



August 2016

Drug Information Update

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NEW GENERIC APPROVALS

Generic Drug Name	Strength & Dosage Form	Generic Manufacturer	Brand Name
Nilutamide	150 mg tablet	Ani Pharmaceuticals	Nilandron
Mesalamine	800 mg DR tablet	Zydus Pharmaceuticals	Asacol HD
Levoleucovorin calcium	50 mg vial	West-Ward Inc.	Fusilev

NEW DRUG ENTITIES/COMBINATIONS/STRENGTHS

Description	Brand Name	Generic Name	Strength	Notes
TOPICAL LOCAL ANESTHETICS	LIDOTRAL	LIDOCAINE HCL	3.88 %	New Strength
HEPATITIS C VIRUS - NS5A, NS3/4A, NS5B INHIB CMB.	VIEKIRA XR	OMBITA/PARITAP/RITON/DASABUVIR	8.33 mg-50 mg-33.33 mg-200 mg	New Strength and Dosage Form
ANTIHYPERTENSIVES, ACE INHIBITORS	QBRELIS	LISINOPRIL	1 mg/mL	New Strength and Dosage Form
ANGIOTENSIN II RECEPTOR BLOCKER-BETA BLOCKER COMB.	BYVALSON	NEBIVOLOL HCL/VALSARTAN	5 mg-80 mg	New Combination
PEDIATRIC VITAMIN PREPARATIONS	QUFLORA FE	PED MULTIVIT#142/IRON/FLUORIDE	9 mg iron-0.25 mg fluoride	New Combination
TOPICAL LOCAL ANESTHETICS	DERMACINRX PHN PAK	LIDOCAINE/EMOLLIEN T CMB NO.102	5 %	New Combination
OTIC PREPARATIONS,ANTI-INFLAMMATORY-ANTIBIOTICS	OTOVEL	CIPROFLOXACIN HCL/FLUOCINOLONE	0.3 %-0.025 % (0.25 mL)	New Combination
INSULINS	AFREZZA	INSULIN REGULAR, HUMAN	4 unit (90)/8 unit (90)	New Strength
LAXATIVES AND CATHARTICS	GIALAX	PEG 3350/SOD CHLOR/POTASS CIT	17 gram/scoop	New Strength and Dosage Form
ANALGESICS, NARCOTICS	OXYCODONE HCL	OXYCODONE HCL	10 mg/0.5 mL	New Strength and Dosage Form
ANTIEMETIC/ANTIVER TIGO AGENTS	EMEND	APREPITANT	125 mg (25 mg/mL final concentration)	New Strength and Dosage Form
OPHTHALMIC ANTI-INFLAMMATORY IMMUNOMODULATOR-TYPE	XIIDRA	LIFITEGRAST	5 %	New Entity
ANTI-INFLAMMATORY/ANTI ARTHRITIS AGENTS, MISC.	GELSYN-3	HYALURONATE SODIUM	16.8 mg/2 mL	New Strength

NEW INDICATIONS (EXISTING DRUGS)

Drug	New Indication	Date of Approval	Source
PREZISTA® (darunavir)	Treatment of HIV during pregnancy and the postpartum period	July 18, 2016	Prezista [package insert] Janssen Therapeutics. July 2016.
BERINERT® (C1 Esterase Inhibitor)	Treatment of Hereditary Angioedema (HAE) attacks in pediatric patients	July 18, 2016	Berinerit [package insert] CSL Behring. July 2016.
SYNJARDY® (empagliflozin/metformin)	Treatment-naïve adults with type 2 diabetes	July 19, 2016	Synjardy [package insert] Eli Lilly and Co. July 2016.
NAMZARIC® (memantine/donepezil)	Treatment for patients with moderate to severe Alzheimer's disease, who are currently stabilized on donepezil 10 mg, can now start combination therapy directly with Namzaric	July 19, 2016	NAMZARIC [package insert] Allergan. July 2016.
BELVIQ XR® (lorcaserin)	Once a day dosing for chronic weight management	July 19, 2016	Belviq XR [package insert] Eisai Inc. July 2016.
KEYTRUDA® (pembrolizumab)	Treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) with disease progression on or after platinum-containing chemotherapy.	August 8, 2016	Keytruda [package insert] Merck. August 2016.

FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

Fluoroquinolone Antibacterial Drugs for Systemic Use: Drug Safety Communication

[UPDATES 07/26/2016]

Including the following currently available fluoroquinolones:

- Avelox (moxifloxacin)
- Cipro (ciprofloxacin)
- Cipro extended-release (ciprofloxacin extended-release)
- Factive (gemifloxacin)
- Levaquin (levofloxacin)
- Ofloxacin (generic brand)

ISSUE: FDA approved changes to the labels of fluoroquinolone antibacterial drugs for systemic use (i.e., taken by mouth or by injection). These medicines are associated with disabling and potentially permanent side effects of the tendons, muscles, joints, nerves, and central nervous system that can occur together in the same patient. As a result, FDA revised the Boxed Warning; FDA's strongest warning, to address these serious safety issues. In addition, FDA updated other parts of the drug label including the Warnings and Precautions and Medication Guide sections.

FDA has determined that fluoroquinolones should be reserved for use in patients who have no other treatment options for acute bacterial sinusitis, acute exacerbation of chronic bronchitis, and uncomplicated urinary tract infections because the risk of these serious side effects generally outweighs the benefits in these patients. For some serious bacterial infections the benefits of fluoroquinolones outweigh the risks, and it is appropriate for them to remain available as a therapeutic option.

FDA is continuing to assess safety issues with fluoroquinolones as part of FDA's usual ongoing review of drugs and will update the public if additional actions are needed. See the FDA Drug Safety Communication for additional information, including a Data Summary and Additional Information for Health Care Professionals and Patients.

BACKGROUND: The labels of fluoroquinolone medicines already have a Boxed Warning for tendinitis, tendon rupture, and worsening of myasthenia gravis. The labels also include warnings about the risks of peripheral neuropathy and central nervous system effects. Other serious risks associated with fluoroquinolones are described in the labels, such as cardiac, dermatologic, and hypersensitivity reactions. After FDA's 2013 review that led to the additional warning that peripheral neuropathy may be irreversible, FDA evaluated postmarketing reports of apparently healthy patients who experienced disabling and potentially permanent side effects involving two or more body systems after being treated with a systemic fluoroquinolone.

RECOMMENDATION: Patients must contact your health care professional immediately if you experience any serious side effects while taking your fluoroquinolone medicine. Some signs and symptoms of serious side effects include unusual joint or tendon pain, muscle weakness, a "pins and needles" tingling or pricking sensation, numbness in the arms or legs, confusion, and hallucinations. Talk with your health care professional if you have any questions or concerns (see List of Serious Side Effects from Fluoroquinolones in the FDA Drug Safety Communication).

Health care professionals should not prescribe systemic fluoroquinolones to patients who have other treatment options for acute bacterial sinusitis (ABS), acute bacterial exacerbation of chronic bronchitis (ABECB), and uncomplicated urinary tract infections (UTI) because the risks outweigh the benefits in these patients. Stop fluoroquinolone treatment immediately if a patient reports serious side effects, and switch to a non-fluoroquinolone antibacterial drug to complete the patient's treatment course.

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

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

SOURCE: U.S. Food and Drug Administration.

STUDIES and RECENT TOPICS

Implant Effective at Combating Opioid Dependence

July 19, 2016

Addicts are twice as likely to kick their dependence on heroin or prescription painkillers if they receive a new long-acting implant rather than a daily treatment pill, a new clinical trial shows. The implant, sold under the name Probuphine, is placed in the upper arm of recovering addicts and releases a steady six-month dose of buprenorphine.

Source: webmd.com

No Clear Survival Benefit Seen Among Diabetes Drugs

July 19, 2016

Eight different diabetes drug classes examined in a meta-analysis failed to demonstrate improved cardiovascular or all-cause mortality compared with placebo. Researchers analyzed 301 randomized clinical trials of patients with type 2 diabetes, and found that, metformin outperformed some other drug classes for its effect on hemoglobin A1c levels, there were no significant differences in mortality -- including when placebo was included as a drug class.

Source: medpagetoday.com

Opioids May Up Mortality Risk in COPD Patients

July 19, 2016

Older adults with chronic obstructive pulmonary disease (COPD) who took incident opioids had a greater risk of dying from respiratory-related causes compared with COPD patients who didn't take the painkillers, according to a Canadian population study.

Source: medpagetoday.com

ADHD medication reduces risky behavior in children, teens, research finds

July 27, 2016

Based on an analysis of Medicaid claims for nearly 150,000 children diagnosed with ADHD in South Carolina between 2003 and 2013, researchers found treatment with ADHD medication made children less likely to suffer consequences of risky behaviors such as sexually transmitted diseases, substance abuse during their teen years and injuries.

Source: medicalxpress.com

Opioid-related insurance claims rose more than 3,000 percent 2007 to 2014

August 1, 2016

Health insurance claims for people hooked on prescription painkillers and heroin skyrocketed as the number of Americans who fatally overdosed on those opioids hit record highs, a new analysis reveals. The number of private health insurance claims related to opioid dependence diagnosis soared by 3,204 percent from 2007 to 2014, the analysis found.

Source: cnbc.com

'Generic' biologic drugs appear comparable to brand-name counterparts

August 1, 2016

Generic forms of a biologic drug used to treat rheumatoid arthritis, inflammatory bowel disease and psoriasis appear to be as safe and effective as their brand-name counterparts, a new Johns Hopkins Bloomberg School of Public Health analysis suggests.

Source: medicalxpress.com

1 in 5 Opioid Users Also Might Be Abusing Seizure Drug: Study

Aug. 3, 2016

Opioid medication users may be abusing and misusing the seizure and nerve pain drug gabapentin, a new study finds. Researchers looked at test results of 323 patients who were prescribed opioid pain medications. The patients were being treated at pain or rehabilitation clinics, primarily in Arizona, Indiana and Massachusetts.

Source: usnews.com

Arthritis Drug May Have Benefits Against Alzheimer's

August 4, 2016

A drug used to treat rheumatoid arthritis may have benefits against Alzheimer's disease, researchers report. Rheumatoid arthritis is an autoimmune disease believed to be driven in part by tumor necrosis factor, or T.N.F., a protein that promotes inflammation. Drugs that block T.N.F., including an injectable drug called etanercept, have been used to treat rheumatoid arthritis for many years.

Source: nytimes.com

Xeljanz Offers Better Outcomes in Early RA

August 9, 2016

The use of tofacitinib (Xeljanz) monotherapy was more effective in reducing the signs and symptoms of early rheumatoid arthritis (RA) versus those of established RA, researchers reported.

Source: medpagetoday.com

RECALLS

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drug	0.03% Bupivacaine HCl (Preservative Free) in Sodium Chloride 0.9%, 250 mL Medical Cassette Reservoir, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-931-11	Class II	Lot # 160410097M; Exp. 05/16 Lot # 160420107M; Exp. 05/16 Lot # 160460117M; Exp. 05/16 Lot # 160530133M; Exp. 05/16 Lot # 160540206M; Exp. 05/16 Lot # 160570008M; Exp. 05/16 Lot # 160670132M; Exp. 06/16 Lot # 160700001C; Exp. 06/16 Lot # 160770020C; Exp. 06/16 Lot # 160900103C; Exp. 06/16	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	0.05 mg/mL Morphine Sulfate and 0.0625% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 250 mL Hospira LifeCare bag, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-995-54 ,	Class II	Lot # 160420165M; Exp. 05/16 Lot # 160540128M; Exp. 05/16 Lot # 160630117M; Exp. 06/16 Lot # 160770157M; Exp. 06/16 Lot # 160870055M; Exp. 06/16 Lot # 160890153M; Exp. 06/16 Lot # 160950340M; Exp. 07/16	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	0.0625% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, a) 250 mL Hospira LifeCare Bag (NDC 61553-197-50), b) 250 mL Hospira LifeCare Bag (NDC 61553-197-50), c) 150 mL Baxter Intravia Bag (NDC 61553-189-48), d) 250 mL Baxter VIAFLEX Bag (NDC 61553-197-02), e) 250 mL White Smiths Medical Cassette	Class II	Service Code 2H8197 , Lot # 160730048M , Exp.6/12/2016 ; Service Code 2H8197 , Lot # 160840111M , Exp.6/22/2016 ; Service Code 2H8197 , Lot # 160870066M , Exp.6/25/2016 ; Service Code 2H8197 , Lot # 160880208M , Exp.6/27/2016 ; Service Code	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	0.1 mg/mL Morphine Sulfate and 0.05% Bupivacaine HCl (Preservative Free) in 0.9%, 150 mL in 250 mL Hospira LifeCare Bag, Service Code 2H9994 , Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-994-83	Class II	Lot #: 160700041M; Exp.6/8/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drug	0.0625% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, a) 250 mL Hospira LifeCare Bag (NDC 61553-197-50), b) 250 mL Hospira LifeCare Bag (NDC 61553-197-50), c) 150 mL Baxter Intravia Bag (NDC 61553-189-48), d) 250 mL Baxter VIAFLEX Bag (NDC 61553-197-02), e) 250 mL White Smiths Medical Cassette	Class II	Service Code 2H8197 , Lot # 160730048M , Exp.6/12/2016 ; Service Code 2H8197 , Lot # 160840111M , Exp.6/22/2016 ; Service Code 2H8197 , Lot # 160870066M , Exp.6/25/2016 ; Service Code 2H8197 , Lot # 160880208M , Exp.6/27/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	0.1 mg/mL Morphine Sulfate and 0.05% Bupivacaine HCl (Preservative Free) in 0.9%, 150 mL in 250 mL Hospira LifeCare Bag, Service Code 2H9994 , Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-994-83	Class II	Lot #: 160700041M; Exp.6/8/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	0.1% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, Service Code 2K8195, 100 ml in 150 ml Baxter Intravia Bag (NDC 61553-195-48), Service Code 2H8266, 250 ml in 250 ml Hospira LifeCare Bag NDC 61553-266-50), 100 ml in 100 ml Hospira LifeCare Bag, Service Code 2H8272(NDC 61553-272-52), 100 ml	Class II	Service Code 2K8195 , Lot # 160390084M , Exp.5/9/2016 ; Service Code 2K8195 , Lot # 160530298M , Exp.5/23/2016 ; Service Code 2K8195 , Lot # 160540203M , Exp.5/24/2016 ; Service Code 2K8195 , Lot # 160550182M , Exp.5/25/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	0.125% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 100 mL in 100 mL Hospira LifeCare Bag Service Code 2H8194 (NDC 61553-194-52) , 250 mL in 250 mL Cormix Bag ,Service Code 2C8192 (NDC 61553-192-17), 400 mL in 500 mL Baxter Intravia Bag, Service Code 2K8169 (NDC 61553-169-01), Rx Only	Class II	Service Code 2C8192 , Lot # 160830033M , Exp.5/7/2016 ; Service Code 2H8192 , Lot # 160380144M , Exp.5/8/2016 ; Service Code 2H8192 , Lot # 160480178M , Exp.5/18/2016 ; Service Code 2H8192 , Lot # 160610225M , Exp.5/31/2016 ; Service Code	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	0.15% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 250 mL in 250 mL Yellow Smiths Medical Cassette, flow stop free-flow protection, Service Code 2T8217, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-217-50	Class II	Lot # 160380121M , Exp.5/7/2016 ; Lot # 160420113M , Exp.5/11/2016 ; Lot # 160450116M , Exp.5/15/2016 ; Lot # 160470127M , Exp.5/16/2016 ; Lot # 160480136M , Exp.5/18/2016 ; Lot # 160490132M , Exp.5/18/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drug	0.2% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 400 mL in 500 mL Baxter Intravia Bag, Service Code 2K8119 (NDC 61553-119-09), 250 mL in 250 mL Baxter Intravia Bag, Service Code 2K8171(NDC 61553-171-37)150 mL in 150 mL Baxter Intravia Bag, Service Code 2K8463 (NDC 61553-463-47)	Class II	Service Code 2K8119, Lot # 160480208M, Exp.5/18/2016 ; Service Code 2K8119, Lot # 160490134M, Exp.5/19/2016 ; Service Code 2K8119, Lot # 160520129M, Exp.5/22/2016 ; Service Code 2K8119, Lot # 160530167M, Exp.5/23/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	0.25% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride; , Service Code 2H8120, NDC 61553-120-50 , 2 250 ml in 250 ml Hospira LifeCare Bag ; , Service Code 2H8243, NDC 61553-243-54 , 200 ml in 250 ml Hospira LifeCare Bag ; , Service Code 2K8120, NDC 61553-120-09	Class II	Service Code 2H8120, Lot # 160380137M, Exp.5/8/2016 ; Service Code 2H8120, Lot # 160420181M, Exp.5/12/2016 ; Service Code 2H8120, Lot # 160450166M, Exp.5/15/2016 ; Service Code 2H8120, Lot # 160460209M, Exp.5/16/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	0.4 mcg/mL Sufentanil Citrate and 0.0625% Bupivacaine HCl (Preservative Free), 150 mL in 150 mL Baxter Intravia Bag, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-713-95	Class II	Lot #: 160970109M, Exp.5/7/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	0.4 mcg/mL Sufentanil Citrate and 0.1% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 250 mL in 250 mL Hospira LifeCare Bag, Service Code 2H8577, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-577-50	Class II	Lot # 161080149M; Exp.5/18/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	0.5 mcg/mL Sufentanil Citrate and 0.1% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 100 mL in 100 mL Yellow Smiths Medical Cassette, Service Code 2T8317, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-317-52	Class II	Lot # 160960175M; Exp.5/6/2016 Lot # 160970036M; Exp.5/7/2016 Lot # 161080071M; Exp.5/18/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drug	0.5% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 250 mL in 250 mL Baxter Intravia Bag, Service Code 2N1488 (NDC 61553-488-11), 500 mL in 500 mL Baxter Intravia Bag, Service Code 2N1489 (NDC 61553-489-01)Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141	Class II	Service Code 2N1488 , Lot # 160520176M , Exp.5/22/2016 ; Service Code 2N1488 , Lot # 160600059M , Exp.5/30/2016 ; Service Code 2N1488 , Lot # 160970115M , Exp.7/5/2016 ; Service Code 2N1489 , Lot # 160490027C , Exp.5/19/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	1 mcg/mL Fentanyl Citrate and 0.08% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 100 mL in 100 mL Yellow Smiths Medical Cassettes, Service Code 2T8175 Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-175-48	Class II	Lot # 160630037M , Exp.5/23/2016 ; Lot # 160640007M , Exp.5/24/2016 ; Lot # 160700207M , Exp.5/31/2016 ; Lot # 160730149M , Exp.6/3/2016 ; Lot # 160830163M , Exp.6/12/2016 ; Lot # 160880258M , Exp.6/18/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	1 mcg/mL Fentanyl Citrate and 0.1% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 150 mL in 150 mL Baxter Intravia Bag, Service Code 2K9232, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-032-95	Class II	Lot # 160460204M , Exp.5/10/2016 ; Lot # 160560170M , Exp.5/20/2016 ; Lot # 160700007M , Exp.6/2/2016 ; Lot # 160810176M , Exp.6/14/2016 ; Lot # 160830325M , Exp.6/16/2016 ; Lot # 160880270M , Exp.6/21/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	1 mcg/mL Fentanyl Citrate and 0.125% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride; 150 mL in 150 mL Baxter Intravia Bag, Service Code 2K9998, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-998-95	Class II	Service Code 2K9998 , Lot # 160460135M , Exp.5/10/2016 ; Service Code 2K9998 , Lot # 160530146M , Exp.5/17/2016 ; Service Code 2K9998 , Lot # 160590137M , Exp.5/23/2016 ; Service Code 2K9998 , Lot # 160660221M , Exp.5/30/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	1 mcg/mL Sufentanil Citrate and 0.1% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 100 ml in 100 ml Hospira LifeCare Bag, Service Code 2H8919, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-0919-52	Class II	Lot # 160970162M; Exp.5/7/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drug	1.5 mcg/mL Fentanyl Citrate and 0.125% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride; Service Code 2T8232, (NDC 61553-232-97)250 ml in 250 ml Yellow Smiths Medical Cassette, flow stop free-flow protection Service Code 2T8878 100 ml in 100 ml Yellow Smiths Medical Cassette, flow stop free-flow protection ((NDC 61553-878-52)	Class II	Service Code 2T8232 , Lot # 160970019C , Exp.5/7/2016 ; Service Code 2T8878 , Lot # 160450193M , Exp.5/6/2016 ; Service Code 2T8878 , Lot # 160470227M , Exp.5/8/2016 ; Service Code 2T8878 , Lot # 160590187M , Exp.5/19/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	10 mcg/mL Fentanyl Citrate and 0.0625% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 250 ml in 250 ml Hospira LifeCare Bag ,Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-143-50	Class II	Service Code 2H8143 , Lot # 160830115M , Exp.6/22/2016 ; Service Code 2H8143 , Lot # 160910155M , Exp.6/30/2016 ; Service Code 2K8448 , Lot # 160480205M , Exp.5/12/2016 ; Service Code 2K8448 , Lot # 160610064M , Exp.5/24/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	10 mcg/mL Fentanyl Citrate and 0.075% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 100 mL in 100 mL Hospira LifeCare Bag, Service Code 2H9155, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 3614, NDC 61553-1552-52	Class II	Lot # 160460017C , Exp.5/12/2016 ; Lot # 160600019C , Exp.5/26/2016 ; Lot # 160670016C , Exp.6/2/2016 ; Lot # 160740027C , Exp.6/9/2016 ; Lot # 160810024C , Exp.6/16/2016 ; Lot # 160880005C , Exp.6/23/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	10 mcg/mL Fentanyl Citrate and 0.1% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 250 mL in 250 mL Baxter Intravia Bag, Service Code 2K8142, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-142-02	Class II	Lot # 160460189M , Exp.5/10/2016 ; Lot # 160480179M , Exp.5/12/2016 ; Lot # 160520105M , Exp.5/15/2016 ; Lot # 160530291M , Exp.5/17/2016 ; Lot # 160540130M , Exp.5/17/2016 ; Lot # 160550186M , Exp.5/19/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	10 mcg/mL Fentanyl Citrate and 0.125% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride;, 10 mL in 12 mL Monoject Syringe, Service Code 2T6014 (NDC 61553-014-20), 50 mL in 60 mL BD Syringe , Service Code 2T6636 (NDC 61553-636-27), Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141	Class II	Service Code 2T6014 , Lot # 160390220M , Exp.5/9/2016 ; Service Code 2T6014 , Lot # 160700029M , Exp.6/8/2016 ; Service Code 2T6636 , Lot # 160380145M , Exp.5/7/2016 ; Service Code 2T6636 , Lot # 160390003M , Exp.5/8/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drug	10 mcg/mL Fentanyl Citrate and 0.2% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 10 mL in 10 mL BD Syringe, Service Code 2T6203Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-203-27	Class II	Lot # 160380150M , Exp.5/7/2016 ; Lot # 160420180M , Exp.5/11/2016 ; Lot # 160450106M , Exp.5/14/2016 ; Lot # 160480109M , Exp.5/17/2016 ; Lot # 160660210M , Exp.6/5/2016 ; Lot # 160700121M , Exp.6/8/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	10 mcg/mL HYDROmorphone HCl and 0.0625% Bupivacaine HCl in 0.9% Sodium Chloride, 250 mL in 250 mL Baxter Intravia Bag, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-733-17	Class II	Lot # 160470116M , Exp.5/17/2016 ; Lot # 160490123M , Exp.5/19/2016 ; Lot # 160800048M , Exp.6/18/2016 ; Lot # 160890060M , Exp.6/27/2016 ; Lot # 160940050M , Exp.7/2/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	10 mcg/mL HYDROmorphone HCl and 0.0625% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 50 mL in 60 mL BD Syringe, Service Code 2T6733, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-733-20	Class II	Service Code 2T6733 , Lot # 160560088M , Exp.5/25/2016 ; Service Code 2T6733 , Lot # 160590097M , Exp.5/28/2016 ; Service Code 2T6733 , Lot # 160610032M , Exp.5/31/2016 ; Service Code 2T6733 , Lot # 160630191M , Exp.6/2/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	10 mcg/mL HYDROmorphone HCl and 0.075% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 250 mL in 250 mL Hospira LifeCare Bag, Service Code 2H8480, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-480-50	Class II	Lot # 160890042M; Exp.5/13/2016 Lot # 160960052M; Exp.5/20/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	10 mcg/mL HYDROmorphone HCl and 0.1% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 250 mL in 250 mL Yellow Smiths Medical Cassette (stop free-flow protection), Service Code 2K8909, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-909-02	Class II	Service Code 2H8481 , Lot # 160460180M , Exp.5/16/2016 ; Service Code 2H8481 , Lot # 160540181M , Exp.5/24/2016 ; Service Code 2H8481 , Lot # 160830170M , Exp.6/22/2016 ; Service Code 2K8481 , Lot # 160380110M , Exp.5/8/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drug	10 mcg/mL HYDROMORPHONE HCl and 0.125% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride; 250 mL in 250 mL Baxter Intravia Bag, Service Code 2K8908, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-908-02	Class II	Service Code 2K8482, Lot # 160400113M, Exp.5/10/2016 ; Service Code 2K8482, Lot # 160460097M, Exp.5/16/2016 ; Service Code 2K8482, Lot # 160470229M, Exp.5/17/2016 ; Service Code 2K8482, Lot # 160530109M, Exp.5/23/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	16.67 mcg/mL Fentanyl Citrate and 0.1667% Bupivacaine HCl (Preservative Free), 1.5 mL in 3 mL BD Syringe, Service Code 2T6228, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-228-96	Class II	Lot # 160410126M, Exp.5/10/2016 ; Lot # 160450114M, Exp.5/14/2016 ; Lot # 160460158M, Exp.5/15/2016 ; Lot # 160670040M, Exp.6/5/2016 ; Lot # 160730148M, Exp.6/12/2016 ; Lot # 160840112M, Exp.6/22/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	2 mcg/mL Fentanyl Citrate and 0.25% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 100 mL in 150 mL Baxter Intravia Bag, Service Code 2K8103, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-103-48	Class II	Lot # 160390174M, Exp.5/9/2016 ; Lot # 160400196M, Exp.5/10/2016 ; Lot # 160470128M, Exp.5/17/2016 ; Lot # 160530287M, Exp.5/23/2016 ; Lot # 160540190M, Exp.5/24/2016 ; Lot # 160590168M, Exp.5/29/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	2 mcg/mL Fentanyl Citrate and 0.06% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 250 mL in 250 mL Hospira LifeCare Bag, Service Code 2H8095, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-095-50	Class II	Lot # 160390213M, Exp.5/9/2016 ; Lot # 160420162M, Exp.5/12/2016 ; Lot # 160480197M, Exp.5/18/2016 ; Lot # 160600057M, Exp.5/29/2016 ; Lot # 161080145M, Exp.7/17/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	2 mcg/mL Fentanyl Citrate and 0.0625% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 150 mL in 150 mL Baxter Intravia Bag, Service Code 2K9966, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-966-95	Class II	Service Code 2K9966, Lot # 160390021M, Exp.5/9/2016 ; Service Code 2K9966, Lot # 160450151M, Exp.5/15/2016 ; Service Code 2K9966, Lot # 160610223M, Exp.5/31/2016 ; Service Code 2K9966, Lot # 160660080M, Exp.6/5/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drug	2 mcg/mL Fentanyl Citrate and 0.075% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride; 130 mL in 150 mL Baxter Intravia Bag, Service Code, 2K9226 (NDC 61553-226-98), 200 mL in 250 mL Baxter Intravia Bag, Service Code 2K9294 (NDC 61553-0294-92), Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141	Class II	Service Code 2K9226 , Lot # 160450145M , Exp.5/9/2016 ; Service Code 2K9226 , Lot # 160530166M , Exp.5/17/2016 ; Service Code 2K9226 , Lot # 160560080M , Exp.5/19/2016 ; Service Code 2K9226 , Lot # 160670164M , Exp.5/31/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	2 mcg/mL Fentanyl Citrate and 0.08% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 100 mL in 100 mL Hospira LifeCare Bag, Service Code 2H8296 (NDC 61553-296-52), 125 mL in 150 mL Baxter Intravia Bag, Service Code 2K8296 (NDC 61553-296-22), Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141	Class II	Service Code 2H8296 , Lot # 160420192M , Exp.5/8/2016 ; Service Code 2H8296 , Lot # 160450199M , Exp.5/11/2016 ; Service Code 2H8296 , Lot # 160490146M , Exp.5/15/2016 ; Service Code 2H8296 , Lot # 160590180M , Exp.5/25/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	2 mcg/mL Fentanyl Citrate and 0.083% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 100 mL in 100 mL Yellow Smiths Medical Cassette, Service Code 2K8871(NDC 61553-871-48), 250 mL in 250 mL Yellow Smiths Medical Cassette, Service Code 2T8871 (NDC 61553-871-50), Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN	Class II	Service Code 2K8176 , Lot # 160460099M , Exp.5/10/2016 ; Service Code 2K8176 , Lot # 160480269M , Exp.5/12/2016 ; Service Code 2K8176 , Lot # 160560160M , Exp.5/20/2016 ; Service Code 2K8176 , Lot # 160630171M , Exp.5/27/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	2 mcg/mL Fentanyl Citrate and 0.1% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Service Code 2C8201 , NDC 61553-201-58 , 200 ml in 250 ml Cormix Bag ; Service Code 2H8131 , NDC 61553-131-50 , 250 ml in 250 ml Hospira LifeCare Bag ; Service Code 2H8201 , NDC 61553-201-54	Class II	Service Code 3V8701 , Lot # 160390095M , Exp.5/9/2016 ; Service Code 3V8701 , Lot # 160480198M , Exp.5/18/2016 ; Service Code 3V8701 , Lot # 160540108M , Exp.5/24/2016 ; Service Code 3V8701 , Lot # 160690111M , Exp.6/8/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drug	2 mcg/mL Fentanyl Citrate and 0.125% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride; Service Code 2H8125 , NDC 61553-125-52 , 100 ml in 100 ml Hospira LifeCare Bag ; Service Code 2H8204 , NDC 61553-204-54 , 200 ml in 250 ml Hospira LifeCare Bag ; Service Code 2H8205	Class II	Service Code 3V8705 , Lot # 160380161M , Exp.5/8/2016 ; Service Code 3V8705 , Lot # 160400200M , Exp.5/10/2016 ; Service Code 3V8705 , Lot # 160460205M , Exp.5/15/2016 ; Service Code 3V8705 , Lot # 160530278M , Exp.5/23/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	2 mcg/mL Fentanyl Citrate and 0.15% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 200 mL in 250 mL Baxter Intravia Bag, Service Code 2K8433, NDC 61553-433-58, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141	Class II	Lot # 160470226M , Exp.5/11/2016 ; Lot # 160540237M , Exp.5/18/2016 ; Lot # 160600045M , Exp.5/23/2016 ; Lot # 160750052M , Exp.6/7/2016 ; Lot # 160950043M , Exp.6/27/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	2 mcg/mL Fentanyl Citrate and 0.16% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 100 mL in 150 mL Baxter Intravia Bag, Service Code 2K8102, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-102-48	Class II	Lot # 160380168M , Exp.5/8/2016 ; Lot # 160410137M , Exp.5/11/2016 ; Lot # 160460150M , Exp.5/16/2016 ; Lot # 160530279M , Exp.5/23/2016 ; Lot # 160590185M , Exp.5/29/2016 ; Lot # 160630160M , Exp.6/2/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	2 mcg/mL Fentanyl Citrate and 0.162% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 250 mL in 250 mL Yellow Smiths Medical Cassette, flow stop free flow-flow protection, Service Code 2T8229, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-229-97	Class II	Lot #160960135M; Exp.5/6/2016 Lot #161080053M; Exp. 5/17/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	2 mcg/mL Fentanyl Citrate and 0.167% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 200 mL in 250 mL Baxter Intravia Bag, Service Code 2K9276, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-276-98	Class II	Lot # 160480033C , Exp.5/12/2016 ; Lot # 160520027C , Exp.5/16/2016 ; Lot # 160610040C , Exp.5/25/2016 ; Lot # 160750051C , Exp.6/8/2016 ; Lot # 160800038C , Exp.6/13/2016 ; Lot # 160880045C , Exp.6/21/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drug	2 mcg/mL Fentanyl Citrate and 0.2% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 250 mL in 250 mL Baxter Intravia Bag, Service Code 2K8108, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-108-02	Class II	Lot # 160420104M , Exp.5/6/2016 ; Lot # 160450187M , Exp.5/9/2016 ; Lot # 160530126M , Exp.5/17/2016 ; Lot # 160680200M , Exp.6/1/2016 ; Lot # 160730047M , Exp.6/5/2016 ; Lot # 160750130M , Exp.6/8/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	2 mcg/mL Fentanyl Citrate and 0.25% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 100 mL in 100 mL Hospira LifeCare Bag, Service Code 2H8103 (NDC 61553-103-52), 250 mL in 250 mL Baxter Intravia Bag, Service Code 2K8444 (NDC 61553-444-61), Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141	Class II	Service Code 2H8103 , Lot # 160450153M , Exp.5/11/2016 ; Service Code 2K8444 , Lot # 160490047C , Exp.5/13/2016 ; Service Code 2K8444 , Lot # 160540031C , Exp.5/18/2016 ; Service Code 2K8444 , Lot # 160610039C , Exp.5/25/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	2.5 mcg/mL Fentanyl Citrate and 0.0312% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 250 mL in 250 mL Hospira LifeCare Bag, Service Code 2H9195, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-195-50	Class II	Lot # 160890247M , Exp.6/28/2016 ; Lot # 160380151M , Exp.5/8/2016 ; Lot # 160490238M , Exp.5/19/2016 ; Lot # 160550208M , Exp.5/25/2016 ; Lot # 160610062M , Exp.5/30/2016 ; Lot # 160630184M , Exp.6/2/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	2.5 mcg/mL Fentanyl Citrate and 0.0625% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 100 mL in 100 mL Yellow Smiths Medical Cassette, Service Code 2K8892, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-882-48	Class II	Service Code 2K8892 , Lot # 160560168M , Exp.5/17/2016 ; Service Code 2K8892 , Lot # 160810001M , Exp.6/10/2016 ; Service Code 2K8219 , Lot # 160530297M , Exp.5/23/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drug	2.5 mcg/mL Fentanyl Citrate and 0.1% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 200 mL in 250 mL Baxter Intravia Bag, Service Code K8255 (NDC 61553-255-37), 200 ml in 250 ml Baxter Intravia Bag ; Service Code 2K8464 (NDC 61553-464-61), Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN	Class II	Service Code 2H8255 , Lot # 160550161M , Exp.5/11/2016 ; Service Code 2H8255 , Lot # 160620170M , Exp.5/18/2016 ; Service Code 2H8255 , Lot # 160760132M , Exp.6/1/2016 ; Service Code 2H8255 , Lot # 160830148M , Exp.6/8/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	2.5 mcg/mL Fentanyl Citrate and 0.125% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 100 mL in 100 mL Smiths Medical Cassette, flow stop free flow protection, Service Code 2K8972, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-0972-48	Class II	Service Code 2K8210 , Lot # 160390175M , Exp.5/9/2016 ; Service Code 2K8210 , Lot # 160400226M , Exp.5/10/2016 ; Service Code 2K8210 , Lot # 160520170M , Exp.5/22/2016 ; Service Code 2K8210 , Lot # 160590066M , Exp.5/29/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	2.5 mcg/mL Fentanyl Citrate and 0.15% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 250 mL in 250 mL Baxter Intravia Bag, Service Code 2K8297, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-297-02	Class II	Lot # 160530277M , Exp.5/17/2016 ; Lot # 160610199M , Exp.5/25/2016 ; Lot # 160660176M , Exp.5/30/2016 ; Lot # 160690200M , Exp.6/2/2016 ; Lot # 160770187M , Exp.6/10/2016 ; Lot # 160890268M , Exp.6/22/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	20 mcg/mL Fentanyl Citrate and 0.125% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 100 mL in 150 mL Baxter Intravia Bag, Service Code 2K8146, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-189-48	Class II	Lot # 160630032M; Exp. 6/1/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	20 mcg/mL HYDROMorphone HCl and 0.06% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride; 55 mL in 60 mL Monoject Syringe, Service Code 2T6620, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-620-12	Class II	Service Code 2K8157 , Lot # 160420116M , Exp.5/12/2016 ; Service Code 2K8157 , Lot # 160540135M , Exp.5/24/2016 ; Service Code 2K8157 , Lot # 160630121M , Exp.6/2/2016 ; Service Code 2K8157 , Lot # 160730218M , Exp.6/12/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drug	20 mcg/mL HYDROmorphone HCl and 0.075% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 250 mL in 250 mL Baxter Intravia Bag, Service Code 2K8494, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-494-61	Class II	Lot # 160530134M , Exp.5/23/2016 ; Lot # 160630039M , Exp.6/1/2016 ; Lot # 160900044M , Exp.6/28/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	20 mcg/mL HYDROmorphone HCl and 0.1% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 100 ml in 100 mL Yellow Smiths Medical Cassette, flow stop free-flow protection, Service Code 2T8216, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-216-96	Class II	Lot # 160600315M , Exp.5/7/2016 ; Lot # 160670256M , Exp.5/14/2016 ; Lot # 160730057M , Exp.5/20/2016 ; Lot # 160740144M , Exp.5/20/2016 ; Lot # 160800152M , Exp.5/27/2016 ; Lot # 160900142M , Exp.6/5/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	20 mcg/mL HYDROmorphone HCl and 0.125% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 100 mL in 100 mL Yellow Smiths Medical Cassette, Service Code 2K8947, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-947-48	Class II	Service Code 2K8158 , Lot # 160380113M , Exp.5/8/2016 ; Service Code 2K8158 , Lot # 160410115M , Exp.5/11/2016 ; Service Code 2K8158 , Lot # 160420111M , Exp.5/12/2016 ; Service Code 2K8158 , Lot # 160450184M , Exp.5/15/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	3 mcg/mL Fentanyl Citrate and 0.01% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 250 mL in 250 mL Baxter Intravia Bag, Service Code 2K9217, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-217-97	Class II	Lot # 160420248M , Exp.5/6/2016 ; Lot # 160490250M , Exp.5/13/2016 ; Lot # 160600329M , Exp.5/24/2016 ; Lot # 160620002M , Exp.5/25/2016 ; Lot # 160660181M , Exp.5/30/2016 ; Lot # 160760025M , Exp.6/9/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	3 mcg/mL Fentanyl Citrate and 0.0625% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 100 mL in 100 mL Hospira LifeCare Bag, Service Code 2H8180 (NDC 61553-180-52), 250 mL in 250 mL Hospira LifeCare Bag Service Code 2H8262 (NDC 61553-262-50), 250 mL in 250 mL Baxter Intravia Bag	Class II	Service Code 2H8180 , Lot # 160450152M , Exp.5/11/2016 ; Service Code 2H8180 , Lot # 160830040M , Exp.6/17/2016 ; Service Code 2H8262 , Lot # 160380102M , Exp.5/8/2016 ; Service Code 2H8262 , Lot # 160750131M , Exp.6/14/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drug	3 mcg/mL Fentanyl Citrate and 0.1% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 250 mL in 250 mL Hospira LifeCare Bag, Service Code 2H8239 (NDC 61553-239-50), 250 mL in 250 mL Baxter Intravia Bag, Service Code 2K8239 (NDC 61553-239-02), 150 mL in 150 mL Baxter Intravia Bag, Service Code 2K8284	Class II	Service Code 2H8239 , Lot # 160400232M , Exp.5/10/2016 ; Service Code 2H8239 , Lot # 160630193M , Exp.6/2/2016 ; Service Code 2K8239 , Lot # 160520143M , Exp.5/16/2016 ; Service Code 2K8239 , Lot # 160530306M , Exp.5/17/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	3 mcg/mL Fentanyl Citrate and 0.125% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride; 100 mL in 100 mL Yellow Smiths Medical Cassette, Service Code 2K8837 (NDC 61553-837-48), Service Code 2K8906 (NDC 61553-906-48), Service Code 2K8963 (NDC 61553-963-48), Service Code 2K8976 (NDC 61553-976-48), Rx Only, Compounded by PharMEDium Services, LLC	Class II	Service Code 3V8708 , Lot # 160410168M , Exp.5/11/2016 ; Service Code 3V8708 , Lot # 160600286M , Exp.5/30/2016 ; Service Code 3V8708 , Lot # 160810284M , Exp.6/20/2016 ; Service Code 3V8708 , Lot # 160820091M , Exp.6/20/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	3.5 mcg/mL Fentanyl Citrate and 0.0625%Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 125 mL in 150 mL Baxter Intravia Bag, Service Code 2K8470, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-470-30	Class II	Lot # 160390336M , Exp.5/9/2016 ; Lot # 160530318M , Exp.5/23/2016 ; Lot # 160600347M , Exp.5/30/2016 ; Lot # 160750243M , Exp.6/14/2016 ; Lot # 160760164M , Exp.6/14/2016 ; Lot # 160830228M , Exp.6/22/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	4 mcg/mL Fentanyl Citrate and 0.0625% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 250 mL in 250 mL Hospira LifeCare Bag, Service Code 2H8126 (NDC 61553-126-50), Service Code 2K8127 (NDC 61553-127-02), 125 mL in 150 mL Baxter Intravia Bag, Service Code 2K8211 (NDC 61553-211-08)	Class II	Service Code 2H8126 , Lot # 161080146M , Exp.7/17/2016 ; Service Code 2K8127 , Lot # 160460115M , Exp.5/10/2016 ; Service Code 2K8127 , Lot # 160560222M , Exp.5/20/2016 ; Service Code 2K8127 , Lot # 160610209M , Exp.5/25/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drug	4 mcg/mL Fentanyl Citrate and 0.1% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride 50 mL in 60 mL Monoject Syringe, Service Code 2K8983, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-983-48	Class II	Service Code 2H8267, Lot # 160630024M, Exp.5/28/2016 ; Service Code 2K8128, Lot # 160490252M, Exp.5/13/2016 ; Service Code 2K8128, Lot # 160530274M, Exp.5/17/2016 ; Service Code 2K8128, Lot # 160600213M, Exp.5/24/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	4 mcg/mL Fentanyl Citrate and 0.125% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride; 100 mL in 100 mL Yellow Smiths Medical Cassette, flow stop, free-flow protection, Service Code 2T8214, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-214-48	Class II	Service Code 2K8130, Lot # 160450167M, Exp.5/9/2016 ; Service Code 2K8130, Lot # 160460113M, Exp.5/10/2016 ; Service Code 2K8130, Lot # 160490184M, Exp.5/13/2016 ; Service Code 2K8130, Lot # 160540122M, Exp.5/17/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	5 mcg/mL Fentanyl Citrate and 0.04% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 100 mL in 100 mL Yellow Smiths Medical Cassette, flow stop free-flow protection, Service Code 2K8809, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-809-48	Class II	Lot # 160460023M, Exp.5/7/2016 ; Lot # 160460024M, Exp.5/7/2016 ; Lot # 160460025M, Exp.5/7/2016 ; Lot # 160460328M, Exp.5/7/2016 ; Lot # 160540052M, Exp.5/15/2016 ; Lot # 160600338M, Exp.5/21/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	5 mcg/mL Fentanyl Citrate and 0.05% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 250 mL in 250 mL Hospira LifeCare Bag, Service Code 2H8256, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-256-50 ,	Class II	Service Code 2H8256, Lot # 160410124M, Exp.5/11/2016 ; Service Code 2H8256, Lot # 160560146M, Exp.5/26/2016 ; Service Code 2H8256, Lot # 160590041M, Exp.5/29/2016 ; Service Code 2H8256, Lot # 160690131M, Exp.6/8/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	5 mcg/mL Fentanyl Citrate and 0.0625% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride Service Code 2K8135, NDC 61553-135-48 , 100 ml in 150 ml Baxter Intravia Bag ; Service Code 2K8136, NDC 61553-136-02 , 250 ml in 250 ml Baxter Intravia Bag ; Service Code 2K8447	Class II	Service Code 2H8136, Lot # 160390196M, Exp.5/9/2016 ; Service Code 2H8136, Lot # 160400231M, Exp.5/10/2016 ; Service Code 2H8136, Lot # 160410114M, Exp.5/11/2016 ; Service Code 2H8136, Lot # 160460187M, Exp.5/16/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drug	4 mcg/mL Fentanyl Citrate and 0.1% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride 50 mL in 60 mL Monoject Syringe, Service Code 2K8983, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-983-48	Class II	Service Code 2H8267, Lot # 160630024M, Exp.5/28/2016 ; Service Code 2K8128, Lot # 160490252M, Exp.5/13/2016 ; Service Code 2K8128, Lot # 160530274M, Exp.5/17/2016 ; Service Code 2K8128, Lot # 160600213M, Exp.5/24/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	4 mcg/mL Fentanyl Citrate and 0.125% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride; 100 mL in 100 mL Yellow Smiths Medical Cassette, flow stop, free-flow protection, Service Code 2T8214, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-214-48	Class II	Service Code 2K8130, Lot # 160450167M, Exp.5/9/2016 ; Service Code 2K8130, Lot # 160460113M, Exp.5/10/2016 ; Service Code 2K8130, Lot # 160490184M, Exp.5/13/2016 ; Service Code 2K8130, Lot # 160540122M, Exp.5/17/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	5 mcg/mL Fentanyl Citrate and 0.04% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 100 mL in 100 mL Yellow Smiths Medical Cassette, flow stop free-flow protection, Service Code 2K8809, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-809-48	Class II	Lot # 160460023M, Exp.5/7/2016 ; Lot # 160460024M, Exp.5/7/2016 ; Lot # 160460025M, Exp.5/7/2016 ; Lot # 160460328M, Exp.5/7/2016 ; Lot # 160540052M, Exp.5/15/2016 ; Lot # 160600338M, Exp.5/21/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	5 mcg/mL Fentanyl Citrate and 0.05% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 250 mL in 250 mL Hospira LifeCare Bag, Service Code 2H8256, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-256-50 ,	Class II	Service Code 2H8256, Lot # 160410124M, Exp.5/11/2016 ; Service Code 2H8256, Lot # 160560146M, Exp.5/26/2016 ; Service Code 2H8256, Lot # 160590041M, Exp.5/29/2016 ; Service Code 2H8256, Lot # 160690131M, Exp.6/8/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	5 mcg/mL Fentanyl Citrate and 0.0625% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride Service Code 2K8135, NDC 61553-135-48 , 100 ml in 150 ml Baxter Intravia Bag ; Service Code 2K8136, NDC 61553-136-02 , 250 ml in 250 ml Baxter Intravia Bag ; Service Code 2K8447	Class II	Service Code 2H8136, Lot # 160390196M, Exp.5/9/2016 ; Service Code 2H8136, Lot # 160400231M, Exp.5/10/2016 ; Service Code 2H8136, Lot # 160410114M, Exp.5/11/2016 ; Service Code 2H8136, Lot # 160460187M, Exp.5/16/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drug	5 mcg/mL Fentanyl Citrate and 0.075% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride; 250 mL in 250 mL Hospira LifeCare Bag, Service Code 2H8287 (NDC 61553-287-50), 250 mL in 250 mL Baxter Intravia Bag, Service Code 2K8287 (NDC 61553-287-02), Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141	Class II	Service Code 2H8287 , Lot # 160390110M , Exp.5/9/2016 ; Service Code 2H8287 , Lot # 160450123M , Exp.5/15/2016 ; Service Code 2H8287 , Lot # 160470115M , Exp.5/17/2016 ; Service Code 2H8287 , Lot # 160600178M , Exp.5/30/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	5 mcg/mL Fentanyl Citrate and 0.1% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 50 mL in 60 mL BD Syringe, Service Code 2T6257, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-257-20	Class II	Service Code 2H8138 , Lot # 160410192M , Exp.5/11/2016 ; Service Code 2H8138 , Lot # 160600314M , Exp.5/30/2016 ; Service Code 2H8138 , Lot # 160690002M , Exp.6/7/2016 ; Service Code 2H8138 , Lot # 160690191M , Exp.6/8/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	5 mcg/mL Fentanyl Citrate and 0.125% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride 50 mL in 60 mL BD Syringe, Service Code 2T6140 (NDC 61553-140-20) , 60 mL in 60 mL BD Syringe, Service Code 2T6222 (NDC 61553-222-31), Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141	Class II	Service Code 2H8139 , Lot # 160420171M , Exp.5/12/2016 ; Service Code 2H8139 , Lot # 160460111M , Exp.5/16/2016 ; Service Code 2H8139 , Lot # 160490001M , Exp.5/18/2016 ; Service Code 2H8139 , Lot # 160530289M , Exp.5/23/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	5 mcg/mL Fentanyl Citrate and 0.25% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 100 mL in 100 mL Smiths Medical Cassette, Service Code 2T8200, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-200-52	Class II	Lot # 160500008M , Exp.5/10/2016 ; Lot # 160940038C , Exp.6/24/2016 ; Lot # 160970126M , Exp.6/27/2016 ; Lot # 161080140M , Exp.7/8/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	5 mcg/mL HYDROMorphone HCl and 0.0625% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 250 mL in 250 mL Baxter Intravia Bag, Service Code 2K8483, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-483-61	Class II	Lot # 160380152M , Exp.5/8/2016 ; Lot # 160400233M , Exp.5/10/2016 ; Lot # 160540186M , Exp.5/24/2016 ; Lot # 160660046M , Exp.6/4/2016 ; Lot # 160730154M , Exp.6/12/2016 ; Lot # 160750176M , Exp.6/14/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drug	5 mcg/mL HYDROmorphine HCl and 0.075% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 250 mL in 250 mL Hospira LifeCare Bag, Service Code 2H8477 (NDC 61553-477-50), 250 mL in 250 mL Baxter Intravia Bag, Service Code 2K8477 (NDC 61553-477-61), Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141	Class II	Service Code 2H8477 , Lot # 160400137M , Exp.5/10/2016 ; Service Code 2H8477 , Lot # 160450131M , Exp.5/15/2016 ; Service Code 2H8477 , Lot # 160470138M , Exp.5/17/2016 ; Service Code 2H8477 , Lot # 160480132M , Exp.5/18/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	5 mcg/mL HYDROmorphine HCl and 0.1% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 200 mL in 250 mL Hospira LifeCare Bag, Service Code 2H8233, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-233-54	Class II	Lot # 160730064M , Exp.6/2/2016 ; Lot # 160800057M , Exp.6/9/2016 ; Lot # 160820113M , Exp.6/11/2016 ; Lot # 160960142M , Exp.6/26/2016 ;	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	5 mcg/mL HYDROmorphine HCl and 0.125% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 50 mL in 60 mL BD Syringe, Service Code 2T6197, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-197-20	Class II	Lot # 160540183M , Exp.5/23/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	6.66 mcg/mL Fentanyl Citrate and 0.125% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride; 15 mL in 20 mL BD Syringe, Service Code 2T6993Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-993-86	Class II	Lot # 160480035C , Exp.5/18/2016 ; Lot # 160560026C , Exp.5/26/2016 ; Lot # 160620029C , Exp.6/1/2016 ; Lot # 160630001C , Exp.6/1/2016 ; Lot # 160810283M , Exp.6/20/2016 ; Lot # 160880013C , Exp.6/27/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	6.66 mcg/mL Fentanyl Citrate and 0.22% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 15 mL in 20 mL BD Syringe, Service Code 2T6156, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-156-86	Class II	Lot # 160450146M , Exp.5/14/2016 ; Lot # 160520168M , Exp.5/22/2016 ; Lot # 160620181M , Exp.6/1/2016 ; Lot # 160760038M , Exp.6/14/2016 ; Lot # 160900172M , Exp.6/29/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drug	8 mcg/mL HYDROMorphone HCl and 0.05% Bupivacaine HCl (Preservative Free) in 0.9% Sodium Chloride, 250 mL in 250 mL Hospira LifeCare Bag, Service Code 2H9310, Rx Only, Compounded by PharMEDium Services, LLC, Memphis, TN 36141, NDC 61553-310-50	Class II	Lot # 160390094M , Exp.5/9/2016 ; Lot # 160450111M , Exp.5/15/2016 ; Lot # 160520101M , Exp.5/22/2016 ; Lot # 160550109M , Exp.5/25/2016 ; Lot # 160610124M , Exp.5/31/2016 ; Lot # 160620115M , Exp.6/1/2016	Presence of Particulate Matter: API contaminated with glass particulate was used to produce sterile injectable drugs.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drug	buPROPion Hydrochloride Extended Release Tablets USP (SR) 150 mg Rx Only 60 tablets Distributed by Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Ind. Ltd., Halol-Baroda Highway, Halol 389-350 Gujarat India ---- NDC 47335-737-86	Class III	Lot JKN3477A, exp 07/2016	Failed Dissolution Specifications	Sun Pharmaceutical Industries, Inc. 270 Prospect Plains Rd Cranbury, NJ 08512-3605
Drug	Oxacillin for Injection, USP, 10 grams per pharmacy bulk package, Buffered - For IV Use, Sterile, Nonpyrogenic, Preservative-free, Rx Only, Mfd for Sagent Pharmaceuticals, Schaumburg, IL, 60196, USA, Made in India, NDC 25021-163-69	Class II	Lot #: OXT515, Exp. July 2017	Presence of Particulate Matter; The firm received two product complaints for small, dark particulate matter identified in solution post reconstitution.	Sagent Pharmaceuticals Inc 1901 N Roselle Rd Ste 700 Schaumburg, IL 60195-3194
Drug	buPROPion Hydrochloride Extended Release Tablets USP (SR) 150 mg Rx Only 60 tablets Distributed by Sun Pharmaceutical Industries, Inc. Cranbury, NJ 08512, Manufactured by: Sun Pharmaceutical Ind. Ltd., Halol-Baroda Highway, Halol 389-350 Gujarat India ---- NDC 47335-737-86	Class III	Lot JKN3477A, exp 07/2016	Failed Dissolution Specifications	Sun Pharmaceutical Industries, Inc. 270 Prospect Plains Rd Cranbury, NJ 08512-3605

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drug	Divalproex Sodium Delayed-release Tablets USP, RX, 250 mg, 100 count bottles, Manufactured in Israel by: TEVA PHARMACEUTICALS IND. LTD. Jerusalem, 9777402, Israel, Manufactured for: TEVA PHARMACEUTICALS USA, INC. North Wales, PA 19454, NDC 0093-7440-01.	Class III	Lot #: 02D163, Exp. 9/2017	Failed Tablet/Capsule Specifications	Teva North America 425 Privet Rd Horsham, PA 19044-1220
Drug	mitoXANTRONE Injection USP (concentrate), 20 mg/10 mL (2 mg/mL), 10 mL Multiple Dose Vial packaged in a carton, Rx only, Teva Parenteral Medicines, Inc., Irvine, CA 92618, NDC 0703-4685-01.	Class III	Lot # 31318659B, Exp 02/17	Failed Impurities/Degradation Specifications: High out of specification results for Impurity D.	Teva North America 425 Privet Rd Horsham, PA 19044-1220
Drug	Children's Qnasl 40 mcg (beclomethasone dipropionate) Nasal Aerosol, 40 mcg per spray, 60 Metered Sprays per canister, 4.9g Net Contents, Rx only; Professional Sample; Manufactured for Teva Respiratory, LLC, Horsham, PA 19044; By: 3M Drug Delivery Systems, Northridge, CA 91324; NDC 59310-206-08.	Class III	Lot # 150328, Exp 10/17	Failed Content Uniformity Specifications: out of specification test result for spray content uniformity.	Teva North America 425 Privet Rd Horsham, PA 19044-1220

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

CURRENT DRUG SHORTAGES

Yellow Fever Vaccine Injection

July 20, 2016

Reason of Shortage

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

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

Liotrix Tablets

July 20, 2016

Reason of Shortage

- Thyrolar tablets from Actavis (formerly Forest) are on shortage due to manufacturing changes.

Source: <http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=24>

Cefotetan Disodium Injection

July 20, 2016

Reason of Shortage

- BBraun had cefotetan on allocation due to current market conditions.
- Fresenius Kabi states the reason for the shortage is manufacturing delay.
- Teligent received FDA approval for Cefotan in 2015. Teligent launched Cefotan in March 2016.

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

Atropine Sulfate Ophthalmic Solution

July 20, 2016

Reason of Shortage

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

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

BCG Vaccine Live Intravesical

July 22, 2016

Reason of Shortage

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

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

Follitropin Beta

July 24, 2016

Reason of Shortage

- Merck did not provide a reason for the shortage of Follistim AQ.
- Merck discontinued Follistim AQ 75 unit and 150 unit presentations.
- Merck is the sole supplier of follitropin beta.

Source: <http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1240>

Dopamine Hydrochloride Injection

July 26, 2016

Reason of Shortage

- American Regent has dopamine on shortage due to manufacturing delays.
- Baxter could not provide a reason for the shortage.
- Hospira states the shortage is due to manufacturing delays.

Source: <http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1243>

L-Cysteine Hydrochloride Injection

July 28, 2016

Reason of Shortage

- American Regent has L-cysteine hydrochloride injection on back order due to manufacturing delays.
- Sandoz has discontinued L-cysteine hydrochloride 50 mL vials. The 10 mL vials (NDC 66758-0004-02) were replaced with new 10 mL vials (NDC 00781-8940-95).

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

Vitamin E Aqueous Oral Solution

August 01, 2016

Reason of Shortage

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

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

Procainamide Hydrochloride Injection

August 01, 2016

Reason of Shortage

- Hospira (Pfizer) has procainamide hydrochloride injection on shortage due to manufacturing delays.

Source: <http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=868>

Penicillin G Procaine Injection

August 01, 2016

Reason of Shortage

- Pfizer has penicillin G procaine on shortage due to manufacturing delays.
- Pfizer is the sole supplier of penicillin G procaine.

Source: <http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1238>

Methylphenidate Transdermal

August 01, 2016

Reason of Shortage

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

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

Hydroxyamphetamine Hydrobromide and Tropicamide Ophthalmic Solution

August 01, 2016

Reason of Shortage

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

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

Haemophilus B Conjugate Vaccine

August 01, 2016

Reason of Shortage

- GlaxoSmithKline relaunched Hiberix in August 2016.
- Sanofi Pasteur has ActHIB in short supply due to the shortage of other combination vaccines (eg, Pentacel).
- Merck has PedvaxHIB (Haemophilus b meningococcal protein conjugate vaccine) available.

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

Electrolyte Concentrate

August 01, 2016

Reason of Shortage

- American Regent has Nutrilite and Nutrilite II on back order due to manufacturing delays.

Source: <http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1054>

Dexpanthenol Injection

August 01, 2016

Reason of Shortage

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

Source: <http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1103>

Vinblastine Injection

August 02, 2016

Reason of Shortage

- Fresenius Kabi has vinblastine on shortage due to manufacturing delays.
- Fresenius Kabi is the sole supplier of vinblastine.

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

Vitamin A Injection

August 03, 2016

Reason of Shortage

- Pfizer (Hospira) has Aquasol A injection on shortage due to manufacturing delays.

Source: <http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=704>

Leucovorin Calcium Injection

August 03, 2016

Reason of Shortage

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

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

5% Lidocaine and 7.5% Dextrose Injection

August 03, 2016

Reason of Shortage

- Pfizer (Hospira) has 5% lidocaine and 7.5% dextrose 2 mL ampules on shortage due to manufacturing delays.
- Pfizer is the sole supplier of this combination.

Source: <http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1245>

Torsemid Injection

August 05, 2016

Reason of Shortage

- Roche discontinued Demadex injection for business reasons. Demadex tablets are not affected by this shortage.
- American Regent has torsemide on shortage due to manufacturing delays.

Source: <http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=344>

Sterile Empty Vials

August 05, 2016

Reason of Shortage

- Hospira states the shortage was due to increased demand.
- Fresenius Kabi reduced production of sterile empty vials to permit increased production of drug products affected by critical shortages.
- Sterile empty vials may be available from medical supply distributors.

Source: <http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=890>

Estradiol Valerate Injection

August 05, 2016

Reason of Shortage

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

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

Ammonium Chloride Injection

August 05, 2016

Reason of Shortage

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

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

Sodium Chloride 0.9% Injection Bags

August 06, 2016

Reason of Shortage

- Baxter discontinued 0.9% sodium chloride 250 mL and 500 mL AVIVA bags. The other presentations are available or on allocation.
- BBraun has 0.9% sodium chloride available for current customers.
- Hospira cites increased demand as the reason for the shortage.
- Fresenius Kabi is no longer importing product.

- Baxter has received FDA approval for 0.9% sodium chloride in Viaflo containers manufactured in an FDA-approved facility in Spain.

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

Phenazopyridine Hydrochloride

August 06, 2016

Reason of Shortage

- Amneal Pharmaceuticals, Avkare, SDA Laboratories discontinued phenazopyridine tablets.
- Gemini Laboratories has new NDC numbers for Pyridium products. Gemini has product available.
- Marlex has new NDC numbers for the generic phenazopyridine 100 mg and 200 mg tablets. These are available.

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

Vancomycin Hydrochloride Injection

August 06, 2016

Reason of Shortage

- Hospira had vancomycin on shortage due to increased demand.
- Fresenius Kabi has vancomycin injection on shortage due to increased demand.
- Mylan Institutional has vancomycin injection available.
- Baxter is allocating vancomycin.
- Sagent had vancomycin injection on allocation due to increased demand.

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

Testosterone Cypionate Intramuscular Injection

August 08, 2016

Reason of Shortage

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

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

Sodium Nitroprusside Injection

August 08, 2016

Reason of Shortage

- Valeant only has short-dated Nitropress available.

Source: <http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1223>

Mannitol Injection

August 08, 2016

Reason of Shortage

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

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

Cisplatin Injection

July 7, 2016

Reason of Shortage

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

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

Acetylcysteine Oral and Inhalation Solution

August 08, 2016

Reason of Shortage

- American Regent has a consistent supply of acetylcysteine oral and inhalation solution.
- Roxane Labs discontinued acetylcysteine oral and inhalation solution in April 2014.
- Hospira states the reason for the shortage is manufacturing delays.
- Fresenius Kabi states the reason for the shortage was manufacturing delays.

Source: <http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=932>

Levetiracetam Injection

August 09, 2016

Reason of Shortage

- American Regent states the reason for the shortage is manufacturing delay.
- AuroMedics has product available.
- Caraco has temporarily discontinued levetiracetam.
- Hospira has product available. Sagent has product available.
- X-Gen states the reason for the shortage is change in manufacturing site.
- West-Ward is no longer actively marketing the 10 count presentation. They launched the 25 count in July 2016.

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

Tetracaine Hydrochloride Ophthalmic Drops

August 10, 2016

Reason of Shortage

- Alcon, Valeant, and OCuSOFT did not provide a reason for the shortage.

Source: <http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1242>

Retepase Injection

August 10, 2016

Reason of Shortage

- Chiesi USA acquired Cornerstone Therapeutics in March 2014.
- Cornerstone Therapeutics acquired EKR Therapeutics in June 2012. EKR Therapeutics had previously purchased Retavase from PDL BioPharma.
- Cornerstone Therapeutics was seeking FDA approval of a new supplier of the active pharmaceutical ingredient for Retevase.

Source: <http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=569>

Methyldopate Injection

August 10, 2016

Reason of Shortage

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

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

Lidocaine Injection

August 11, 2016

Reason of Shortage

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

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

Ferrous Sulfate Oral Pediatric Drops

August 11, 2016

Reason of Shortage

- Several liquid products were affected by a recall from PharmaTech due to potential contamination from B. cepacia. These included the ferrous sulfate liquid products from Akorn and Major. [FDA](#) issued a MedWatch report with the products affected.

Source: <http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1246>

Avibactam/Ceftazidime Injection

August 11, 2016

Reason of Shortage

- Allegan has Avycaz on shortage due to manufacturing issues.

Source: <http://www.ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1244>

Sodium Acetate Injection

August 13, 2016

Reason of Shortage

- American Regent has sodium acetate injection on backorder due to manufacturing delays.
- Fresenius Kabi has sodium acetate injection on shortage. The company has not provided a reason.
- Hospira had sodium acetate injection on back order due to increased demand.

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

Fluorouracil Injection

August 13, 2016

Reason of Shortage

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

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

NEW DRUGS COMING TO MARKET

Product	Mfr	Route	Indication	Pharmacology	Market Release
AC-170 (cetirizine)	Nicox S.A.	Topical	Allergic Conjunctivitis (Ophthalmology)	Histamine H1 receptor inverse agonist	10/2016
Andexxa (Andexanet Alfa)	Portola	Intravenous (IV)	Drug Toxicity	Reverse the anticoagulant effects of Factor Xa inhibitors	(delayed, FDA required more data)
Apadaz (benzhydrocodone hydrochloride and acetaminophen)	KemPharm	Oral (PO)	Acute Pain	Targets opioid receptors; designed to deter tampering and abuse	09/2016
Arymo ER (morphine sulfate)	Egalet Corporation	Intranasal, Oral (PO)	Moderate to Severe Pain	Targets opioid receptors; controlled-release formulation of morphine	10/2016
Bezlotoxumab	Merck	Intravenous (IV)	Clostridium difficile-Associated Diarrhea/Infection (CDAD/CDI)	Human antibody which targets and neutralizes the effects of Toxin B	10/2016
Biosimilar Adalimumab	Amgen	Subcutaneous (SQ)	Psoriasis, Rheumatoid Arthritis (RA)	Recombinant human IgG1 monoclonal antibody specific for human necrosis factor (TNF)	08/2016
Biosimilar Etanercept	Novartis AG	Subcutaneous (SQ)	Psoriasis, Rheumatoid Arthritis (RA), Ankylosing Spondylitis, Psoriatic Arthritis (PA)	Recombinant protein with properties of a monoclonal antibody; specific for human necrosis factor (TNF)	08/2016-09/2016 (Psoriasis), 07/2016-08/2016 (for other indications)
Biosimilar Pegfilgrastim	Novartis AG	Subcutaneous (SQ)	Neutropenia / Leukopenia	Pegylated form of recombinant human granulocyte-colony stimulating factor (G-CSF), filgrastim	07/2016-08/2016
Brodalumab	Valeant Pharmaceuticals International	Intravenous (IV), Subcutaneous (SQ)	Psoriasis	Human monoclonal antibody that binds to and blocks signaling via the interleukin-17 (IL-17) receptor	11/2016 (for psoriasis) 07/2017-09/2017 (for psoriatic arthritis)
Carbella (carbamazepine)	H. Lundbeck A/S	Intravenous (IV)	Seizure Disorders (Epilepsy) - Partial	Reduces polysynaptic responses and blocks post-tetanic potentiation by stabilizing the	10/2016

Product	Mfr	Route	Indication	Pharmacology	Market Release
				inactive state of voltage-gated sodium channels in neurons	
Dextenza	Ocular Therapeutix	Intraocular/Subretinal/Subconjunctival	Ocular Inflammation (Ophthalmology)	Release sustained level of dexamethasone depot via a hydrogel punctum plug	09/2016-12/2016
ELI-200	Elite	Oral (PO)	Moderate to Severe Pain	Abuse deterrent opioid product	12/2016
Eleclazine	Gilead Sciences Inc.	Oral (PO)	Atrial fibrillation	Late sodium current inhibitor	09/2016
Equin (apaziquone)	Spectrum	Intravesical	Bladder Cancer	Prodrug that is activated to cytotoxic alkylating agent by bio-reductive enzymes	12/2016
Epinephrine PFS	Allergan plc	Intramuscular (IM)	Anaphylaxis	Direct-acting sympathomimetic drug that acts as an agonist at alpha and beta-adrenergic receptors	09/2016
Etelcalcetide (velcalcetide)	Amgen	Intravenous (IV)	Hyperparathyroidism (Secondary)	Peptide protein kinase C (PKC) epsilon inhibitor	08/2016
Eteplirsen	Sarepta Therapeutics	Intravenous (IV)	Muscular Dystrophy	Novel phosphorodiamidate morpholino oligomer (PMO) designed to induce the skipping of exon 51 in the dystrophin gene	08/2016
FIAsp	Novo Nordisk A/S	Subcutaneous (SQ)	Diabetes Mellitus, Type II	Ultra-fast-acting insulin analogue intended to provide faster onset of action than the currently available agents	12/2016
Hepilisav	Dynavax Technologies Corporation	Intramuscular (IM)	Hepatitis B Prevention (Vaccines, Antiviral)	Specifically targets Toll-Like Receptor 9 (TLR-9) to stimulate an innate immune response	12/2016
Invokamet XR (canagliflozin / extended release)	Johnson & Johnson	Oral (PO)	Diabetes Mellitus, Type II	Sodium-glucose cotransporter-2 (SGLT2) inhibitor;	09/2016

Product	Mfr	Route	Indication	Pharmacology	Market Release
metformin)				also targets AMP-activated protein kinase, which regulates lipid and glucose metabolism	
IVIG-SN	Green Cross Corporation	Intravenous (IV)	Primary Immunodeficiency	Immunoglobulin with higher safety attained through adding the nano-filtration process	11/2016
LCS-16	Bayer AG	Intrauterine	Contraception	Initially releases progestogen levonorgestrel directly into the uterus and provides effective birth control for up to five years	09/2016
Lifitegrast	Shire	Topical	Dry Eye (Ophthalmology)	Small-molecule integrin antagonist designed to specifically and potently block the lymphocyte function-associated antigen-1/intercellular adhesion molecule (LFA-1/ICAM-1) interaction	07/2016
LixiLan (insulin glargine/lixisenatide)	Sanofi	Subcutaneous (SQ)	Diabetes Mellitus, Type II	Combination of exendin-4 analogue to mimic glucagon-like peptide (GLP-1) and insulin glargine	08/2016
LPCN 1021 (testosterone undecanoate)	Lipocine	Oral (PO)	Hypogonadism	Lipophilic prodrug testosterone undecanoate	12/2016
Lyxumia (lixisenatide)	Sanofi	Subcutaneous (SQ)	Diabetes Mellitus, Type II	Exendin-4 analogue to mimic glucagon-like peptide (GLP-1)	08/2016
Olaratumab	Eli Lilly	Intravenous (IV)	Sarcoma	Human IgG1 monoclonal antibody designed to bind to PDGFRA, leading to inhibition of ligand-dependent signaling in PDGFRA- as well as stromal cells in the tumor	10/2016-11/2016
Oxymetazoline	Allergan plc	Topical	Rosacea	Selective G-Protein	11/2016-01/2017

Product	Mfr	Route	Indication	Pharmacology	Market Release
				Modulator primarily through alpha adrenergic receptor activation	
Remoxy (oxycodone)	Pain Therapeutics	Oral (PO)	Chronic Pain	Abuse-resistant version of extended release oxycodone	09/2016
RI-002	ADMA Biologics	Intravenous (IV)	Primary Immunodeficiencies	Plasma-derived, polyclonal, Intravenous Immune Globulin, or IGIV, derived from human plasma containing naturally occurring polyclonal antibodies	N/A
Sarilumab	Regeneron	Subcutaneous (SQ)	Rheumatoid Arthritis (RA)	Fully-human antibody to the Interleukin-6 receptor (IL-6R)	10/2016
SER-120	Allergan plc	Intranasal	Urinary Symptoms (e.g. Nocturia, Polyuria)	Synthetic replacement for the hormone vasopressin	12/2016-01/2017
Solanuzumab	Eli Lilly	Intravenous (IV)	Alzheimer's disease	Humanized monoclonal antibody that binds amyloid, failed to improve cognition or functional ability	10/2016
Tbria	Tarsa Therapeutics	Oral (PO)	Osteoporosis / Osteopenia	Directly inhibits osteoclasts and interferes with the membrane transport mechanisms of phosphate and calcium	06/2016-09/2016
Telotristat Etiprate	Lexicon	Oral (PO)	Neuroendocrine Tumors (NET)	Orally-delivered small molecule designed to inhibit peripheral serotonin (5-HT) synthesis	11/2016
Vantrela ER	Teva Pharmaceutical Industries	Oral (PO)	Chronic Pain	Tamper-deterrent hydrocodone for the treatment of pain	08/2016
Vesneo (latanoprostene bunod)	Valeant Pharmaceuticals International	Topical	Glaucoma / Ocular Hypertension (Ophthalmology)	Lower intraocular pressure (IOP) by improving conventional and uveoscleral outflow	12/2016
Xeglyze (5,5'-dimethyl-2,2'-	Dr. Reddy's Laboratories	Topical	Anti-Parasitic and Anti-Protozoal	Binds metals and inhibits	09/2016

Product	Mfr	Route	Indication	Pharmacology	Market Release
bipyridyl)				metalloproteases	
Xultophy (degludec and liraglutide)	Novo Nordisk A/S	Subcutaneous (SQ)	Diabetes Mellitus, Type II	Fixed ratio combination of a basal insulin, degludec, and GLP-1 compound, liraglutide	08/2016-10/2016
Yosprala 325/40	Aralez	Oral (PO)	Cardiovascular Disease	Combination of 325 mg of pH-sensitive coated aspirin with 40 mg of immediate release omeprazole	09/2016
Yosprala 81/40	Aralez	Oral (PO)	Cardiovascular Disease	Combination of 81 mg of pH-sensitive coated aspirin with 40 mg of immediate release omeprazole	09/2016
ZS-9 (sodium zirconium cyclosilicate)	AstraZeneca PLC	Oral (PO)	Hyperkalemia	Crystallized zirconium silicate designed as a sorbent, acting specifically to trap potassium ions over other ions in the gastrointestinal tract	03/2017
Ztlido (lidocaine patch 1.8%)	SCILEX	Transdermal	Postherpetic Neuralgia (PHN)	Blocks the initiation and conduction of nerve impulses by decreasing the neuronal membrane's permeability to sodium ions	10/2016