They have reverted to the 1 mg vials from the 2 mg vials and have begun manufacturing this new presentation.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1065
Source link: http://www.ashp.org

Pantoprazole Tablets
September 16, 2014

Reason for the Shortage

- Actavis, Aurobindo, Mylan, Teva, and Torrent could not provide a reason for the shortage.
- Kremers Urban state the shortage is due to increased demand.
- FDA imposed an import ban in mid-2013 on several Wockhardt products including pantoprazole.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=979

Source link: http://www.ashp.org

Methylprednisolone Sodium Succinate Injection

September 16, 2014

Reason for the Shortage

- Hospira discontinued all methylprednisolone sodium succinate products in January 2013 due to raw material issues.
- Bedford discontinued methylprednisolone in May, 2011 to concentrate on the manufacturing of other products.
- Pfizer had Solu-Medrol on shortage due to manufacturing delays.
- Fresenius Kabi (formerly APP) has methylprednisolone sodium succinate on shortage due to priority of other medications.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1077
Source link: http://www.ashp.org

Indigo Carmine Injection

September 16, 2014

Reason for the Shortage

- American Regent has indigo carmine on back order due to manufacturing delays.
- Akorn has discontinued production of indigo carmine due to shortage of raw material. Akorn is looking for a new raw material supplier.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=861
Source link: http://www.ashp.org

Denileukin Diftitox Injection

September 16, 2014

Reason for the Shortage

- Eisai is working to resolve a manufacturing problem.
- Eisai is the sole manufacturer of denileukin diftitox.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1009
Source link: http://www.ashp.org

Atorvastatin Tablets
September 16, 2014

Reason for the Shortage

- In November 2012, Ranbaxy voluntarily recalled 41 lots of atorvastatin tablets due to possible contamination with very small glass particles. Ranbaxy resumed supply of atorvastatin tablets in late-March 2013.
- Ranbaxy has atorvastatin on shortage due to manufacturing delay.
- Sandoz could not provide a reason for the shortage.
- Watson discontinued all atorvastatin presentations in February 2013.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=989
Source link: http://www.ashp.org

Albuterol Sulfate 0.5% Inhalation Solution
September 16, 2014

Reason for the Shortage

- Enterovirus D68 can cause mild to severe respiratory illness. In 2014, hospitals are seeing more children than usual with severe respiratory illness from enterovirus D68. This is leading to an increased demand for albuterol solution.
- Hi-Tech and Valeant had albuterol 0.5% solution on back order due to increased demand.
- Albuterol sulfate 0.083% solution and albuterol HFA inhalers supplies remain available.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1130
Source link: http://www.ashp.org

Nalbuphine Injection
September 17, 2014

Reason for the Shortage

- Endo discontinued Nubain in 2008.
- Teva discontinued all nalbuphine injections in July, 2010.
- Hospira has nalbuphine on shortage due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=665
Source link: http://www.ashp.org

Dibucaine Ointment
September 17, 2014

Reason for the Shortage

- Perrigo and Fougera cannot provide a reason for the shortage.
- Geritrex introduced dibucaine 1% ointment in March 2014.
- Novartis divested the rights for all Nupercainal ointment products to Ducere Pharma in 2013.
- These products are available Over-The-Counter.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1074
Source link: http://www.ashp.org

Clarithromycin Immediate-release tablets
September 17, 2014

Reason for the Shortage

- Ranbaxy has an import ban on their products.
- Apotex import ban has been lifted, but the company is not marketing clarithromycin immediate-release tablets in the US.
- Abbvie discontinued Biaxin 500 mg 100 count unit-dose in 2014.
- Mylan discontinued clarithromycin tablets in 2013.
- Teva could not provide a reason for the shortage.
- UDL discontinued clarithromycin 500 mg 100 count unit-dose in May 2013.

- Wockhardt has clarithromycin tablets on shortage due to regulatory delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=945
Source link: http://www.ashp.org

Barium Sulfate Oral suspension
September 17, 2014

Reason for the Shortage

- Bracco Diagnostics states the reason for the shortage is manufacturing delay, as well as increased demand. Bracco Diagnostics has provided a customer letter detailing the reason for the shortage and barium sulfate presentations affected.
- Bracco discontinued multiple products in August 2013 in order to streamline their product portfolio. Table 1 summarizes the barium products that were discontinued. Bracco has provided an updated product portfolio detailing the product changes and the recommended alternate products.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=963
Source link: http://www.ashp.org

Bacitracin Topical Ointment
September 17, 2014

Reason for the Shortage

- Actavis. Altaire, Sandoz, and Qualitest cannot provide a reason for the shortage.
- Perrigo states the shortage is due to increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=677
Source link: http://www.ashp.org

Tamsulosin hydrochloride capsules
September 18, 2014

Reason for the Shortage

- Boehringer Ingelheim could not provide a reason for the shortage.
- Actavis and Zydus state the reason for the shortage is 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.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1112
Source link: http://www.ashp.org

Sincalide Injection
September 18, 2014

Reason for the Shortage

- Bracco Diagnostics has Kinevac on shortage due to manufacturing delays.
- There are no approved alternatives to Kinevac for the labeled indications.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1032
Source link: http://www.ashp.org

Reserpine Oral tablets
September 18, 2014

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
Source link: http://www.ashp.org

Paclitaxel Injection
September 18, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) has paclitaxel on shortage due to increase demand for the product.

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired paclitaxel injection from Bedford in July 2014. West-Ward is not actively marketing paclitaxel.
- Teva has paclitaxel on shortage due to manufacturing delays.
- Sandoz has paclitaxel on back order due to a raw material shortage.
- Hospira had paclitaxel on shortage due to increased demand.
- Sagent has paclitaxel on shortage due to increased demand.
- Pfizer launched paclitaxel 100 mg and 300 mg vials in March, 2012 and launched the 30 mg vials in April, 2012.
- Mylan Institutional acquired paclitaxel injection from Pfizer on December 7, 2013.
- WG Critical Care launched paclitaxel injection in September 2014.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=790
Source link: http://www.ashp.org

Oxytocin Injection
September 18, 2014

Reason for the Shortage

- Fresenius Kabi, USA (formerly APP) states the shortage is due to increased demand.
- Par Sterile Products (formerly JHP) discontinued generic oxytocin injection in July 2014.
- West-Ward states the shortage is due to stock becoming short-dated.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=876
Source link: http://www.ashp.org

Methylene blue injection
September 18, 2014

Reason for the Shortage

- Akorn had methylene blue on back order due to increased demand for the product.
- American Regent has methylene blue on back order due to manufacturing delays.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=27
Source link: http://www.ashp.org

Methyldopate Injection
September 18, 2014

Reason for the Shortage

- American Regent has methyldopate injection on shortage due to manufacturing delays.
- There are no other suppliers of methyldopate injection.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=844
Source link: http://www.ashp.org

Methazolamide tablets
September 18, 2014

Reason for the Shortage

- Sandoz cannot provide a reason for the shortage.
- Perrigo acquired Neptazane tablets and methazolamide tablets from Fera

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=901
Source link: http://www.ashp.org

Hydroxychloroquine sulfate
September 18, 2014

Reason for the Shortage

- Ranbaxy and Sandoz state the hydroxychloroquine shortage is due to increased demand.
- West-Ward and Zydus could not provide a reason for hydroxychloroquine shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1126
Source link: http://www.ashp.org

Fluorouracil Injection
September 18, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) states fluorouracil was on allocation to prevent excessive purchases.
- Teva has fluorouracil on back order due to manufacturing issues.
- Mylan Institutional discontinued their fluorouracil injection in Fall 2014.
- Mylan Institutional acquired fluorouracil injection from Pfizer on December 6, 2013, but is not marketing these proudcts.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=798
Source link: http://www.ashp.org

Calcium gluconate injection
September 18, 2014

Reason for the Shortage

- American Regent has calcium gluconate on shortage due to manufacturing delays.
- Fresenius Kabi had calcium gluconate on shortage due to increase demand for the product.
- 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
Source link: http://www.ashp.org

Calcitriol injection
September 18, 2014

Reason for the Shortage

- Akorn had calcitriol injection on shortage due to increased demand for the product.
- American Regent has calcitriol on back order due to manufacturing delays.
- Abbott discontinued Calcijex in April 2012.
- West-Ward discontinued their calcitriol injection in May, 2011.
- Calcitriol capsule and oral solution presentations are available from multiple manufacturers.
- Fresenius Kabi (formerly APP) discontinued calcitriol injection in January 2014.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=940
Source link: http://www.ashp.org

Bleomycin Injection
September 18, 2014

Reason for the Shortage

- Fresenius Kabi states bleomycin was on shortage due to increased demand.
- Hospira states bleomycin is in short supply due to manufacturing delays.
- Teva states bleomycin is on shortage due to increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=276
Source link: http://www.ashp.org

Benztropine Injection
September 18, 2014

Reason for the Shortage

- American Regent has benztropine injection on back order due to manufacturing delays.
- Fresenius Kabi USA recalled benztropine injection due to potential for glass particles in the vials. Product may have been under APP or Nexus labels. Detailed information on the recall can be found online.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1042
Source link: http://www.ashp.org

Bupivacaine Injection
September 18, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) has Sensorcaine on shortage due to increased demand for the product.
- Hospira has Marcaine and bupivacaine on shortage due to manufacturing delays.
- AuroMedics introduced bupivacaine injection in February 2014.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=864
Source link: http://www.ashp.org

Ammonium chloride injection

September 19, 2014

Reason for the Shortage

- Hospira states the shortage of ammonium chloride is due to manufacturing delays.
- Hospira is the sole manufacturer of ammonium chloride injection.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=933
Source link: http://www.ashp.org

Thiotepa for Injection

September 22, 2014

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including thiotepa injection. West-Ward is not actively marketing thiotepa injection at this time.
- FDA is allowing temporary importation of Tepadina (thiotepa), from Adienne Srl in Italy. Product may be ordered directly through Adienne Srl. The solution is similar in formulation to US thiotepa. The main differences between the two products are listed below:
- Tepadina comes in 15 mg and 100 mg vials while the US thiotepa from Bedford only comes in a 15 mg vial. Reconstitution of the products should still yield a final concentration of 10 mg/mL and therefore use caution in choosing vial size and volume of diluent.
- Tepadina is indicated for different uses and therefore different dosing regimens are on the Europe labeling compared to US labeling, but it is the same product as in the US.
- The bar coding for the Italian product will not provide correct information to bar code readers since the manufacturing code is not an NDC number. More information on the product packaging and ordering procedures can be found online.
- Adienne Srl is supplying Tepadina directly to hospitals and not through wholesalers. Orders can be placed directly with Adienne. Orders are shipped Monday through

Wednesday to ensure product can arrive prior to the weekend to prevent temperature deviations.

- There are no other manufacturers of thiotepa for injection.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=589
Source link: http://www.ashp.org

Polymyxin B Sulfate Injection
September 22, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) could not provide a reason for the shortage.
- Sagent suspended manufacturing of Polymyxin B sulfate injection in October, 2012.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including polymyxin B sulfate injection. West-Ward is not actively marketing polymyxin B sulfate injection.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=974
Source link: http://www.ashp.org

Piperacillin Tazobactam Injection
September 22, 2014

Reason for the Shortage

- Hospira has piperacillin/tazobactam on shortage due to manufacturing delays.
- Pfizer has Zosyn on shortage due to manufacturing delays.
- WG Critical Care states the reason for the shortage was increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1075
Source link: http://www.ashp.org

Midazolam Injections
September 22, 2014

Reason for the Shortage

- West-Ward acquired Baxter's midazolam injection products in May, 2011.
- Ben Venue stopped production in its plant in Bedford, Ohio and closed in 2014.
- Hospira has midazolam on shortage due to manufacturing delays and demand exceeding supply due to current market conditions.
- Hospira discontinued midazolam 5 mg/mL 1 mL iSecure syringes in July 2011.
- Fresenius Kabi (formerly APP) had midazolam on shortage due to increased demand.
- Due to low demand, Akorn is focusing on other medications that are in greater need of supply.
- Caraco discontinued two midazolam presentations in 2014.
- FDA imposed an import ban in mid-2013 on several Wockhardt products including midazolam injection.
- Medicines Company launched midazolam injection in early 2014.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=858
Source link: http://www.ashp.org

Methylprednisolone Acetate Injection
September 22, 2014

Reason for the Shortage

- Sandoz and Teva could not provide a reason for the shortage.
- Pfizer had Depo-Medrol injection on shortage due to manufacturing delay.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=923
Source link: http://www.ashp.org

Mecasermin Injection
September 22, 2014

Reason for the Shortage

- Ipsen Pharmaceuticals states the shortage is due to a manufacturing delay and raw material shortage.

- Ipsen is working with FDA to allow the release of Increlex lot #341203F. This lot was produced at an alternate manufacturing site that has not been approved by FDA. Please see the Dear Health Care Provider letter for additional information.
- Additional information is available here and here.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1058
Source link: http://www.ashp.org

Indocyanine green
September 22, 2014

Reason for the Shortage

- Akorn states the reason for the shortage was increased demand.
- Hub Pharmaceuticals cannot provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1107
Source link: http://www.ashp.org

Clonidine Injection
September 22, 2014

Reason for the Shortage

- American Regent has clonidine injection temporarily unavailable due to manufacturing delay.
- X-Gen states the reason for the shortage was increased demand.
- Mylan Institutional could not provide a reason for the shortage.
- West-Ward states the reason for the shortage is manufacturing delay.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1111
Source link: http://www.ashp.org

Ciprofloxacin Immediate-release tablets
September 22, 2014

Reason for the Shortage

- Ranbaxy has an FDA import ban on several of their products manufactured in India.
- Carlsbad Technology discontinued ciprofloxacin tablets in 2014.
- Marlex is unable to provide a reason for their shortage.
- Major discontinued their ciprofloxacin immediate-release tablets in February, 2010.
- Teva discontinued their ciprofloxacin immediate-release tablet, unit dose presentations in June, 2010.
- Schering has discontinued all Cipro immediate-release tablet presentations.
- UDL has discontinued all ciprofloxacin immediate-release 250 mg unit-dose tablets.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=572
Source link: http://www.ashp.org

Chorionic Gonadotropin (Human) Injection
September 22, 2014

Reason for the Shortage

- Merck (formerly Schering-Plough) states their product is on allocation to prevent use in the gray market.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=382
Source link: http://www.ashp.org

Vecuronium bromide injection
September 23, 2014

Reason for the Shortage

- Hospira states the shortage is due to manufacturing delays.
- Teva states the shortage is due to manufacturing delays.
- Pfizer sold vecuronium injection to Mylan Institutional in December 2013.
- Ben Venue has stopped production in its plant in Bedford, Ohio and closed in 2014.
- Sagent temporarily suspended the manufacture of vecuronium 10 mg and 20 mg vials.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=490
Source link: http://www.ashp.org

Oxacillin Sodium Injection

September 23, 2014

Reason for the Shortage

- Auromedics states the reason for the shortage is increased demand.
- Sagent states the reason for the shortage is manufacturing delay.
- Sandoz states the reason for the shortage is difficulty obtaining the active pharmaceutical ingredient.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1121
Source link: http://www.ashp.org

Doxorubicin Injection
September 23, 2014

Reason for the Shortage

- West-Ward Pharmacetuicals' parent company, Hikma Pharmaceuticals, acquired Adriamycin injection from Bedford in July 2014. West-Ward is not actively marketing Adriamycin injection at this time.
- Pfizer had doxorubicin solution for injection on shortage due to shipping delays.
- Sagent introduced doxorubicin injection in November 2013.
- Mylan Institutional acquired doxorubicin lyophilized powder from Pfizer on December 6, 2013
- Teva could not provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=464
Source link: http://www.ashp.org

Cisplatin Injection
September 23, 2014

Reason for the Shortage

- Fresenius states the shortage was due to increased demand and manufacturing delays.
- Teva is allocating cisplatin to prevent stockpiling.
- WG Critical Care is allocating product due to increased demand.

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

Source link: http://www.ashp.org

Carboplatin Solution for Injection
September 23, 2014

Reason for the Shortage

- Bedford discontinued carboplatin in May, 2011 to concentrate on the manufacturing of other products.
- Teva has carboplatin injection on shortage due to manufacturing delays.
- Fresenius Kabi has carboplatin on shortage due to increased demand for the product.
- Sandoz has carboplatin on shortage due to manufacturing delays.
- Sagent launched carboplatin in November 2013.

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

Source link: http://www.ashp.org

Atenolol tablets
September 23, 2014

Reason for the Shortage

- Avkare and Pack Pharmaceuticals could not provide a reason for the shortage.
- Ranbaxy has atenolol tablets on shortage due to manufacturing delays.
- Zydus has atenolol tablets on allocation due to increased demand.
- Aurobindo and Caraco have discontinued atenolol tablets.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1127
Source link: http://www.ashp.org

Adenosine Injection
September 23, 2014

Reason for the Shortage

- Akorn launched adenosine 3 mg/mL 2 mL vials 25 count in April 2013.

- Astellas had Adenoscan on back order due to increased demand. This back order is now resolved. Adenoscan is used for diagnostic purposes as an adjunct to thallium-201 myocardial perfusion scintigraphy. Adenocard and generic adenosine products are labeled for use in paroxysmal supraventricular tachycardia.
- Ben Venue has stopped production in its plant in Bedford, Ohio and closed in July 2014.
- Sagent has adenosine vials on shortage due to manufacturing delay.
- Teva has discontinued their adenosine injection.
- West-Ward could not provide a reason for the shortage.
- Wockhardt discontinued their adenosine 3 mg/mL 2 mL and 4 mL syringes.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=976
Source link: http://www.ashp.org

Vancomycin Hydrochloride Injection
September 24, 2014

Reason for the Shortage

- Hospira has vancomycin on shortage due to increased demand.
- Fresenius Kabi (formerly APP) has vancomycin injection on shortage due to increased demand.
- Sagent has vancomycin on shortage due to increased demand.
- Akorn has sold their vancomycin products to Pfizer and stopped distributing on April 29, 2011.
- Mylan Institutional acquired vancomycin injection from Pfizer on December 6, 2013.
- Mylan Institutional (formerly Bioniche) has acquired multiple products from Generamedix, including vancomycin hydrochloride.
- Mylan Institutional discontinued two vancomycin presentations in September 2013.
- Pfizer acquired multiple products from Akorn, including vancomycin hydrochloride in early-May, 2011.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=132
Source link: http://www.ashp.org

Sumatriptan succinate injection
September 24, 2014

Reason for the Shortage

- Sagent states the reason for the shortage is increased demand.
- GlaxoSmithKline could not provide a reason for the shortage.
- Pfizer has had Alsuma on shortage since September 2013 due to manufacturing issues.
- Teva has temporarily suspended the production of sumatriptan injection.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1085
Source link: http://www.ashp.org

Sterile Water for injection Large Volume Bags
September 24, 2014

Reason for the Shortage

- Baxter has sterile water for injection on shortage due manufacturing delays.
- BBraun has sterile water for injection on shortage due to increased demand and only has product available for existing customers.
- Hospira has sterile water for injection on shortage due to increased demand and only has product available for existing customers.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1132
Source link: http://www.ashp.org

Rocuronium Injection
September 24, 2014

Reason for the Shortage

- Merck discontinued Zemuron 10 mL multidose vials in the 3rd Quarter of 2013. Merck discontinued Zemuron 5 mL vials in June 2014.
- Mylan Institutional states the reason for the shortage was increased demand.
- Hospira had rocuronium on shortage due to manufacturing delays.
- Teva has rocuronium on shortage due to manufacturing delays.
- Fresenius Kabi and Sagent cited increased demand as the reason for this shortage.
- The Medicines Company launched rocuronium in early 2014.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=434
Source link: http://www.ashp.org

Prednisone tablets
September 24, 2014

Reason for the Shortage

- Cadista states the shortage was due to a raw materials shortage.
- Perrigo discontinued prednisone tablets in 2013.
- Roxane and Watson could not provide a reason for the shortage.
- Qualitest discontinued prednisone 20 mg tablets in August 2013.
- West-Ward states the reason for the shortage is manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=930
Source link: http://www.ashp.org

Potassium Chloride Injection
September 24, 2014

Reason for the Shortage

- Hospira states the reason for the shortage is manufacturing delays.
- Fresenius Kabi and Baxter could not provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=696
Source link: http://www.ashp.org

Ondansetron Injection
September 24, 2014

Reason for the Shortage

- AuroMedics did not provide a reason for the shortage.
- Caraco temporarily discontinued ondansetron injection.
- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July, 2014.
- Hospira had ondansetron on shortage due to manufacturing delays.

- Mylan Institutional temporarily discontinued ondansetron 2 mg/mL injectable products in February 2014.
- Teva temporarily discontinued ondansetron 20 mL injection.
- West-Ward had ondansetron on back order due to increased demand.
- Wockhardt has ondansetron injection on shortage due to an FDA import alert.
- All presentations of ondansetron 32 mg/50 mL premixed bags have been discontinued.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1040
Source link: http://www.ashp.org

Mupirocin Calcium 2% Nasal Ointment
September 24, 2014

Reason for the Shortage

- GlaxoSmithKline could not provide a reason for the shortage.
- Mupirocin cream is not affected by this shortage.
- Mupirocin 22 gram tubes are not affected by this shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1094
Source link: http://www.ashp.org

Methylphenidate Hydrochloride
September 24, 2014

Reason for the Shortage

- Mallinckrodt states the shortage was due to delay in obtaining raw materials. The company has stopped using the trade name Methylin and all products are now marketed as methylphenidate immediate-release or extended-release tablets with new NDC numbers.
- Sandoz states that the shortage is due to delay in obtaining raw materials.
- Teva introduced generic methylphenidate extended release capsules (CD) in late-September 2012, and these capsules are AB-rated to Metadate CD capsules.
- UCB states methylphenidate IR tablets were on shortage due to supply and demand.
- Actavis says the methylphenidate IR tablets were on shortage due to supply constraints.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=752
Source link: http://www.ashp.org

Methotrexate Injection
September 24, 2014

Reason for the Shortage

- Hospira states the reason for the shortage is a manufacturing delay.
- Sandoz recalled two lots of methotrexate 40 mL preservative-free vials in May 2013 due to discover of particulate matter during routine quality control inspection.
- Mylan Institutional acquired methotrexate injection from Pfizer on December 6, 2013.
- Mylan Institutional divested three presentations of methotrexate injection to Intas (Accord Healthcare) in April 2014.
- Bioniche was acquired by Mylan Institutional in September, 2011.
- Teva discontinued methotrexate 4 mL vials in October 2013 due to business reasons.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including methotrexate injection. West-Ward is not actively marketing methotrexate injection.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=26
Source link: http://www.ashp.org

Mannitol Injection
September 24, 2014

Reason for the Shortage

- Hospira had mannitol injection on shortage due to manufacturing delays.
- Fresenius Kabi had mannitol injection on shortage due to increased demand for the product.
- American Regent has mannitol injection on shortage due to manufacturing delays.
- Baxter could not provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=863
Source link: http://www.ashp.org

Magnesium sulfate injection

September 24, 2014

Reason for the Shortage

- American Regent has magnesium sulfate on shortage due to manufacturing delays.
- Fresenius Kabi (formerly APP) had magnesium sulfate injection on shortage due to increased demand for the product.
- Hospira had magnesium sulfate injection on shortage due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=757
Source link: http://www.ashp.org

Leucovorin Calcium Injection

September 24, 2014

Reason for the Shortage

- 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.
- Teva has leucovorin on shortage due to manufacturing delays. Teva imported leucovorin calcium (calcium folinate solution) 30 mL vials available; however, all products expired in July 2014. Teva will not be importing any additional calcium folinate solution.
- Fresenius Kabi (formerly APP) has leucovorin on shortage due to increase demand.
- Fusilev (levoleucovorin) and leucovorin oral tablets are not affected by the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=488
Source link: http://www.ashp.org

Hydromorphone hydrochloride injection

September 24, 2014

Reason for the Shortage

- Hospira has hydromorphone injection on shortage due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=856

Source link: http://www.ashp.org

Haloperidol lactate Injection

September 24, 2014

Reason for the Shortage

- 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.
- Mylan Institutional could not provide a reason for the shortage.
- Sagent has haloperidol lactate on shortage due to manufacturing delays.
- Teva has haloperidol lactate on shortage due to manufacturing delays.
- Mylan Institutional acquired haloperidol lactate injection from Pfizer on December 6, 2013.
- Patriot Pharmaceuticals states the reason for the shortage was increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=527
Source link: http://www.ashp.org

Haloperidol deconoate injection

September 24, 2014

Reason for the Shortage

- Teva products are on shortage due to manufacturing delays.
- Fresenius Kabi could not provide a reason for the shortage.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired haloperidol decanoate injection from Bedford in July 2014. West-Ward is not actively marketing haloperidol decanoate injection at this time.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=526

Source link: http://www.ashp.org

Furosemide Injection

September 24, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) has furosemide injection on shortage due to increased demand for the product.
- American Regent has furosemide injection on shortage due to manufacturing delays.
- Hospira states the shortage was due to manufacturing delays.
- Wockhardt has discontinued all furosemide injection presentations.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=636
Source link: http://www.ashp.org

Cyanocobalamin Injection
September 24, 2014

Reason for the Shortage

- American Regent has cyanocobalamin injection on shortage due to manufacturing delays.
- Fresenius Kabi had cyanocobalamin injection on shortage due to increased demand for the product.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=947
Source link: http://www.ashp.org

Clindamycin Injection
September 24, 2014

Reason for the Shortage

- Pfizer states the Cleocin Add-Vantage vials are on shortage due to manufacturing delays.
- Hospira has clindamycin injection on shortage due to manufacturing delays.
- Akorn launched clindamycin injection in June 2013.
- Sandoz had clindamycin injection on shortage due to increased demand.
- Sagent has clindamycin injection on shortage due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1029
Source link: http://www.ashp.org

Chloroprocaine Injection
September 24, 2014

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including chloroprocaine injection. West-Ward is not actively marketing chloroprocaine injection.
- Hospira discontinued chloroprocaine injection in January, 2012 due to inability to obtain raw materials. All supply was depleted in January.
- Fresenius Kabi (formerly APP) has transitioned from 1 count presentations to 25 count sizes. All 1 count presentations were depleted in early 2012.
- Fresenius Kabi (formerly APP) had Nesacaine on shortage from depletion of raw materials due increased demand for the product.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=849
Source link: http://www.ashp.org

BCG Vaccine Live Intravesical
September 24, 2014

Reason for the Shortage

- Sanofi Pasteur states the reason for the shortage is manufacturing delay.
- Merck states the reason for the shortage is manufacturing delay.
- Merck states Tice BCG vaccine percutaneous for tuberculosis (Merck, NDC 00052-0603-02) is also affected because this product is manufactured at the same facility.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=915
Source link: http://www.ashp.org

Ceftriaxone Sodium Injection
September 25, 2014

Reason for the Shortage

- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- Fresenius Kabi states the reason for the shortage is increased demand.
- Hospira 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 was increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1101
Source link: http://www.ashp.org

Buproprion hydrochloride 24 hour ER tablets
September 25, 2014

Reason for the Shortage

- Global and Par state the reason for the shortage is increased demand for product.
- Mylan cannot provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1106
Source link: http://www.ashp.org

Verapamil Injection
September 26, 2014

Reason for the Shortage

- Hospira states the shortage is due to manufacturing delays.
- Hospira is the sole supplier if verapamil injection.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=744
Source link: http://www.ashp.org

Orphenadrine Citrate Injection
September 26, 2014

Reason for the Shortage

- Sagent had orphenadrine on shortage due to increased demand for the product.

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired orphenadrine injection from Bedford in July 2014. West-Ward is not actively marketing orphenadrine injection at this time.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=884
Source link: http://www.ashp.org

Lorazepam Injectable presentations

September 26, 2014

Reason for the Shortage

- Bedford discontinued lorazepam in May, 2011 to concentrate on the manufacturing of other products.
- West-Ward acquired Baxter's lorazepam injection products in May, 2011. NDC numbers for the lorazepam and Ativan products were changed in April, 2012.
- West-Ward has Ativan on back order due to increase surplus of the lorazepam presentations.
- Hospira states lorazepam vials are on shortage due to increased demand and manufacturing delays. The 1 mL iSecure syringes were discontinued in September 2011.
- Akorn increased production to help meet demand.
- Amphastar had lorazepam 2 mg/mL vials on shortage due to increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=747
Source link: http://www.ashp.org

Intravenous fat emulsion

September 26, 2014

Reason for the Shortage

- Hospira has discontinued the Liposyn II presentations because the raw material is unavailable.
- Hospira has Liposyn III on shortage due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=651
Source link: http://www.ashp.org

Dexamethasone sodium phosphate

September 26, 2014

Reason for the Shortage

- American Regent has dexamethasone sodium phosphate on shortage due to manufacturing delays.
- Fresenius Kabi (formerly APP) states the dexamethasone sodium phosphate shortage was due to supply and demand issues.
- Baxter could not provide a reason for the shortage. Baxter sold several products to West-Ward in mid-2011.
- West-Ward had dexamethasone sodium phosphate injection on shortage due to increased demand.
- Pfizer divested all dexamethasone presentation to Mylan Institutional on December 6, 2013.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=751
Source link: http://www.ashp.org

Cefuroxime Sodium Injection

September 26, 2014

Reason for the Shortage

- Sagent states manufacture of cefuroxime 1.5 gram was suspended in March, 2013. No further production is planned.
- Hospira discontinued cefuroxime 1.5 gram and 7.5 gram vials in January, 2013.
- Covis launched the new NDC numbers in August 2013.
- BBraun discontinued their cefuroxime solution in December 2013.
- Fresenius Kabi discontinued manufacturing cefuroxime in 2013.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=990
Source link: http://www.ashp.org

Ampicillin sulbactam

September 26, 2014

Reason for the Shortage

- AuroMedics Pharma launched new product in mid-June, 2012.
- Hospira states that ampicillin sulbactam vials are on back order due to manufacturing delay.
- Mylan Institutional discontinued ampicillin sulbactam injection in late 2013.
- 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.
- WG Critical Care launched ampicillin sulbactam 1.5 gram vials in March 2014.
- West-Ward acquired several Baxter products in early 2011.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=805
Source link: http://www.ashp.org

Alcohol dehydrated injection (Ethanol)

September 26, 2014

Reason for the Shortage

- American Regent has alcohol dehydrated on back order due to manufacturing delays.
- Hospira and Consolidated Midland discontinued all injectable alcohol dehydrated products.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=778
Source link: http://www.ashp.org

Tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap) vaccine

September 29, 2014

Reason for the Shortage

- Sanofi-Pasteur has Adacel is in short supply due to manufacturing delays. This product is also known as adult tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap) vaccine.

- Sanofi-Pasteur is in the process of implementing new NDC numbers for vaccine products.
- GlaxoSmithKline has available Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine (Boostrix). The 1 count Boostrix syringe is no longer made.
- GlaxoSmithKline has Boostrix on shortage due to increased demand.
- Adult Tetanus and Diphtheria Toxoids Adsorbed (Td) (Tenivac, Sanofi-Pasteur) is not affected by this shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1051
Source link: http://www.ashp.org

Succinylcholine chloride injection
September 29, 2014

Reason for the Shortage

- Hospira had Quelicin on shortage due to manufacturing delays.
- Sandoz had Anectine on shortage due to extra quality reviews.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=582
Source link: http://www.ashp.org

Pancuronium Injection
September 29, 2014

Reason for the Shortage

- Teva discontinued their pancuronium presentations in May, 2010.
- Hospira's product is on back order due to manufacturing delays and retesting of raw material. Hospira is the only manufacturer of pancuronium.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=851
Source link: http://www.ashp.org

Nimodipine Capsules
September 29, 2014

Reason for the Shortage

- Caraco cannot provide a reason for the shortage.
- Heritage could not provide a reason for the shortage.
- Teva discontinued nimodipine capsules in early-March, 2013.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=970
Source link: http://www.ashp.org

Memantine hydrochloride
September 29, 2014

Reason for the Shortage

- Forest states the reason for the shortage of Namenda XR capsules is manufacturing delay.
- Forest plans to discontinue all Namenda immediate-release tablets in Fall 2014. The discontinuation date was extended from August 2014 to Fall 2014 to ensure adequate supplies of the Namenda XR product. Forest states the reason for discontinuing the Namenda immediate-release tablets is to focus on the Namenda XR extended-release capsules.
- Forest will continue to market Namenda oral solution.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1082
Source link: http://www.ashp.org

Fluorescein sodium injection
September 29, 2014

Reason for the Shortage

- Altaire Pharmaceuticals temporarily discontinued fluorescein and fluorescein lite products. Altaire Pharmaceuticals could not provide a reason for the temporary discontinuation.
- Alcon could not provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1104

Source link: http://www.ashp.org

Echothiphate powder for ophthalmic solution
September 29, 2014

Reason for the Shortage

- Pfizer is the only manufacturer of echothiophate powder for ophthalmic solution (Phospholine Iodide).

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=85

Source link: http://www.ashp.org

Chromium (Chromic chloride) injection
October 7, 2014

Reason for the Shortage

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

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=943
Source link: http://www.ashp.org

Atracurium injection
September 29, 2014

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including atracurium injection. West-Ward is not actively marketing atracurium.
- Hospira launched atracurium in mid-2013.
- Sagent as atracurium on shortage due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=872
Source link: http://www.ashp.org

Trace Elements Injection
September 30, 2014

Reason for the Shortage

- American Regent has trace element injection on back order due to manufacturing delays.
- American Regent is the sole supplier of FDA-approved combined trace elements.
- In cooperation with FDA, Fresenius Kabi USA is providing Addamel N (adult trace element injection) and Peditrace (pediatric trace element injection) to the US market to help alleviate the shortage. Addamel N and Peditrace are manufactured in an FDA-approved facility in Norway by Fresenius Kabi AG, the parent company of Fresenius Kabi, USA.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=785
Source link: http://www.ashp.org

Tenecteplase Injection
September 30, 2014

Reason for the Shortage

- Genentech states TNKase was on shortage due to increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1115
Source link: http://www.ashp.org

Phenylephrine Hydrochloride
September 30, 2014

Reason for the Shortage

- American Regent has phenylephrine injection on shortage due to increased demand for the product.
- Sandoz could not provide a reason for the phenylephrine injection shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=184
Source link: http://www.ashp.org

Enalaprilat Injection
September 30, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and closed in 2014.
- Teva has discontinued both of their products.
- Hospira has enalaprilat injection on shortage due to manufacturing delays.
- West-Ward has enalaprilat injection on shortage due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=587
Source link: http://www.ashp.org

Bumetanide tablets
September 30, 2014

Reason for the Shortage

- Mylan Institutional discontinued bumetanide tablets in March 2014.
- Sandoz 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=1073
Source link: http://www.ashp.org

70% Dextrose Injection large volume bags
September 30, 2014

Reason for the Shortage

- BBraun and Baxter cannot provide a reason for the shortage.
- Hospira has 70% dextrose on back order due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1133
Source link: http://www.ashp.org

Triamcinolone injection
October 1, 2014

Reason for the Shortage

- Sandoz could not provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1134
Source link: http://www.ashp.org

Testosterone cypionate
October 1, 2014

Reason for the Shortage

- Paddock has testosterone on shortage due to increased demand and shipping delays from their contract manufacturer.
- West-Ward has 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.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=638
Source link: http://www.ashp.org

Promethazine Injection
October 1, 2014

Reason for the Shortage

- Teva states the shortage is due to manufacturing delays.
- West-Ward states the shortage was due to manufacturing delays. The company has also changed the NDC numbers for products that were formerly Baxter products.
- Hospira states the shortage is due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=654
Source link: http://www.ashp.org

Pramipexole dihydrochloride tablets
October 1, 2014

Reason for the Shortage

- Avkare, Aurobindo, Mylan, Sandoz, and Torrent cannot provide a reason for the shortage.
- Zydus has pramipexole on allocation due to increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1131
Source link: http://www.ashp.org

Lidocaine Injection
October 1, 2014

Reason for the Shortage

- Hospira has lidocaine presentations on shortage due to manufacturing delays.
- Fresenius Kabi, USA (formerly APP) has Xylocaine and lidocaine presentations on shortage due to increased demand for the product.
- Amphastar had lidocaine 2% emergency syringes on shortage due to increased demand for the product.
- BBraun has lidocaine and dextrose premixed bags on shortage due to increased demand for the product.
- Baxter discontinued two lidocaine and dextrose premixed bag presentations in March, 2012.
- AuroMedics introduced lidocaine injection in February 2014.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=859
Source link: http://www.ashp.org

Heparin Sodium injection
October 1, 2014

Reason for the Shortage

- FDA has issued import bans against 22 Chinese manufacturers of heparin due to inadequate good manufacturing practices (GMPs).
- West-Ward obtained five presentations of the heparin sodium injection from Baxter in September, 2011. Baxter only retained two large volume heparin presentations. All other Baxter presentations have been discontinued.
- Fresenius Kabi (formerly APP) reports that heparin products are on back order due to increased demand for the product.
- Hospira states the shortage of heparin vials is due to manufacturing delays.
- Covidien and B. Braun could not provide a reason for the shortage.
- Sagent had heparin on shortage due to increased demand for the product.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=387
Source link: http://www.ashp.org

Cefotetan disodium injection
October 1, 2014

Reason for the Shortage

- BBraun could not provide a reason for the shortage.
- Fresenius Kabi states the reason for the shortage is manufacturing delay.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1097
Source link: http://www.ashp.org

Cefazolin Injection
October 1, 2014

Reason for the Shortage

- Fresenius Kabi, BBraun, West-Ward, and WG Critical Care have cefazolin on shortage due to increased demand.
- Apotex and Sandoz have cefazolin on shortage due to manufacturing delays.
- Hospira has cefazolin on shortage due to manufacturing delays and increased demand.
- Sagent has cefazolin on shortage due to increased demand and shipping delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=987
Source link: http://www.ashp.org

Sodium phosphate injection
October 2, 2014

Reason for the Shortage

- American Regent has sodium phosphate injection on back order due to manufacturing delays.
- American Regent has issued a statement that all lots of sodium phosphate have potential for crystallization. Do not use if any particles are present.
- Hospira had sodium phosphate injection on shortage due to manufacturing delays.
- In cooperation with FDA, Fresenius Kabi USA is providing Glycophos (sodium glycerophosphate) injection to the US market to help alleviate the shortage. Glycophos is manufactured in an FDA-approved facility in Norway by Fresenius Kabi AG.
- Fresenius Kabi launched sodium phosphate injection in mid-January 2014.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=770
Source link: http://www.ashp.org

Potassium phosphate injection
October 2, 2014

Reason for the Shortage

- American Regent has potassium phosphate injection on back order due to manufacturing delays.
- American Regent has issued a statement that all lots of potassium phosphate may contain glass particles and filters must be used. Do not use if there are visible glass particles and filter all other product.
- Hospira had potassium phosphate 15 mL vials on shortage due to increased demand.
- In cooperation with FDA, Fresenius Kabi USA is providing Glycophos (sodium glycerophosphate) injection to the US market to help alleviate the shortage. Glycophos is manufactured in an FDA-approved facility in Norway by Fresenius Kabi AG.
- Fresenius Kabi, USA (formerly APP) launched potassium phosphate injection in November 2013.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=709
Source link: http://www.ashp.org

Phenytoin injection
October 2, 2014

Reason for the Shortage

- West-Ward has phenytoin on allocation due to increased demand.
- Hospira has phenytoin ampules on shortage due to increased demand for the product. Hospira discontinued phenytoin Carpuject syringes in August 2013 for business reasons.
- X-Gen Pharmaceuticals had phenytoin on shortage due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=740
Source link: http://www.ashp.org

Phentolamine mesylate for injection
October 2, 2014

Reason for the Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired phentolamine injection from Bedford in July 2014. West-Ward is actively marketing phentolamine injection.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=349
Source link: http://www.ashp.org

Morphine injections
October 2, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) states the shortage is due to a change in manufacturing sites.
- Hospira states the shortage is due to manufacturing delays.

- Hospira discontinued preservative-containing Carpuject syringes in August, 2012 and replaced them with preservative-free Carpuject syringes.
- West-Ward states the shortage was due to increased demand for product. West-Ward changed old Baxter to new West-Ward NDC codes in early 2012.
- IMS (Amphastar) discontinued morphine 1 mg/mL 10 mL Luer-lock syringes in March, 2012 due to low demand for the product.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=664
Source link: http://www.ashp.org

Milrinone Injection
October 2, 2014

Reason for the Shortage

- Fresenius Kabi states the reason for the shortage is increased demand for the product.
- West-Ward acquired Baxter's milrinone injection vials in May 2011.
- West-Ward states the shortage is due to manufacturing delays.
- Baxter had milrinone premixed bags on shortage due to increased demand.
- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- Apotex, Bioniche, and Teva discontinued milrinone 1 mg/mL vials.
- Sanofi-Aventis discontinued Primacor injection.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=741
Source link: http://www.ashp.org

Hydralazine injection
October 2, 2014

Reason for the Shortage

- American Regent has hydralazine injection on shortage due to manufacturing delays.
- Fresenius Kabi has hydralazine injection on shortage due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1129
Source link: http://www.ashp.org

Gentamicin Injection

October 2, 2014

Reason for the Shortage

- Hospira has gentamicin on shortage due to manufacturing delays
- Fresenius Kabi (formerly APP) had gentamicin on shortage due to increased demand. Fresenius Kabi discontinued their 10 mg/mL 2 mL multi-dose vial in mid-2011.
- Baxter has gentamicin on shortage due to increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=728
Source link: http://www.ashp.org

Erythromycin lactobionate injection

October 2, 2014

Reason for the Shortage

- Hospira has Erythrocin 500 mg vials on shortage due to manufacturing delays.
- Hospira is the sole supplier of erythromycin lactobionate.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=546
Source link: http://www.ashp.org

Ephedrine Injection

October 2, 2014

Reason for the Shortage

- Hospira discontinued ephedrine in March, 2011.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=351
Source link: http://www.ashp.org

Dopamine Injection

October 2, 2014

Reason for the Shortage

- B Braun discontinued their dopamine premix in November 2012 due to raw material supply issues.
- Hospira states the shortage is due to manufacturing delays.
- American Regent has recently upgraded their manufacturing plant. Product will become available in stages as production resumes.
- Baxter had dopamine on allocation due to increased demand.

Article link: http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=88
Source link: http://www.ashp.org

Divalproex Sodium delayed release tablets
October 2, 2014

Reason for the Shortage

- Caraco, Mylan, Teva and Unichem Laboratories cannot provide a reason for the shortage.
- Aurobindo, Dr. Reddy's Laboratories, Lupin, and Qualitest discontinued divalproex sodium delayed release tablets.
- Upsher-Smith had divalproex sodium on long-term back order due to manufacturing delay. Product has recently become available but is being allocated to wholesalers.
- Zydus has divalproex sodium delayed-release tablets on allocation due to increased demand.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1124
Source link: http://www.ashp.org

Diltiazem injection
October 2, 2014

Reason for the Shortage

- Ben Venue stopped product in its plant in Bedford, Ohio and closed in July 2014.
- 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.
- Akorn states the reason for the shortage is increased demand due to market conditions.
- Teva discontinued all diltiazem presentations in March, 2011.
- Biovail discontinued Cardizem Lyo-Ject in 2007 due to business reasons.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=217
Source link: http://www.ashp.org

Dacarbazine Injection
October 2, 2014

Reason for the Shortage

- Teva had dacarbazine on back order due to manufacturing delays.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired dacarbazine injection from Bedford in July 2014. West-Ward is not actively marketing dacarbazine injection at this time.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=949
Source link: http://www.ashp.org

Bupivacaine with epinephrine injection
October 2, 2014

Reason for the Shortage

- Fresenius Kabi (formerly APP) has Sensorcaine with epinephrine on shortage due to increased demand for the product.
- Hospira has bupivacaine with epinephrine and Marcaine with epinephrine on shortage due to manufacturing delays.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=937
Source link: http://www.ashp.org

Tobramycin injection
October 3, 2014

Reason for the Shortage

- Teva has tobramycin solution for injection on shortage due to manufacturing delays.
- Hospira has tobramycin on shortage due to manufacturing delays.
- Fresenius Kabi has tobramycin solution for injection on shortage due to increased demand.
- Pfizer acquired tobramycin injection from Akorn in early-May, 2011.
- Pfizer divested tobramycin injection to Mylan Institutional on December 6, 2013.
- Mylan Institutional could not provide a reason for the shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=701
Source link: http://www.ashp.org

Metronidazole Injection
October 3, 2014

Reason for the Shortage

- Hospira has metronidazole injection on back order due to manufacturing delays.
- Baxter and BBraun are allocating metronidazole injection due to increased demand for the product.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=643
Source link: http://www.ashp.org

Etomidate injection
October 3, 2014

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 had Amidate injection on shortage due to manufacturing delays.
- Mylan Institutional acquired etomidate injection from Pfizer on December 6, 2013. Mylan Institutional divested some presentations of etomidate injection to JHP Pharmaceuticals in April 2014.

- Mylan recalled 10 lots of etomidate injection with the Pfizer label in February 2014. The recall was due to the presence of particulate matter and missing lot numbers and expiration dates on the vials.
- Par Pharmaceuticals acquired JHP Pharmaceuticals in early 2014.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=419
Source link: http://www.ashp.org

Dihydroergotamine mesylate injection
October 3, 2014

Reason for the Shortage

- Ben Venue has stopped production in its plant in Bedford, Ohio and closed in 2014.
- Valeant cannot provide a reason for the shortage of dihydroergotamine mesylate injection.
- Paddock states the reason for the shortage is manufacturing delay.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1050
Source link: http://www.ashp.org

Ceftazidime injection
October 3, 2014

Reason for the Shortage

- Pfizer discontinued all of its ceftazidime injection products in late-November, 2011.
- West-Ward discontinued all of its ceftazidime injection products in January 2012.
- Hospira has ceftazidime on shortage due to manufacturing delays.
- Covis purchased all rights to Fortaz from GlaxoSmithKline. Covis began changing NDC numbers in December 2012.
- Sagent had ceftazidime injection on shortage due to increased demand for the product.
- WG Critical Care launched ceftazidime 1 gram vials in July 2013 and product is available at wholesalers. Ceftazidime 2 gram and 6 gram presentations were launched in August 2013.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=869
Source link: http://www.ashp.org

Selenium injection
October 7, 2014

Reason for the Shortage

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

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=784
Source link: http://www.ashp.org

Papaverine injection
October 7, 2014

Reason for the Shortage

- Bedford and Sandoz have discontinued their papaverine presentations.
- American Regent has papaverine on shortage due to manufacturing delays.
- American Regent is the sole supplier of papaverine.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=781
Source link: http://www.ashp.org

Oxycodone/Acetaminophen Oral solution
October 7, 2014

Reason for the Shortage

- Roxane states that the reason for the shortage is that they are validating a new source for raw materials.
- Roxane discontinued oxycodone/acetaminophen 5 mL unit-dose cups in July 2014.
- Oxycodone/acetaminophen oral solution is not available from other manufacturers or in other concentrations.
- This shortage does not affect single-ingredient oxycodone solutions or oxycodone/acetaminophen solid oral dosage forms.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1117
Source link: http://www.ashp.org

Fosphenytoin Injection
October 7, 2014

Reason for the Shortage

- Akorn discontinued fosphenytoin injection in 2011.
- Fresenius Kabi recalled numerous lots of fosphenytoin due to particulate matter potentially from glass delamination and consistent with glass particulates observed in samples. Fresenius Kabi has a letter discussing the lot numbers and what to do with affected product.
- American Regent discontinued fosphenytoin injection in late-2010.
- Bedford discontinued fosphenytoin in May, 2011 to concentrate on the manufacturing of other products.
- Hospira states the shortage is due to manufacturing delays.
- Pfizer discontinued the Cerebyx 500 mg presentation in September, 2009 and the 1 gram presentation in early-February, 2010.
- Pfizer launched Cerebyx 2 mL and 10 mL vials in October 2013.
- Teva, Apotex, Baxter, GeneraMedix, and Wockhardt have discontinued their fosphenytoin presentations.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=127
Source link: http://www.ashp.org

Caffeine and Sodium benzoate injection
October 7, 2014

Reason for the Shortage

- American Regent had temporarily suspended manufacture of multiple drug products including caffeine and sodium benzoate injection in April, 2011.
- American Regent resumed manufacturing in Shirley, New York in early-May, 2011.
- American Regent is the sole manufacturer of caffeine and sodium benzoate injection.
- Caffeine citrate injection is not affected by this shortage.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=817
Source link: http://www.ashp.org

BCG Vaccine Live intravesical

October 7, 2014

Reason for the Shortage

- Sanofi Pasteur states the reason for the shortage is manufacturing delay.
- Merck states the reason for the shortage is manufacturing delay.
- Merck states Tice BCG vaccine percutaneous for tuberculosis (Merck, NDC 00052-0603-02) is also affected because this product is manufactured at the same facility.

Article link:
http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=915
Source link: http://www.ashp.org

‡ Please refer to ASHP website for more information

NEW DRUGS COMING TO MARKET

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
Lumigan® (Bimatoprost)	Allergan	Opthalamic	Glaucoma	A prostaglandin analog with hypotensive activity	Patent Extended until March 2025
Nasonex® (mometasone furoate monohydrate)	Merck	Inhaled insulin	Nasal symptoms of allergic rhinitis, nasal congestions associated with seasonal allergic rhinitis, treatment of nasal polyps	Metered, nasal spray of corticosteroid demonstrating potent anti-inflammatory properties.	Patent extended until October 3, 2017 or April 3, 2018
Renagel® (sevelamer hydrochloride)	Genzyme	PO	Hyperphosphatemia in chronic kidney disease on dialysis	Phosphate binder to control serum phosphorus	Impax Lab granted license to sell oral suspension 9/16/2014
Celebrex®(celecoxib)	Pfizer	PO	Anti-inflammatory drug for osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, acute pain, and primary dysmenorrhea	Nonsteroidal anti-inflammatory drug that inhibits prostaglandin synthesis primarly via COX-2 resulting in anti-inflammatory, analgesic, and antipyretic activities.	Teva and Mylan received approval to market 5/30/2014
Exforge® (amlodipine besylate and valsartan)	Novartis	PO	Treatment of hypertension	Single tablet combining a dihydropyridine calcium channel blocker and an angiontensin II receptor blocker causing a reduction in blood pressure	Par Pharma began shipment of generic 9/30/2014
Intuniv® (guanfacine hydrochloride)	Shire	PO	Attention Deficit Hyperactivity Disorder (ADHD)	Central α-2 adrenergic receptor agonist used as monotherapy or adjunctive therapy for ADHD.	FDA granted Actavis' ANDA 180 days market exclusivity. Actavis can launch 12/1/2014
Invega® (paliperidone	Janssen	PO	Schizophrenia and schizoaffective	Proposed central dopamine type 2	Patent expires

PRODUCT	MFR	ROUTE	INDICATION	PHARMACOLOGY	MARKET RELEASE
			disorder	(D_2) and serotonin type 2 ($5HT_{2A}$) receptor antagonism	October 6, 2014 but no known generic release date
Travatan Z® (travoprost)	Alcon	Opthalamic	Open-angle glaucoma or ocular hypertension	Prostaglandin analog that binds to prostanoid receptor thus reducing intraocular pressure by increasing uveosacleral outflow.	Patent doesn't expire until October 13, 2029.
Copaxone® (glatiramer acetate)	Teva pharma	INJ (SQ)	Relapsing-forms of multiple sclerosis	Modfies the immune processes that are believed to be responsible for the pathogenesis of MS	Patent expired May 2014; Teva appeal 10/15/2014 for validity of patent.
Nexium® (esomeprazole)	AstraZeneca	PO	Gastroesophageal reflux disease (GERD)	Proton pump inhibitor (PPI)	AstraZeneca made a patent settlement with Ranbaxy to launch a generic on 5/27/2014. Due to quality concerns, FDA hasn't approved the company's generic. Pfizer launched OTC 5/2014