College of Pharmacy and Pharmaceutical Sciences
WASHINGTON STATE UNIVERSITY

Drug Information Center

Highlights of FDA Activities – 01/1/19 – 01/31/19

FDA Drug Safety Communications & Drug Information Updates:

Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program Modifications 1/17/19

The FDA approved a modification to the clozapine REMS program with requirements to take effect on February 28, 2019. Health care professionals prescribing clozapine and pharmacies dispensing clozapine will need to be certified in the clozapine REMS program by that date in order to continue prescribing/dispensing clozapine. Pharmacies are no longer allowed to enroll patients after February 28 since enrollment will need to be completed by the prescriber or prescriber designee. Inpatient prescribers are not required to be certified if they are prescribing for patients already enrolled in the program. If a patient's absolute neutrophil count (ANC) measurement is not current, clozapine will not be able to be dispensed.

Major Medication/Drug-Related Product Recalls Announced Through MedWatch:

Losartan Potassium Tablets, USP and Losartan Potassium and Hydrochlorothiazide Tablets, USP from Torrent Pharmaceuticals Limited – Recall: Contaminant 1/4/19 & 1/22/19

During January Torrent Pharmaceuticals Limited twice expanded the recall of losartan products due to trace amounts of the probable human carcinogen N-nitrosodiethylamine (NDEA) detected in the active pharmaceutical ingredient manufactured by Hetero Labs Limited. The recall was expanded to include 8 additional lots of losartan potassium tablets for a total of 10 lots and 6 lots of losartan potassium and hydrochlorothiazide tablets, USP. Torrent recalled only those lots of losartan containing products that contain NDEA above the acceptable daily intake levels released by the FDA. Additional information on the Torrent products recalled can be found on the FDA site, as well as an updated list of losartan medications under recall, and an FDA update on angiotensin II receptor blocker (ARB) recalls.

Ceftriaxone for Injection USP from Lupin Pharmaceuticals, Inc. – Recall: Particulate Matter 1/5/19

Lupin Pharmaceuticals, Inc. recalled Ceftriaxone for injection, USP 250 mg (5 lots), 500 mg (10 lots), 1 g (24 lots) and 2 g (3 lots) due to the presence of a visual grey rubber particulate matter from the stopper in reconstituted vials. A completed list of recalled lots can be found on the FDA site.

Vecuronium Bromide for Injection from Sun Pharmaceutical Industries, Inc. – Recall: Particulate Matter 1/8/19

Sun Pharmaceutical Industries, Inc. recalled 3 lots of Vecuronium Bromide for Injection 10 mg (lyophilized powder) (lots JKS0443A, JKS0444A, JKS0477A), and 1 lot of Vecuronium Bromide for Injection 20 mg (lyophilized powder) (lot JKS0400A) due to the presence of a particulate matter identified as glass.

Irbesartan and Irbesartan HCTZ Tablets from Prinston Pharmaceutical Inc. – Recall: Contaminant 1/18/19

Prinston Pharmaceutical Inc., as Solco Healthcare LLC., recalled of 1 lot of Irbesartan and 7 lots of Irbesartan HCTZ Tablets due to the detection of trace amounts of NDEA in the active pharmaceutical ingredient manufactured by Zhejiang Huahai Pharmaceuticals. Prinston is only recalling lots of Irbesartan-containing products that contain NDEA above the acceptable daily intake levels released by the FDA. The specific lot numbers can be found on the FDA site as can an FDA update on angiotensin II receptor blocker (ARB) recalls.

Ibuprofen Oral Suspension Drops from Tris Pharma, Inc – Recall: Higher Ibuprofen Concentrations 1/29/19

Tris Pharma, Inc. expanded the scope of its November 2018 recall by adding 3 additional lots of Ibuprofen Oral Suspension Drops, USP, 50 mg per 1.25 mL, to the retail level. Some units from these batches have been found to have levels of Ibuprofen concentration than labeled. A complete list of recalled products can be found on the FDA site. Recalled products are marketed under the CVS Health, Equate, and Family Wellness brands.

Dietary Supplement Recalls & Public Notifications

Notifications were issued regarding undeclared active ingredients or contaminants in the following products. Patients are advised not to purchase or use these products.

Product	***Promoted Use***	***Undeclared Ingredient(s) or Contaminants***
1 Day Diet	Weight loss	Sibutramine[1], N-desmethylsibutramine
Black King Kong	Sexual enhancement	Moroxydine[2], sildenafil[3]
GoLean Detox	Weight loss	Sibutramine[1], phenolphthalein[4]
Golden Ant	Sexual enhancement	Sildenafil[3]
Instinct Best Sexual Enjoyment	Sexual enhancement	Sildenafil[3]
Natural V=GRA	Sexual enhancement	Sildenafil, tadalafil[3]
Nectar Del Amor	Sexual enhancement	Sildenafil[3]
Red Stallion	Sexual enhancement	Tadalfil[3]
Rhino 5k capsules by Happy Together, Inc*	Sexual enhancement	Sildenafil, tadalafil[3]
Silver Bullet 10x*	Sexual enhancement	Sildenafil, tadalafil[3]
Slim Bio Capsules	Weight loss	Sibutramine[1], N-desmethylsibutramine, sildenafil[3], tadalafil[3], benproperine[5], diphenhydramine[6]
Slimina	Weight loss	Sibutramine[1]
Slimmer Extreme Thermogenic Formula	Weight loss	Sibutramine[1], phenolphthalein[4]
Ultra Fit	Weight loss	Sibutramine[1], N-desmethylsibutramine
Yong Gang	Sexual enhancement	Sildenafil, tadalafil[3]

*recalled

[1]Sibutramine has been associated with increased cardiovascular events; removed from market for safety reasons in 2010[FDA]; N-desmethylsibutramine is an active metabolite of sibutramine

[2]Moroxydine is an antiviral that is not FDA approved

[3]Sildenafil and tadalafil may interact with nitrates to lower blood pressure to dangerous levels

[4]Phenolphthalein was an over-the-counter laxative that is no longer marketed in the US due to carcinogenicity concerns

[5]Benproperine is a cough suppressant that is not FDA approved

[6]Diphenhydramine is a sedating antihistamine

New Product Shortages	***Date Initially Posted***
Calcitriol injection	1/2/19
Timolol maleate tablets	1/3/19
Nystatin oral suspension	1/8/19
Hydroxyprogesterone caproate injection	1/25/19

Product Discontinuations/Withdrawals	***Date Posted***
Norethindrone acetate and ethinyl estradiol plus ferrous fumarate chewable tablets (Minastrin 24Fe, Mylan); generics remain available	1/2/19
Levonorgestrel and ethinyl estradiol tablets 0.1 mg/0.02 mg (Mylan): generics remain available	1/2/19
Daclatasvir 30 mg and 60 mg tablets (Daklinza, Bristol Myers Squibb Co.); alternative treatments for hepatitis C are available	1/4/19
Norethindrone and ethinyl estradiol and ferrous fumarate tablets (Allergan); generics remain available	1/11/19
Pegademase bovine injection 250 units/mL (Adagen, Leadiant Biosciences); alternative treatment for severe combined immunodeficiency disease associated with adenosine deaminase deficiency are available	1/18/19
Emedastine difumarate 0.05% ophthalmic solution (Emadine, Novartis); other ophthalmic antihistamines are available	1/29/19
Nevirapine extended release tablets (Mylan); generics remain available	1/31/19

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
No new molecular entities were approved in January		

New Indications:	***Description***	***Date Approved***
Docetaxel Injection / Docefrez / Sun Pharmaceutical	With cisplatin and fluorouracil for untreated, advanced gastric adenocarcinoma and with cisplatin and fluorouracil for induction treatment of locally advanced squamous cell carcinoma of the head and neck	1/8/19
Tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap) vacine adsorbed / Adacel / Sanofi Pasteur	Repeat vaccination 8 or more years after the previous Tdap vaccination in patients 10-64 years old	1/11/19
Cabozantinib / Cabometyx / Exelixis Inc.	Treatment of patients with hepatocellular carcinoma who have been previously treated with sorafenib	1/14/19
Influenza vaccine / Fluzone Quadrivalent / Sanofi	Indication expanded to include children 6 to 35 months of age; 0.25 mL and 0.5 mL doses will be available for 2019-2020 influenza season	1/23/19
Ospemifene/ Osphena / Duchesnay	Vaginal dryness due to menopause	1/25/19
Epinephrine injection/ Adrenalin / Par Pharmaceutical	To increase mean arterial blood pressure in adults with hypotension associated with septic shock	1/29/19

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Trastuzumab-dttb / Ontruzant / Merck	Biosimilar to Herceptin for the treatment of HER2-overexpressing breast cancer or metastatic gastric or gastroesophageal junction adenocarcinoma	1/18/19
Sumatriptan nasal spray / Tosymra / Dr. Reddy's	Nasal spray: 10 mg. For the acute treatment of migraine as a single 10 mg dose with a maximum dose of 30 mg/24 hour period with doses separated by at least one hour	1/25/19
Colchicine oral solution / Gloperba / Romeg Therapeutics	Oral solution: 0.6 mg/5 mL. For the prophylaxis of gout flares in adults at a dose of 0.6 mg once or twice daily	1/30/19
Amphetamine sulfate orally disintegrating tablet / Evekeo ODT / Arbor Pharms	Oral disintegrating tablet: 5 mg, 10 mg, 15 mg, 20 mg. For the treatment of attention deficit hyperactivity disorder in patients 6 to 17 years of age	1/30/19

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