Highlights of FDA Activities – 1/1/2017 – 1/31/2017

FDA Drug Safety Communications & Drug Information Updates:

Implantable Cardiac Devices and Merlin@home Transmitter by St. Jude Medical: Cybersecurity Vulnerabilities Identified 1/9/17

FDA has confirmed cybersecurity vulnerabilities associated with St. Jude Medical's Merlin@home Transmitter that if exploited, could allow an unauthorized user to remotely access and alter the implanted cardiac device. Patients should be reminded to keep their Merlin@home Transmitter connected, as this will ensure the device receives necessary patches and updates to reduce the risk of cybersecurity vulnerabilities.

Cancer Patients Warned Not to Use PNC-27 for Treatment 1/10/17

The FDA warned consumers not to purchase or use PNC-27 promoted and sold online as a treatment or cure for cancer. A FDA lab discovered the bacteria *Variovorax paradoxus* in a sample from the PNC-27 solution. No form of PNC-27 has been evaluated or approved by the FDA.

Implantable Infusion Pumps in Magnetic Resonance (MR) Environments 1/11/17

The FDA warned that inaccurate medication dosing and other mechanical problems have been reported with implantable infusion pumps when in a magnetic resonance environment. These malfunctions can lead to serious adverse events, injuries and potentially death. Only patients with implantable infusion pumps labeled as MR conditional may be used in an MR environment and only under specific conditions.

Drug Information Update: FDA Guidance for "Nonproprietary Naming of Biological Products" 1/12/17

The FDA issued a final guidance for manufacturers for the naming of nonproprietary biologics or biosimilars. Under the new naming convention, the FDA will designate a distinguishing suffix that is devoid of meaning and composed of 4 lowercase letters that will be attached to the products core name with a hyphen.

Lifepak 1000 Defibrillators by Physio-Control: Immediately Remove and Reinstall Battery 1/16/17

Physio-Control is launching a voluntary field action for the LIFEPAK 1000 defibrillator due to reported instances where the device has shut down unexpectedly during patient treatment. The company is contacting customers, and customers are advised to implement a weekly schedule of battery removal and reinstallation for all devices.

Certain Homeopathic Teething Products: FDA Warning - Confirmed Elevated Levels of Belladonna 1/27/17

FDA labs confirmed the presence of belladonna in Hyland's homeopathic teething tablets that "far" exceed the amount claimed on the label. The manufacturer, Standard Homeopathic Company, has not agreed to conduct a recall, but the FDA recommends that consumers immediately stop using Hyland's homeopathic teething products, and dispose of any in their possession.

Major Product Recalls Announced Through MedWatch:

Nurse Assist Inc. Normal Saline Flush IV Syringe: Class I Recall - due to possible *Burkholderia cepacia* Bloodstream Infections 1/3/17

The FDA updated this Class I recall, due to *Burkholderia cepacia* contamination. The recall includes all 12 mL IV Flush Syringes with a 3 mL, 5 mL, or 10 mL fill volume with products codes 1203, 1205, 1210, and 1210-BP.

Medrad Intego PET Infusion System Source Administration Sets by Bayer: Recall - Particulates Generated in Vial 1/11/17

Bayer determined that particulate matter may be produced in all medication vials when the Source Administration Sets are used with the Medrad Intego PET infusion system. The tip of the needle pushing through the rubber top of the vial produces the particulate matter. The Source Administration Sets may be returned or quarantined for use when a qualified in-line filter is received.

Vancomycin Hydrochloride for Injection, USP by Hospira: Recall Particulate Matter in Vial 1/24/17
Hospira, Inc recalled one lot of vancomycin hydrochloride vials at the hospital/retail level (NDC 0409-6510-01, Lot 591053A, , Exp.1NOV2017), due to the presence of particulate matter found in a vial by a customer.

NucliSENS easyMAG Magnetic Silica and NucliSENS Magnetic Extraction Reagents by bioMerieux: Recall- Potential Inaccurate Test Results 1/27/17
BioMerieux will be expanding its initial recall due to quality problems with the NucliSENS Magnetic Reagents and accessory products. Quality problem of the magnetic silica can lead to potential inaccurate test results. More information on this recall can be found on the MedWatch page.

Dietary Supplement Recalls & Public Notifications

In January, the FDA issued notifications to the public regarding undeclared active ingredients in the following product. Patients are advised not to purchase or use this product.

Product	*Promoted Use*	*Hidden/Undeclared Drug Ingredient(s)*
XtraHRD	Sexual enhancement	N-desmethyl tadalafil[1]

[1] Tadalafil taken unknowingly with nitrates may lower blood pressure to dangerously low levels

New Product Shortages Reported by the FDA:	*Date Initially Posted*
Panretin® (alitretinoin) gel tubes: NDC (62856-601-22)	1/17/17
Nitrous Oxide Gas (Nitrous Oxide Corporation): (NDC 54260-0001-01)	1/18/17

Product Discontinuations/Withdrawals	*Date Posted*
Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets (Impax Laboratories): Impax Laboratories discontinued manufacturing the following tablets: 5mg (NDC 64720-0130-10), 7.5mg (NDC 64720-0131-10), 10mg (NDC 64720-0132-10), 12.5mg (NDC 64720-0133-10), 15mg (NDC 64720-0134-10), 20mg (NDC 64720-0135-10), 30mg (NDC 64720-0136-10); product remains available from other manufacturers	1/5/17
Synthetic Conjugated Estrogen B tablets (Enjuvia, Teva Pharmaceuticals): Teva Pharmaceuticals discontinued the manufacturing of all Enjuvia tablet strengths: 0.45mg (NDC 1285-0407-02), 0.625mg (NDC 51285-0408-02), 0.9mg (NDC 5128-50409-02), 1.25mg (NDC 51285-0410-02), 0.3mg (NDC 51285-0406-02); no synthetic conjugated estrogen product remains on the market	1/24/17
Acetaminophen and Codeine Phosphate Oral Suspension USP (Capital and Codeine, Valeant Pharmaceuticals North America LLC): Valeant Pharmaceuticals discontinued acetaminophen and codeine phosphate oral suspension 16 oz bottles (NDC 0187-0003-01); acetaminophen and codeine phosphate solution remains available from other manufacturers	1/27/17
Aminohippurate Sodium "PAH" (Merck Sharp &Dohme Corp): Merck Sharp & Dohme have discontinued the manufacturing of aminohippurate sodium injection; no other aminohippurate products are available	1/31/17

New Drug Approvals:	*Description*	*Date Approved*
Plecanatide / Trulance / Synergy	See attached drug summary	1/19/17

New Indications:	***Description***	***Date Approved***
Ranibizumab injection / Lucentis / Genentech	Treatment of myopic choroidal neovascularization	1/6/17
Asenapine sublingual tablets / Saphris / Allergan	Maintenance monotherapy treatment in adults with bipolar I disorder	1/13/17
Ibrutinib / Imbruvica / Pharmacyclics	Treatment for patients who require systemic therapy with marginal zone lymphoma following at least one prior anti-CD20-based therapy	1/19/17
Budesonide and formoterol fumarate dihydrate / Symbicort / AstraZeneca	Long-term maintenance treatment of asthma in children 6 years of age and older	1/27/17
Thiotepa for injection / Tepadina / Adienne SA	To reduce the risk of graft rejection when used in a preparative regimen for stem cell transplantation for pediatric patients with class 3 beta-thalassemia	1/26/17
Levocetirizine dihydrochloride / Xyzal Allery 24HR / sanofi-aventis U.S.	Over-the-counter availability for the treatment of symptoms associated with allergic rhinitis	1/31/17

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Morphine sulfate extended-release tablets / Arymo / Egalet	Abuse-deterrent formulation of morphine for pain severe enough to require daily, around-the-clock, long-treatment for which other options are inadequate	1/9/17
Pirfenidone Film-coated Tablets / Esbriet / Genetech Inc	New 267 mg, 534 mg, and 801 mg film-coated tablets for the treatment of Idiopathic Pulmonary Fibrosis	1/11/17
Hydrocodone bitartrate extended-release / Vantrela ER / Teva	Abuse-deterrent formulation of hydrocodone for pain severe enough to require daily, around-the-clock, long-term treatment for which other options are inadequate	1/18/17
Oxymetazoline 1% cream / Rhofade / Allergan Inc	Topical formulation for treating redness associated with rosacea	1/18/17
Linaclotide / Linzess / Forest	New lower dose 72 mcg capsule for treatment of chronic idiopathic constipation	1/25/17
Fluticasone propionate inhalation powder / ArmonAir RespiClick / Teva	Maintenance treatment of asthma as prophylactic therapy in patients aged 12 years and older	1/27/17
Fluticasone propionate and salmeterol inhalation powder / AirDue RespiClick / Teva	Treatment of asthma in patients 12 years and older	1/27/17
Lisdexamfetamine dimesylate chewable tablets / Vyvanse / Shire	10, 20, 30, 40, 50 and 60 mg chewable tablets	1/28/17

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Plecanatide / Trulance™ / Synergy Pharmaceuticals Inc.	
Generic Name / Brand Name / Company	Plecanatide / Trulance / Synergy Pharmaceuticals Inc.
Date of approval	January 19, 2017
Drug Class (Mechanism of Action if novel agent)	Guanylate cyclase-C agonist, acting locally in the intestines to increase fluid secretion and intestinal transit
Indication	For treatment of chronic idiopathic constipation in adults
Comparative agent – Therapeutic interchange?	Linaclotide (Linzess®)
Dosage forms/strengths. Common Dose/sig	Tablet: 3 mg, Take 3 mg once daily
DEA Schedule	Not scheduled
Date of market availability	1st Quarter 2017
Similar Medications (Look-Alike Sound-Alike)	Trulicity®, linaclotide
Clinical Use Evaluation	
Common Adverse Effects	Diarrhea (5%), abdominal distension, flatulence, abdominal tenderness,
Severe Adverse Effects	Severe diarrhea, potential increase in liver tests (ALT and AST)
Severe Drug-Drug Interactions	None reported
Severe Drug-Food Interactions	None reported
Important Labs Values to assess prior to order entry or at point of clinical follow up.	No laboratory monitoring required
Used in Pediatric Areas	Safety/efficacy has not been established in patients < 18 years of age
Renal or Hepatic Dosing	None
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients less than 6 years of age, and avoid use in patients less than 18 years of age due to risk of developing severe diarrhea and dehydration. Also contraindicated in setting of suspected GI obstruction.
Special administration technique or considerations	Can be taken with or without food. Can be crushed and administered in applesauce or water. If dose is missed, skip missed dose and take at next regular time.
Prepared by	Tori DeMyer and Courtney Mayo, Pharm.D. students, class of 2017
Source	Plecanatide (Trulance) prescribing information. New York, NY: Synergy Pharmaceuticals Inc; 2017