Highlights of FDA Activities – 3/1/15 – 3/31/15

FDA Drug Safety Communications & Drug Information Updates:

Using Testosterone Products for Low Testosterone Due to Aging Now Requires a Label Change to Inform of Possible Increased Risk of Heart Attack and Stroke: Drug Safety Communication 3/3/2015

Manufacturers of all approved prescription testosterone products are now required to add labeling information that warns about a possible increased risk of heart attacks and strokes in patients taking testosterone. Testosterone is approved for men who have low testosterone levels due to certain medical conditions and not to aging alone. Benefits and safety of testosterone for the treatment of low testosterone due to aging alone have not been established. Labeling information about the approved uses of these medications will be clarified on the products. Patients should be informed of the potential risks when deciding to start or continue testosterone therapy.

Safety Communication FDA Update: Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes – Design May Impede Effective Cleaning 3/4/2015

The FDA has updated its Safety Communication on the ERCP endoscopes and they are closely monitoring the association between reprocessed duodenoscopes and the transmission of infectious agents. It is strongly recommended that healthcare facilities and personnel follow closely all current updated manufacturer instructions for cleaning and processing of these duodenoscopes. By meticulously cleaning, there should be a reduction in the risk of transmitting infection.

FDA updates label for Chantix (varenicline) to include potential alcohol interaction and rare risk of seizures: Drug Safety Communication: 3/9/2015

Chantix (Varenicline) has a new warning that it can change the way people react to alcohol. Patients who drink alcohol should be warned about this risk and decrease their alcohol intake until they know how Chantix affects their tolerance of alcohol. There are also rare accounts of seizures that have been reported in patients treated with Chantix. Caution is advised in patients with a history of seizures. Patients who experience a seizure while on Chantix should stop the medication immediately and seek medical attention.

Treanda (bendamustine hydrochloride) Solution Not Compatible with Closed System Transfer Devices, Adapters, and Syringes Containing Polycarbonate or Acrylonitrile-Butadiene-Styrene 3/10/2015

The FDA warned health care professionals not to use Treanda Injection with closed system transfer devices, adapters, and syringes containing polycarbonate or acrylonitrile-butadiene-styrene (ABS) as these devices have the potential to dissolve when coming into contact with N, N-dimethylacetamide (DMA) found in Treanda Injection. Device failure, possible product contamination, and serious adverse health consequences may arise from this issue.

FDA Warns consumers about the potential health risks of over-the-counter asthma products labeled as homeopathic 3/20/2015

The FDA is warning consumers not to rely on OTC asthma products that are labeled as homeopathic because the safety and effectiveness of these products have not been evaluated.

FDA Review of Study Sheds Light on Two Deaths Associated with the Injectable Schizophrenia Drug Zyprexa Relprevv: Drug Safety Communication: 3/23/15

The FDA has concluded a review of a study undertaken to determine the cause of elevated levels of the injectable schizophrenia drug Zyprexa Relprevv (olanzapine pamoate) in two patients who died. The study results were inconclusive; the extremely high blood levels found in both patients may have occurred after death. The FDA has not made any recommendations to change current prescribing or use of Zyprexa Relprevv at this time.

Mammograms at Richard D. Adelman M.D. in Raleigh, NC: Safety Communication - Quality 3/24/2015
The FDA is alerting patients who had mammograms at Richard D. Adelman, M.D., Family Medicine practice in Raleigh, NC any time after August 24, 2012 that there may be a possible problem with the quality of their mammograms. The American College of Radiology revoked the facility's accreditation. Although problems with the quality of the mammograms were found, this does not mean that the results are inaccurate.

FDA Warns of Serious Slowing of the Heart Rate When Antiarrhythmic Drug Amiodarone is used with Hepatitis C Treatments Containing Sofosbuvir (Harvoni or Sovaldi) in Combination with another Direct Acting Antiviral for Hepatitis C: Drug Safety Communication 3/24/2015
A warning has been issued stating that serious slowing of the heart rate can occur when the antiarrhythmic drug amiodarone is taken together with either the hepatitis C drug Harvoni (ledipasvir/sofosbuvir) or with Sovaldi (sofosbuvir) taken in combination with another direct acting antiviral for the treatment of hepatitis C infection. Information about this symptomatic bradycardia will be added to the Harvoni and Sovaldi labels. The FDA is currently recommending neither therapy should be prescribed with amiodarone. If alternate regimens are not appropriate, patients should be monitored in an inpatient hospital setting for the first 48 hours and with daily heart rate monitoring for at least 2 weeks.

Feraheme (ferumoxytol): Drug Safety Communication - Warnings Strengthened and Prescribing Instructions Changed 3/31/15
The FDA is strengthening an existing warning that serious, potentially fatal allergic reactions can occur with the anemia drug ferumoxytol following postmarketing reports of serious reactions, including deaths. Updated prescribing information includes a Boxed Warning and a new contraindication for the use of ferumoxytol in patients who have had an allergic reaction to any intravenous iron replacement product. Ferumoxytol should be administered as an IV infusion over at least 15 minutes and patients should be monitored for at least 30 minutes following each infusion. Risks and benefits of therapy should be carefully considered in elderly patients with multiple or serious medical conditions and patients with a history of multiple drug allergies, as these populations may be a greater risk for severe reactions.

Major Product Recalls Announced Through MedWatch:

0.9% Sodium Chloride Injection 250 mL VisIV: Recall – Particulate Matter 3/6/2015
A voluntary recall for one lot (NDC 0409-7983-25, Lot 45-110-C6, Expiry 1MAR2016) of 0.9% Sodium Chloride Injection 250 mL VisIV flex container was announced by Hospira following identification of a foreign particle in a single unit that was confirmed to be human hair. The affected lot was distributed nationwide from December 2014 through January 2015.

Hospira Plum A+ and Plum A+3 Infusion Systems: Recall – Alarm Volume Failure 3/6/2015
A recall has been issued for Hospira Plum A+ and Plum A+3 Infusion Systems due to alarm volume failure. The alarm, which sounds off when therapy is interrupted, does not properly sound off in some situations. This may cause a long delay before health care professionals are aware of the need to restore therapy.

Magnesium Sulfate in 5% Dextrose Injection by Hospira: Recall – Incorrect Barcode Labeling 3/6/2015
One lot (NDC: 0409-6727-23, Lot 42-120-JT, Expiry 1DEC2015) of Magnesium Sulfate in 5% dextrose was found to have an incorrect barcode on the primary bag labeling. Although the overwrap barcode is correct, some products may have the primary container barcode that scans for Heparin Sodium 2000 units/1000 mL in 0.9% Sodium Chloride Injection. There is a potential for life-threatening delay in magnesium sulfate treatment due to this issue. Those with recalled product on-hand should stop use and distribution and quarantine the product immediately.

Lactated Ringer's Irrigation, 3000 mL by Hospira: Recall – Mold Contamination 3/12/2015
Hospira has initiated a voluntary recall of Lactated Ringer's Irrigation, 3000 mL due to a report of dark, fibrous particulates floating within the solution. This particulate was confirmed to be a common non-toxic, non-invasive mold called *Aspergillus kanagawaensis*. The lot (NDC: 0409-7828-08, Lot 40-008-JT, Expiry 1APR2016) was distributed nationwide from June 2014 through September 2014.

Dietary Supplement Recalls & Public Notifications

In March, the FDA issued notifications to the public regarding undeclared active ingredients in the following products. Patients are advised not to purchase or use these products.

Product	***Promoted Use***	***Hidden/Undeclared Drug Ingredient(s)***
Vigour 300	Sexual enhancement	Sildenafil
Hard Wang	Sexual enhancement	Sildenafil
FX3000	Sexual enhancement	Sildenafil
MME MAXMAN	Sexual enhancement	Sildenafil
Sex Men	Sexual enhancement	Sildenafil
Super Hard	Sexual enhancement	Sildenafil
Vigra	Sexual enhancement	Sildenafil
Plant Vigra	Sexual enhancement	Sildenafil
Santi Scalper	Sexual enhancement	Sildenafil
Baolong	Sexual enhancement	Sildenafil
Rhino Blitz Gold 3000	Sexual enhancement	Sildenafil
Vim-25	Sexual enhancement	Sildenafil
Black Mamba Premium	Sexual enhancement	Sildenafil
African Superman	Sexual enhancement	Sildenafil
Black Ant King	Sexual enhancement	Sildenafil
Bigger Longer More Time More Sperms (sic)	Sexual enhancement	Sildenafil
Stiff Nights	Sexual enhancement	Sildenafil
Herb Viagra	Sexual enhancement	Sildenafil
Herb Viagra Male Sexual Stimulant	Sexual enhancement	Sildenafil
La Pepa Negra	Sexual enhancement	Sildenafil
Male Silkworm Moth Nourishing Oral Liquid	Sexual enhancement	Vardenafil
Xcel	Weight loss	Fluoxetine
Botanical Slimming (Red)	Weight loss	Fluoxetine
Green algae Combination by Crane Beauty	Weight loss	Lorcaserin
Elimulating Weight & Toxin Keeping Beauty	Weight loss	Sibutramine
L-Carnitine Sob Strengthening Version Slimming Miracle Capsule	Weight loss	Sibutramine
Black Mamba Hyperrush	Weight loss	Sibutramine
Ultra ZX*	Weight loss	Sibutramine, phenolphthalein
Ultimate Boost	Weight loss	Phenolphthalein
Xcel Advanced	Weight loss	Phenolphthalein
Diablos Eca Fire Caps	Weight loss	Sibutramine, deisobutylbenzylsibutramine, sildenafil, phenolphthalein
Natural Max Slimming	Weight loss	Sibutramine, sildenafil, fluoxetine
Lean Body Extreme	Weight loss	Sibutramine, desmethyl sibutramine, phenolphthalein, sildenafil

*Recalled

New Product Shortages Reported by the FDA:	***Date Initially Posted***
Fomepizole injection	3/18/15

In March, the FDA announced availability of its first mobile application that can be used to identify current drug shortages, resolved shortages, and discontinuations of drug products, and to report a suspected drug shortage or supply issue. The app is available for free download via iTunes and the Google Play store.

Product Discontinuations/Withdrawals	***Date Posted***
PEGINTRON (peginterferon alfa-2b) REDIPEN	3/18/2015

New Drug Approvals:	***Description***	***Date Approved***
Filgrastim-sndz / Zarxio / Sandoz	Biosimilar to filgrastim (Neupogen, Amgen)	3/6/15
Isavuconazonium sulfate / Cresemba / Astellas	See attached drug summary	3/6/15
Dinutuximab / Unituxin / United Therapeutics	See attached drug summary	3/10/15
Cholic acid / Cholbam / Asklepion Pharmaceuticals	See attached drug summary	3/17/15
Anthrax Immune Globulin Intravenous (human) / Anthrasil / Cangene	IVIG for treatment of inhalational anthrax in combination with antibacterial agents; will be stored in the U.S. Strategic National Stockpile for use in an anthrax emergency	3/25/15

New Indications:	***Description***	***Date Approved***
Nivolumab / Opdivo / Bristol-Myers Squibb	Metastatic squamous non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy	3/4/15
Asenapine / Saphris / Actavis	Acute treatment of manic or mixed episodes of bipolar I disorder in patients 10-17 years of age	3/12/15
Ivacaftor / Kalydeco / Vertex	Use in children ages 2 to 5 with cystic fibrosis and one of 10 mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene (G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, and R117H)	3/18/15
Budesonide nasal spray / Rhinocort Allergy Spray / AstraZeneca	Over-the-counter use for upper respiratory allergies in adults and children 6 years and older	3/23/15
Aflibercept injection / Eylea / Regeneron Pharmaceuticals	Diabetic retinopathy in patients with diabetic macular edema	3/25/15

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Levetiracetam extended-release tablets / Elepsia SR / Sun Pharmaceutical	Adjunctive therapy in the treatment of partial onset seizures in patients 12 years and older	3/2/15
Albuterol sulfate inhalation powder / ProAir RespiClick / Teva	Breath-actuated dry-powder albuterol inhaler for prevention of bronchospasm in patients 12 years and older with asthma and for prevention of exercise-induced bronchospasm in patients 12 years and older	3/5/15
Deferasirox tablets / Jadenu / Novartis	New once-daily oral tablet formulation for treatment of chronic iron overload	3/30/15

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Isavuconazonium sulfate / Cresemba / Astellas Pharma	
Generic Name / Brand Name / Company	Isavuconazonium sulfate / Cresemba / Astellas Pharma
Date of approval	March 6, 2015
Drug Class (Mechanism of Action if novel agent)	Azole antifungal
Indication	Treatment of invasive aspergillosis & invasive mucormycosis in adults
Comparative agent – Therapeutic interchange?	Posaconazole, voriconazole
Dosage forms/strengths. Common Dose/sig	Capsules: 186 mg (equivalent to 100 mg of isavuconazole) Injection: single-dose vials containing 372 mg (equivalent to 200 mg of isavuconazole) Injection dose: Loading dose 372 mg IV every 8 hours for 6 doses (48 hours); maintenance dose 372 mg IV once daily Oral dose: Loading dose 372 mg (2 capsules) orally every 8 hours for 6 doses (48 hours); maintenance dose 372 mg (2 capsules) orally once daily
DEA Schedule	Not applicable
Date of market availability	Not known
Similar Medications (Look-Alike Sound-Alike)	Cymbalta, Crestor, itraconazole
CLINICAL USE EVALUATION	
Common Adverse Effects	Nausea, vomiting, diarrhea, headache, elevated liver chemistry tests, hypokalemia, constipation, dyspnea, cough, peripheral edema, back pain
Severe Adverse Effects	• Cases of severe hepatic ADRs including hepatitis, cholestasis, or hepatic failure including death have been reported in patients with serious underlying medical conditions during treatment with azole antifungal agents including isavuconazonium. • Infusion-related reactions including hypotension, dyspnea, chills, dizziness, paresthesia, and hypoesthesia. • Hypersensitivity reactions and severe skin reactions such as anaphylaxis or Stevens Johnson syndrome have been reported. • Embryo-fetal toxicity
Severe Drug-Drug Interactions	Contraindicated with strong CYP3A4 inhibitors and inducers; monitoring and dose adjustments may be necessary with lopinavir/ritonavir, atorvastatin, cyclosporine, sirolimus, tacrolimus, midazolam, bupropion, mycophenolate mofetil, digoxin
Severe Drug-Food Interactions	None known.
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	Liver-related lab tests (AST, ALT, Alkaline Phosphate, Total Bilirubin) at initiation and during therapy
Used in Pediatric Areas	Safety and efficacy not established in patients less than 18 years of age.
Renal or Hepatic Dosing	No dose adjustment is needed in patients with mild, moderate, or severe renal impairment, including those patients with End Stage Renal Disease (ESRD). No dose adjustment is necessary in patients with mild or moderate hepatic impairment (Child-Pugh Class A and B). Isavuconazonium has not been studied in patients with severe hepatic impairment (ChildPugh Class C) and should be used in these patients only when the benefits outweigh the risks.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications: co-administration with strong CYP3A4 inhibitors (such as ketoconazole or high-dose ritonavir), coadministration with strong CYP3A4 inducers (such as rifampin, carbamazepine, St John's wort, or long acting barbiturates), use in patients with familial short QT syndrome, hypersensitivity to isavuconazole. Warnings: See Severe Adverse Effects

Special administration technique or considerations	Compatible diluents: 0.9% sodium chloride injection, 5% dextrose injection Intravenous administration instructions: • Intravenous formulation must be administered via an infusion set with an in-line filter (pore size 0.2 to 1.2 micron). • Infuse the intravenous formulation over a minimum of 1 hour in 250 mL of a compatible diluent, to reduce the risk for infusion-related reactions. Do not administer as an intravenous bolus injection. • Do not infuse with other intravenous medications. • Flush intravenous lines with 0.9% sodium chloride injection, USP or 5% dextrose injection, USP prior to and after infusion. • After dilution of the intravenous formulation, avoid unnecessary vibration or vigorous shaking of the solution. Do not use a pneumatic transport system. Dilution and Preparation instructions for injection formulations: • Remove 5 mL of the reconstituted solution from the vial and add it to an infusion bag containing 250 mL (approximately 1.5 mg isavuconazonium sulfate per mL) of compatible diluent. The diluted solution may show visible translucent to white particulates of isavuconazole (which will be removed by in-line filtration). • Use gentle mixing or roll bag to minimize the formation of particulates. Avoid unnecessary vibration or vigorous shaking of the solution. • Apply in-line filter with a microporous membrane pore size of 0.2 to 1.2 micron and in-line filter reminder sticker to the infusion bag. • Do not use a pneumatic transport system. • The intravenous administration should be completed within 6 hours of dilution at room temperature. If this is not possible, immediately refrigerate (2° to 8°C / 36° to 46°F) the infusion solution after dilution and complete the infusion within 24 hours. Do not freeze the infusion solution. Oral capsules can be taken with or without food. Capsules should be swallowed whole, not chewed, crushed, dissolved or opened.
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Dinutuximab / Unituxin / United Therapeutics Corporation	
Generic Name / Brand Name / Company	Dinutuximab / Unituxin / United Therapeutics Corporation
Date of approval	March 10, 2015
Drug Class (Mechanism of Action if novel agent)	GD2-binding monoclonal antibody
Indication	Used in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13-cis-retinoic acid (RA) for the treatment of pediatric patients with high-risk neuroblastoma who achieve at least a partial response to prior first-line multiagent, multimodality therapy.
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths. Common Dose/sig	Injection: 17.5 mg/5 mL (3.5 mg/mL) in a single-use vial Dose: 17.5 mg/m^2/day as a diluted intravenous infusion over 10 to 20 hours for 4 consecutive days for up to 5 cycles.
DEA Schedule	Not applicable
Date of market availability	Not known
Similar Medications (Look-Alike Sound-Alike)	Cetuximab, rituximab

CLINICAL USE EVALUATION	
Common Adverse Effects	(all ≥25%) Severe pain, fever, low platelet counts, infusion reactions, low blood pressure, hyponatremia, elevated liver enzymes, anemia, vomiting, diarrhea, hypokalemia, capillary leak syndrome, neutropenia, lymphopenia, urticaria, hypocalcemia
Severe Adverse Effects	Bone marrow suppression and infections, infusion reactions, hypokalemia, hypotension, pain, fever, capillary leak syndrome, neuropathy
Severe Drug-Drug Interactions	No drug-drug interaction studies have been conducted with dinutuximab.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	CBC with differential, arterial blood gas test, liver enzyme tests, serum creatinine/creatinine clearance, electrolytes
Used in Pediatric Areas	The safety and effectiveness have been established in pediatric patients.
Renal or Hepatic Dosing	Has not been studied in patients with renal or hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	• Contraindicated in patients with a history of anaphylaxis to dinutuximab • Black box warning for serious infusion reactions and neuropathy. • Life-threatening infusion reactions have occurred: administer required prehydration and premedication. Immediately interrupt for severe infusion reactions and permanently discontinue for anaphylaxis. • Causes severe neuropathic pain: administer intravenous opioid prior to, during, and for 2 hours following completion of the dinutuximab infusion. Discontinue for severe unresponsive pain, severe sensory neuropathy, or moderate to severe peripheral motor neuropathy. • Capillary leak syndrome and hypotension: administer required prehydration and monitor patients. Manage by interruption, infusion rate reduction, or permanent discontinuation. • Infection: Interrupt until resolution of systemic infection. • Neurological disorders of the eye: interrupt for dilated pupil with sluggish light reflex or other visual disturbances and permanently discontinue for recurrent eye disorders or loss of vision. • Bone marrow suppression: Monitor peripheral blood counts. • Electrolyte abnormalities: Monitor serum electrolytes. • Atypical hemolytic uremic syndrome: Permanently discontinue therapy and institute supportive management. • Embryo-Fetal toxicity: May cause fetal harm. Advise females of potential risk to fetus and to use effective contraception.
Special administration technique or considerations	• Hydration: administer 0.9% Sodium Chloride Injection USP 10 mL/kg as IV infusion over 1 hour just prior to initiating dinutuximab infusion. • Analgesics: administer morphine sulfate 50 mcg/kg IV immediate prior to initiation of dinutuximab infusion, and then continue morphine sulfate drip at infusion rate of 20 to 50 mcg/kg/hour during and for 2 hours following completion of dinutuximab infusion. Additional doses may be administered as needed. • Antihistamines and antipyretics: administer an antihistamine, such as diphenhydramine IV over 10-15 minutes starting 20 minutes prior to initiation of dinutuximab infusion and as tolerated every 4 to 6 hours during the infusion. • Administer acetaminophen 20 minutes prior to dinutuximab infusion and every 4 to 6 hours as needed for fever or pain. Administer ibuprofen every 6 hours as needed for control of persistent fever or pain. • Dinutuximab should be diluted into a 100 mL bag of 0.9% Sodium Chloride Injection USP and mixed by gentle inversion. Do not shake.

	• Administer as diluted IV infusion only. Do not administer as an IV push or bolus.
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Cholic acid / Cholbam / Asklepion Pharmaceuticals	
Generic Name / Brand Name / Company	Cholic acid / Cholbam / Asklepion Pharmaceuticals
Date of approval	March 17, 2015
Drug Class (Mechanism of Action if novel agent)	Bile acid replacement
Indication	Treatment of bile acid synthesis disorders due to single enzyme defects and peroxisomal disorders (including Zellweger spectrum disorders) in both pediatric and adult patients
Comparative agent – Therapeutic interchange?	Not applicable; first-in-class
Dosage forms/strengths. Common Dose/sig	Capsules: 50 mg, 250 mg Patients aged 1 month and older and adults: 10 to 15 mg/kg once daily or in two divided doses. Patients with concomitant familial hypertriglyceridemia: 11 to 17 mg/kg once daily or in two divided doses.
DEA Schedule	Not applicable
Date of market availability	Not known
Similar Medications (Look-Alike Sound-Alike)	Cholestyramine, cholecalciferol
CLINICAL USE EVALUATION	
Common Adverse Effects (≤2%)	Diarrhea, reflux esophagitis, malaise, jaundice, abdominal pain, nausea, intestinal polyp, urinary tract infection, peripheral neuropathy, skin lesion
Severe Adverse Effects	Exacerbation of liver impairment
Severe Drug-Drug Interactions	Avoid concomitant use with bile salt efflux pump inhibitors (eg, cyclosporine) if possible. Separate administration from bile acid resins and aluminum-based antacids.
Severe Drug-Food Interactions	None known.
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	Monitor AST, ALT, GGT, alkaline phosphatase, bilirubin, and INR every month for 3 months, every 3 months for the next 9 months, every 6 months for the next 3 years, and annually thereafter. Increase monitoring frequency during periods of rapid growth, concomitant disease, or pregnancy.
Used in Pediatric Areas	Safety and effectiveness established in patients 3 weeks of age and older
Renal or Hepatic Dosing	Discontinue treatment with cholic acid if liver function does not improve within 3 months of the start of treatment. No data in renal impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	• Exacerbation of liver impairment
Special administration technique or considerations	• Take with food. • Take at least one hour before or 4 to 6 hours after taking a bile acid binding resin or an aluminum-based antacid. • Do not crush or chew the capsules; capsules can be opened and the contents mixed with infant formula, expressed breast milk, or a soft food.
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