

Highlights of FDA Activities – 1/1/16 – 1/31/16

FDA Drug Safety Communications & Drug Information Updates:

Drug Safety Communication: Label Changes Approved for Noxafil (posaconazole) Oral Formulations 1/4/16

Noxafil (posaconazole) is available as a delayed release tablet and an oral suspension. Interchange of the two oral formulations requires dose adjustments, because they are not equivalent. Merck has updated the outside of the carton and the information for prescribers and patients in the drug label to make it clear that the two formulations are not interchangeable. Prescribers and pharmacists must communicate clearly about the dosage form, strength, and frequency of Noxafil.

Major Product Recalls Announced Through MedWatch:

Baxter IV Solutions: Recall - Due to Potential Presence of Particulate Matter 1/4/16

Baxter International Inc. recalled two lots of IV solutions at the hospital/end-user level in response to a customer complaint of particulate matter. The particulate matter in each case was an insect. The recalled products are 0.9% Sodium Chloride Injection USP 250 mL Viaflex (NDC 0338-0049-02; lot C980227, exp. 11/30/16) and 70% Dextrose Injection USP 2000 mL (NDC 0338-0719-06; lot C985150, exp. 7/31/16).

Hospira Magnesium Sulfate in Water for Injection: Recall - Due to Incorrect Barcode Labeling on the Primary Container 1/5/16

Hospira Inc. recalled one lot of Magnesium Sulfate in Water for Injection (0.325 mEq Mg⁺⁺/mL) 40 mg/mL, 2 g total, 50 mL (NDC: 0409-6729-24, Lot 53-113-JT, Expiry 1NOV2016) for an incorrect barcode on the primary labeling. The product has a barcode identifying the product on both the overwrap and the primary container. The barcode on the overwrap is correct, but the barcode on the primary container could possibly be mislabeled with the barcode for Heparin Sodium 2000 USP Units/1000 mL in 0.9% Sodium Chloride Injection.

Children's Guaifenesin Grape Liquid and Guaifenesin DM Cherry Liquid by Perrigo Company: Recall – Potential Defect with Dosage cup 1/13/16

Perrigo Company recalled 2 batches of its children's guaifenesin grape liquid (100 mg/5 mL) and 3 batches children's guaifenesin DM cherry liquid (100 mg guaifenesin-5 mg dextromethorphan/5 mL) solid in 4 ounce bottles. Some packages contain an oral dosing cup with incorrect dosing markings and may deliver an incorrect and potentially harmful dose of dextromethorphan. The recall has been initiated at the retail level and involves many store brands, including Sunmark, Rite-Aid, Topcare, Kroger, GoodSense, Dollar General, Care One, and CVS.

All Lots of Unexpired Sterile Human and Animal Compounded Products from Abbott's Compounding Pharmacy: Recall – Lack of Sterility Assurance 1/19/16

Due to a lack of sterility assurance, Abbott has issued a voluntary recall of all sterile compounded products. All unexpired lots of human and animal compounded products are subject to the recall and include injectables, eye ointments, and eye drops distributed within California between 1/1/15 and 1/14/16.

Licorice Coughing Liquid OTC Cough Syrup by Master Herbs, Inc.: Recall – Contains Morphine 1/21/16

Master Herbs, Inc. recalled Licorice Coughing Liquid due to the presence of morphine that is not identified on the labeling. This is a nationwide recall of the 100 mL bottles distributed to Chinese grocery stores in various cities in California, New Jersey, Hawaii, Illinois, Ohio, and Nevada, and also sold online.

Baxter IV Solutions: Recall - Due to the Potential for Leaking Containers and Particulate Matter 1/26/16

Baxter International Inc recalled four lots of IV solutions to the hospital/user level due to the potential for leaking containers and particulate matter. The company was made aware of the problems due to two complaints of leaking containers and one complaint each for three lots due to particulate matter. Solutions affected by this recall are 0.9% Sodium Chloride Injection, USP, 100 mL Mini-Bag Plus Container (NDC 0338-0553-18, lots P337857 & P328997); Metronidazole Injection, USP, 500 mg/100 mL (NDC 0338-1055-48, lot P339135); and Clinimix E 5/15 (5% AA w/ Electrolytes in 15% Dextrose w/ Calcium; NDC 0338-1123-04; lot P333930).

SPOTCHEM II Test Strips by Arkray: Recall – Inaccurate Blood Sugar Readings 1/28/16

Arkray recalled the SPOTCHEM II Basic PANEL-1 Reagent Test Strip and the SPOTCHEM II Glucose Reagent Test Strip because they may report falsely low blood glucose levels. Since the test strips are reporting falsely low blood glucose levels, there is a risk that health care practitioners may not diagnose hyperglycemia in a timely manner. The recall affects lot numbers PN5C26 and EA4M78 and involves a total of 99 boxes distributed to 8 states between February 18, 2015 and October 13, 2015.

Dietary Supplement Recalls & Public Notifications

In January, 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.

<u>Product</u>	<u>Promoted Use</u>	<u>Hidden/Undeclared Drug Ingredient(s)</u>
African Black Ant*#	Sexual Enhancement	Sildenafil
Black Ant*#	Sexual Enhancement	Sildenafil
Herb Viagra*#	Sexual Enhancement	Sildenafil
Real Skill*#	Sexual Enhancement	Sildenafil
Stree Overlord*#	Sexual Enhancement	Sildenafil
Weekend Prince*#	Sexual Enhancement	Sildenafil
Wonder-Erect Male Gum	Sexual Enhancement	Vardenafil
Wonder-Erect Male Pills	Sexual Enhancement	Vardenafil
Lucy's Weight Loss System Pink Bikini Capsules*	Weight Loss	Sibutramine, Phenolphthalein, and/or Diclofenac
Lucy Weight Loss System Shorts on the Beach Capsules*	Weight Loss	Sibutramine, Phenolphthalein, and/or Diclofenac
Bentonite Me Baby by Alikay Naturals	Medicinal Clay	Lead
Crema Piel De Seda by Viansilk	Skin Whitening Cream	Mercury

*Recalled; # the supplier of these products (R. Thomas Marketing LLC) is also recalling the following products sourced from the same manufacturer due to the possibility they may also be misbranded: Bull, Bulls Genital, Zonghua Niu Bian, African Superman, Bigger Longer More Time More Sperms, Black Ant King, Black Storm, Germany Niubian, Happy Passengers, Plant Vigra, Hard Ten Days, Man King, Mojo Risen, Night Man, Tiger King, Samurai-X, Super Hard, and Zhen Gong.

New Product Shortages Reported by the FDA:

	<u>Date Initially Posted</u>
Anagrelide hydrochloride capsules for oral administration (0.5 mg and 1 mg capsules)	1/6/16
Desmopressin acetate for injection (4 mcg/mL, 1 mL and 10 mL vials)	1/11/16

Product Discontinuations/Withdrawals

	<u>Date Posted</u>
Pancrelipase delayed-release capsules (Ultresa, Forest Laboratories, Inc.) Patients will need to be switched to another pancrelipase delayed-release product	1/5/16

New Drug Approvals:

	<u>Description</u>	<u>Date Approved</u>
Elbasvir-Grazoprevir / Zepatier / Merck	See attached drug summary	1/29/16

New Indications:

	<u>Description</u>	<u>Date Approved</u>
Eribulin / Halaven / Eisai	Unresectable or metastatic liposarcoma in patients who have received a prior anthracycline-containing regimen.	1/28/16
Ofatumumab / Arzerra / Novartis	Extended treatment of recurrent or progressive chronic lymphocytic leukemia in patients with partial or complete response after > 2 lines of therapy	1/19/16
OnabotulinumtoxinA / Botox / Allergan	Treatment of lower limb spasticity in adult patients	1/21/16
Secukinumab / Cosentyx / Novartis	Psoriatic arthritis and ankylosing spondylitis	1/15/16

New Dosage Forms or Formulation:

	<u>Description</u>	<u>Date Approved</u>
Acetylcysteine effervescent tablets / Cetylev / Arbor Pharmaceuticals	Effervescent tablets for oral solution, for acetaminophen overdose	1/29/16
Amphetamine extended-release orally disintegrating tablet / Adzenys XR-ODT / Neos Therap	Available in 3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg, and 18.8 mg strengths; for treatment of attention deficit hyperactivity disorder in patients 6 years and older	1/28/16
Dexlansoprazole delayed-release orally disintegrating tablet 30 mg / Dexilant Solutab / Takeda	Contains enteric-coated microgranules; not interchangeable with Dexilant capsules	1/26/16
Sumatriptan injection 3 mg/0.5 mL / Zembrace Symtouch / Dr Reddys Labs	Sumatriptan subcutaneous autoinjector for the acute treatment of migraine	1/28/16
Sumatriptan nasal powder 11 mg / Onzetra Xsail / Avanir	Sumatriptan breath-powered nasal delivery system for acute treatment of migraine	1/27/16

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Elbasvir and grazoprevir / Zepatier / Merck	
Generic Name / Brand Name / Company	Elbasvir and grazoprevir / Zepatier / Merck
Date of approval	1/28/16
Drug Class (Mechanism of Action if novel agent)	NS5A inhibitor/protease inhibitor combination (Anti-HCV)
Indication	<ul style="list-style-type: none"> • Treatment of chronic hepatitis C genotypes 1 or 4 infections in adults • May be used with or without ribavirin
Comparative agent – Therapeutic interchange?	Ledipasvir/sofosbuvir (Harvoni), ombitasvir/paritaprevir/ritonavir with dasabuvir (Viekira Pak) – not interchangeable
Dosage forms/strengths. Common Dose/sig	Tablets – 50 mg elbasvir/100 mg grazoprevir <ul style="list-style-type: none"> • Taken as one tablet daily with or without food for 12 weeks • May be used with ribavirin in certain populations for 16 weeks
DEA Schedule	Not scheduled
Date of market availability	2/4/16
Similar Medications (Look-Alike Sound-Alike) that Increase Potential for Error. Tallman lettering?	None
CLINICAL USE EVALUATION	
Common Adverse Effects	Fatigue, headache, nausea, insomnia, and diarrhea
Severe Adverse Effects	Anemia (in combination with ribavirin)
Severe Drug-Drug Interactions	<ul style="list-style-type: none"> • OATP1B1/3 inhibitors – may cause significant increases in serum grazoprevir levels • CYP3A4 inducers – may decrease plasma concentrations of elbasvir and grazoprevir • CYP3A4 inhibitors – may increase plasma concentrations of elbasvir and grazoprevir • List of specific contraindications and potential drug interactions provided in prescribing information
Severe Drug-Food Interactions	None listed
Important Labs Values to assess prior to order entry or at point of clinical follow up. (Need Pop Up?)	<ul style="list-style-type: none"> • Testing for NS5A resistance recommended prior to treatment. • May increase ALT levels – hepatic testing recommended a baseline, at treatment week 8, and as clinically indicated. • If taken with ribavirin, perform additional hepatic testing at week 12.
Used in Pediatric Areas	No data for patients below 18 years of age
Renal or Hepatic Dosing	<ul style="list-style-type: none"> • No adjustments needed for mild hepatic impairment; contraindicated in moderate or severe hepatic impairment • No adjustments needed for renal impairment
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	<ul style="list-style-type: none"> • Contraindicated in patients with moderate (Child-Pugh B) hepatic impairment due to lack of safety data • Contraindicated in patients with severe (Child-Pugh C) hepatic impairment due to 12-fold increase of grazoprevir exposure • Contraindicated with OATP1B1/3 inhibitors, strong YCP3A inducers and efavirenz • Contraindications for ribavirin apply if given in combination • Consider discontinuing therapy if ALT is persistently > 10 ULN or accompanied by signs/symptoms of liver inflammation or increasing conjugated bilirubin, alkaline phosphatase, or INR.
Special administration technique or considerations	None
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