WASHINGTON STATE UNIVERSITY HEALTH SCIENCES

Drug Information Center
College of Pharmacy and Pharmaceutical Sciences

Highlights of FDA Activities – 7/1/18 – 7/31/18

FDA Drug Safety Communications & Drug Information Updates:

Products from Ranier's Compounding Laboratory Lack Sterility Assurance - Drug Information Update 7/10/18
The FDA advised health care professionals, patients, veterinarians, and animal owners not to use compounded human and animal drug products intended to be sterile from Ranier's Compounding Laboratory due to a lack of sterility assurance. Ranier's subsequently issued a recall 7/30/18 (see entry in recalls below).

FDA reinforces safety information about serious low blood sugar levels and mental health side effects with fluoroquinolone antibiotics; requires label changes - Drug Safety Communication 7/10/18
The FDA is requiring safety labeling changes for the fluoroquinolones antibiotics to strengthen the warnings about the risks of mental health side effects (disturbances in attention, disorientation, agitation, nervousness, memory impairment, and delirium) and serious blood sugar disturbances, and to make these warnings more consistent across the labeling for all fluoroquinolones taken by mouth or given by injection.

FDA warns of imposters sending consumers fake warning letters- Drug Information Update 7/13/18
The FDA warned consumers about criminals forging FDA warning letters to target individuals who tried to purchase medicines online or over the phone. In addition to being the target of scams like these, the FDA reminded consumers who buy medicines from illegal online pharmacies that they may be putting their health at risk. The products purchased from illegal online pharmacies, while marketed as authentic, may be counterfeit, contaminated, expired or otherwise unsafe.

Bulk Drug Substances in Drug Compounding: Drug Information Update 7/23/18
The FDA issued an alert warning of the dangers of using the bulk drug substance cesium chloride and its intent to move the product into category 2 due to its safety risks. If the FDA encounters a compounder using a product in category 2, including cesium chloride, it will take regulatory action. In addition, the FDA announced a collaboration with the University of Maryland and Johns Hopkins University to gather and analyze information to aid in developing that list of bulk drug substances that may be used in compounding. The FDA is currently updating the categories of substances in its policies on compounding with bulk drug substance. On the agenda for the Pharmacy Compounding Advisory Committee meeting on 9/12/2018 are six bulk substances that have been nominated for use in compounding (alpha lipoic acid, coenzyme Q10, creatine monohydrate, pyridoxal 5 phosphate, choline chloride, and quercetin dihydrate).

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

Neostigmine Methylsulfate 5 mL Syringes from Fagron Sterile Services: Recall – Mislabeled 7/2/18
Fagron Sterile Services recalled two lots of neostigmine methylsulfate 5 mL syringes (NDC 71266-2003-02, lot C274-000004690 and NDC 1266-2003-01, lot C274-000004678) after reports that some syringes labeled as containing 1 mg/mL, 5 mg per 5 mL are mislabeled 1 mg/mL, 3 mg per 3 mL.

Sage Splish Splash Gentle Baby Wash- May Contain Pseudomonas Aeruginosa Bacteria 7/6/18
Sage Natural Wellness is warning customers not to use Splish Splash Gentle Baby Wash, 8.5 fl. oz. and 1.7 fl. oz. (found in the Wee and Well Gentle Baby Care Kit) as it may contain the bacteria Pseudomonas aeruginosa. Pseudomonas aeruginosa is an opportunistic pathogen that causes infection and results in bacteria in the blood, particularly in individuals with compromised immune systems.

Valsartan: Recall - Potential Presence of a Probable Carcinogen (NDMA) 7/13/18, 7/17/18, 7/19/18

Select valsartan products have been recalled due to the presence of an impurity, N- nitrosodimethylamine (NDMA), which is a probable carcinogen. It is believed to be present as a result of the way the valsartan was manufactured by Zhejiang Huahai Pharmaceuticals, Linhai, China. Not all valsartan products are affected. The three current recalls are Teva Pharmaceuticals USA labeled as Major (80 mg and 160 mg products), Prinston Pharmaceuticals Inc labeled as Solco Healthcare LLC (40 mg, 80 mg, 160 mg, 320 mg, and valsartan/hydrochlorothiazide 80 mg/12.5 mg, 160 mg/12.5 mg, 160 mg/25 mg, 320 mg/12.5 mg, and 320 mg/25 mg products), and Teva Pharmaceuticals labeled as Actavis LLC (same strengths as Prinston). The FDA has maintained a page with updates.

Aquaflora Candida HP9, Lymph Detox, and Baby Teething Liquids from King Bio: Recall - Microbial Contamination 7/20/18

King Bio is voluntarily recalling four lots of Aquaflora Candida HP9, Lymph Detox, and Baby Teething liquids to the consumer level. During a routine inspection by the FDA, the products were found to contain the microbial contaminants *Pseudomonas bremneri*, *Pseudomonas fluorescens* and *Burkholderia multivorans*.

Ranier's Rx Laboratory Sterile Compounded Products: Recall - Lack of Sterility 7/30/18

Ranier's Rx Laboratory issued a recall to the hospital and consumer level of all compounded sterile products due to concerns that practices at the pharmacy have the potential to pose a risk of contamination to products that are intended to be sterile. These concerns arose following an inspection and warning from the FDA.

Piperacillin and Tazobactam Injection 3.375 g vial from AuroMedics Pharma: Recall – Particulates 7/31/18

AuroMedics Pharma LLC recalled two lots of piperacillin and tazobactam for injection, USP 3.375 g single-dose vials to the hospital level following reports of particulate matter. A vial in lot PP0317012-A was found to contain a glass particle and a vial in lot PP0317059-A was found to contain a silicon particle.

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***
Adipotrim XT	Weight loss	Phenolphthalein[1]
African Superman - Top-Class Permanence, MyNicNaxs LLC*	Sexual enhancement	Sildenafil[2]
African Superman, MyNicNaxs LLC*	Sexual enhancement	Sildenafil[2]
African Viagra, MyNicNaxs LLC*	Sexual enhancement	Sildenafil[2]
Asunsa	Weight loss	Sibutramine[3], N-desmethylsibutramine, benzylsibutramine, phenolphthalein[1] and diclofenac[4]
Black Rhino 25000	Sexual enhancement	Sildenafil[2]
Body Shape Weight Loss System	Weight loss	Phenolphthalein[1]
Boss Rhino 15000	Sexual enhancement	Sildenafil[2]
Botanical Slimming - 100% Natural, MyNicNaxs LLC*	Weight loss	Not stated
C.U. Plus	Sexual enhancement	Sildenafil and tadalafil[2]
Chong Cao Qiang Shen Wang	Sexual enhancement	Sildenafil[2]
Dale Mas	Sexual enhancement	Sildenafil and tadalafil[2]
Fat Loss Slimming Beauty, MyNicNaxs LLC*	Weight loss	Sibutramine[3] and phenolphthalein[1]
FRUTA Bio, MyNicNaxs LLC*	Weight loss	Sibutramine[3] and phenolphthalein[1]
Fruta Planta, MyNicNaxs LLC*	Weight loss	Sibutramine[3] and phenolphthalein[1]
GINSENG, MyNicNaxs LLC*	Sexual enhancement	Sildenafil[2]
Gold Rhino 25000	Sexual enhancement	Sildenafil[2]
Grakcu Capsule	Sexual enhancement	Sildenafil and tadalafil[2]

Product	***Promoted Use***	***Undeclared Ingredient(s) or Contaminants***
Hokkaido, MyNicNaxs LLC*	Weight loss	Phenolphthalein[1]
JIANFEIJINDAN Activity Girl, MyNicNaxs LLC*	Weight loss	Sibutramine[3]
Kratom powder capsule, Blissful Remedies, Lot 112710, Exp 03/2019	Pain	Clostridium difficile, Klebsiella pneumoniae, Pseudomonas aeruginosa, Salmonella
Krazzy Rhino 25000	Sexual enhancement	Sildenafil[2]
Lean Extreme Max, MyNicNaxs LLC*	Weight loss	Sibutramine[3]
Lyn DTOX FS3	Weight loss	Sibutramine[3] and N-desmethylsibutramine
Magic Slim, MyNicNaxs LLC*	Weight loss	Sibutramine[3]
Maxidus	Sexual enhancement	Sildenafil[2]
Maximum Powerful	Sexual enhancement	Sildenafil[2]
Meizi Evolution, MyNicNaxs LLC*	Weight loss	Sibutramine[3]
Meizitang Strong Version, MyNicNaxs LLC*	Weight loss	Sibutramine[3]
Old Chinese, MyNicNaxs LLC*	Sexual enhancement	Sildenafil[2]
Platinum Maximum Strength Blue Pill Version, MyNicNaxs LLC*	Weight loss	Sibutramine[3] and phenolphthalein[1]
Platinum Rhino 25000	Sexual enhancement	Sildenafil[2]
Prescript-Assist Dietary Supplement*	Gastrointestinal support	Allergens including almonds, crustaceans, milk, casein, eggs, and peanuts
Reduce Weight FRUTA PLANTA, MyNicNaxs LLC*	Weight loss	Phenolphthalein[1]
Row of Antibody Pil	Weight loss	Sibutramine[3] and phenolphthalein[1]
Slim Body, MyNicNaxs LLC*	Weight loss	Not stated
Slim Evolution - 100% Natural Ingredients, MyNicNaxs LLC*	Weight loss	Diclofenac[4]
Slim Xtreme, MyNicNaxs LLC*	Weight loss	Sibutramine[3]
SlimEasy Herbs, MyNicNaxs LLC*	Weight loss	Sibutramine[3]
Slimming Plus Advanced Weight Loss, MyNicNaxs LLC*	Weight loss	Sibutramine[3] and phenolphthalein[1]
Super Fat Burning Bomb, MyNicNaxs LLC*	Weight loss	Sibutramine[3] and phenolphthalein[1]
X-treme Beauty Slim, MyNicNaxs LLC*	Weight loss	Sibutramine[3]

*Recalled

[1]Phenolpthalein is genotoxic and potentially carcinogenic; discontinued in 1999[FDA]

[2]Sildenafil/tadalafil/vardenafil may interact with nitrates to lower blood pressure to dangerous levels

[3]Sibutramine has been associated with increased cardiovascular events; discontinued in 2010[FDA]

[4]Diclofenac may increase the risk of cardiovascular events and serious gastrointestinal damage

New Product Shortages	***Date Initially Posted***
Aminophylline Injection, USP (Hospira)	7/24/18
Thiothixene Capsules, (Mylan)	7/27/18

Product Discontinuations/Withdrawals	***Date Posted***
Ondansetron HCl (Zofran) Tablets (Novartis): remains available from other generic manufacturers.	7/2/18
Enoxaparin Sodium Injection (Sandoz): remains available from other generic manufacturers	7/2/18
Pioglitazone HCl and Metformin HCl Tablets (Teva): remains available from other generic manufacturers.	7/3/18
Capromab Pendetide (ProstaScint) Injection (Aytu BioScience): alternative diagnostic tools can be used to evaluate the spread of prostate cancer.	7/9/18
Bromocriptine Mesylate Tablets (Mylan): Mylan capsules still available. Tablets remain available from other generic manufacturers.	7/10/18
Doxycycline Hyclate Capsules and Delayed-Release Tablets (Mylan): remains available from other generic manufacturers.	7/10/18
Omeprazole Capsules (Mylan): remains available from other generic manufacturers.	7/10/18
Risedronate Sodium Tablets (Mylan): remains available from other generic manufacturers.	7/10/18
Amantadine HCl Capsules (Sandoz): remains available from other generic manufacturers.	7/30/18
Metformin HCL Tablets (Teva): remains available from other generic manufacturers.	7/31/18

New Drug Approvals:	***Description (See Attached Drug Summaries)***	***Date Approved***
Tecovirimat / Tpoxx / SIGA Technologies, Inc.	An inhibitor of the orthopoxvirus VP37 envelope wrapping protein and is indicated for the treatment of human smallpox disease in adults and pediatric patients weighing at least 13 kg.	7/13/18
Ivosidenib / TIBSOVO / Agios Pharmaceuticals, Inc.	An isocitrate dehydronase-1 (IDH1) inhibitor indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test.	7/20/18
Tafenoquine / Krintafel / GlaxoSmithKline	An 8-aminoquinolone antimalarial indicated for radical cure (prevention of relapse) of *Plasmodium vivax* malaria in patients aged 16 years and older who are receiving an appropriate antimalarial therapy for acute *P. vivax* infection.	7/20/18
Elagolix / Orilissa / AbbVie	A gonadotropin-releasing hormone (GnRH) receptor antagonist for the management of moderate to severe pain associated with endometriosis in women 18 years and older.	7/23/18
Fish oil triglycerides / Omegaven / Fresenius Kabi	Source of calories and fatty acids in pediatric patients with parenteral nutrition-associated cholestasis.	7/27/18
Lusutrombopag / Mulpleta / Shionogi Inc.	A thrombopoietin receptor agonist for the treatment of thrombocytopenia in adults with chronic liver disease who are scheduled to undergo a procedure	7/31/18

New Indications:	***Description***	***Date Approved***
Incobotulinumtoxin A / Xeomin / Merz Pharmacetuticals, LLC	For adults with chronic sialorrhea	7/3/18
Ipilimumab / Yervoy / Bristol-Myers Squibb	In combination with nivolumab for the treatment of adult and pediatric patients 12 years of age and older with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.	7/10/18
Nivolumab / Opdivo / Bristol-Myers Squibb	In combination with ipilimumab for the treatment of adult and pediatric patients 12 years of age and older with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan; nivolumab was previously approved for this indication as a single agent.	7/11/18
Enzalutamide / Xtandi / Astellas Pharma	Treatment of patients with non-metastatic castration-resistant prostate cancer.	7/13/18
Etravirine / Intelence / Janssen	Indication expanded to include use in patients 2 years to less than 6 years of age weighing at least 10 kg.	7/16/18
Ribociclib / Kisqali / Novartis	With an aromatase inhibitor for treatment of pre/perimenopausal or postmenopausal women with hormone receptor (HR)-positive, HER2 negative advanced or metastatic breast cancer as initial therapy, or in combination with fulvestrant for the treatment of postmenopausal women with HR positive, HER2 negative advanced or metastatic breast cancer, as initial endocrine based therapy or following disease progression on endocrine therapy.	7/18/18
Somatropin / Zomacton / Ferring	Treatment of pediatric patients with idiopathic short stature, short stature associated with Turner syndrome, short stature born small for gestational age with no catch-up growth by 2-4 years, and short stature or growth failure in short stature homeobox-containing gene (SHOX) deficiency.	7/19/18
Tbo-filgrastim / Granix / Sicor	Indication expanded to include patients 1 month of age and older.	7/31/18

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Gemcitabine in sodium chloride / Infugem / Sun Pharmaceuticals	Single-dose premixed infusion bags containing 10 mg/mL of gemcitabine in 0.9% sodium chloride.	7/16/18
Darunavir, cobicistat, emtricitabine, tenofovir alafenamide / Symtuza / Jansssen	Single tablet taken once daily as a complete regimen for the treatment of HIV infection in adults	7/17/18
Filgrastim-aafi / Nivestym / Pfizer	Biosimilar to Neupogen with the same indications except not approved to increase survival in patients acute exposed to myelosuppressive doses of radiation; approved in the same dosage forms and strengths.	7/20/18
Risperidone extended-release injectable suspension / Perseris / Indivior	Once-monthly subcutaneous injection for the treatment of schizophrenia in adults	7/27/18
Iobenguane I 131 / Azedra / Progenics Pharma	I 131 labeled iobenguane intravenous injection for the treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy.	7/30/18

Compiled by:

Terri Levien, Pharm.D.
Jesse Dinh, Pharm.D., PGY1 Drug Information Resident
Sunao Tamukai, Pharm.D. Candidate 2019
Hannah Sanchez, Pharm.D. Candidate 2019

Drug Information Center
College of Pharmacy and Pharmaceutical Sciences
Washington State University
PO Box 1495
Spokane, WA 99210-1495
(509) 358-7662
Pharmacy.druginfo@wsu.edu

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Tecovirimat / TPOXX / SIGA Technologies, Inc.	
Generic Name / Brand Name / Company	Tecovirimat / TPOXX / SIGA Technologies, Inc.
Date of approval	7/13/18
Drug Class (Mechanism of Action if novel agent)	An inhibitor of the orthopoxvirus VP37 envelope wrapping protein.
Indication	For the treatment of human smallpox disease in adults and pediatric patients weighing at least 13 kg.
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths. Common Dose/sig	Capsule: 200 mg. Adults and pediatric patients weighing ≥40 kg: 600 mg twice daily for 14 days. Pediatric patients weighing 13 kg to 25 kg: 200 mg twice daily for 14 days. Pediatric patients weighing 25 kg to 40 kg: 400 mg twice daily for 14 days.
DEA Schedule	Not applicable
Date of market availability	Only available through the US government's Strategic National Stockpile.
Similar Medication Names	Tecomax
Clinical Use Evaluation	
Common Adverse Effects	>2%: headache, nausea, abdominal pain, and vomiting.
Severe Adverse Effects	None known
Severe Drug-Drug Interactions	Tecovirimat is a weak inducer of CYP3A and a weak inhibitor of CYP2C8 and CYP2C19. The effects are not expected to be clinically relevant for most substrates of those enzymes based on the magnitude of affect and the duration of tecovirimat treatment. Tecovirimat may increase the concentration of repaglinide when co-administered and may decrease the concentration of midazolam when co-administered.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Monitor blood glucose and signs and symptoms of hypoglycemia when used concomitantly in patients taken repaglinide.
Used in Pediatric Areas	Can be used in children weighing at least 13 kg.
Renal or Hepatic Dosing	No dosage adjustments required.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Monitor for hypoglycemia in patients also taking repaglinide. No known contraindications. Efficacy may be reduced in immunocompromised patients.
Special administration technique or considerations	Should be taken within 30 minutes after eating a full moderate-to-high fat meal. For adults and children with difficulty swallowing capsules, the capsules may be opened and contents mixed in 30 mL of liquid or soft food.
Prepared by	Hannah Sanchez & Sunao Tamukai
Source	TPOXX (tecovirimat) [prescribing information]. Corvallis, OR: SIGA Pharmaceuticals, Inc.; July 2018.

Ivosidenib / Tibsovo / Agios Pharmaceuticals, Inc.	
Generic Name / Brand Name / Company	Ivosidenib / Tibsovo / Agios Pharmaceuticals, Inc.
Date of approval	7/20/18
Drug Class (Mechanism of Action if novel agent)	Isocitrate dehydrogenase 1 (IDH1) inhibitor that decreases 2-hydroxyglutarate (2HG) levels and induces myeloid differentiation.
Indication	Treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test.
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths. Common Dose/sig	Tablet: 250 mg Dose: 500 mg orally once daily
DEA Schedule	Not applicable
Date of market availability	Available
Similar Medication Names	None
Clinical Use Evaluation	
Common Adverse Effects	≥20%: fatigue, leukocytosis, arthralgia, diarrhea, dyspnea, edema, nausea, mucositis, electrocardiogram QT prolonged, rash, pyrexia, cough, and constipation.
Severe Adverse Effects	Differentiation syndrome, QTc interval prolongation, and Guillain-Barré syndrome.
Severe Drug-Drug Interactions	Strong or moderate CYP3A4 inhibitors: reduce ivosidenib dose with strong CYP3A4 inhibitors. Monitor patients for increased risk of QTc interval prolongation. Strong CYP3A4 substrates: avoid concomitant use. QTc prolonging drugs: avoid concomitant use. If unavoidable, monitor patients for increased risk of QTc interval prolongation.
Severe Drug-Food Interactions	Administration with a high-fat meal (approximately 900 to 1,000 calories, 500 to 600 fat calories, 250 carbohydrate calories and 150 protein calories) increased ivosidenib C_{max} by 98% and AUC_{inf} by approximately 25%. Avoid administration with a high-fat meal.
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Assess blood counts and blood chemistries prior to the initiation of ivosidenib, at least once weekly for the first month, once every other week for the second month, and once monthly for the duration of therapy. Monitor blood creatinine phosphokinase weekly for the first month of therapy. Monitor electrocardiogram at least once weekly for the first 3 weeks of therapy and then at least once monthly for the duration of therapy.
Used in Pediatric Areas	Safety and effectiveness have not been established.
Renal or Hepatic Dosing	No adjustment required in mild to moderate renal impairment or mild hepatic impairment; no data in severe renal impairment, end-stage renal disease, or severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No contraindications in labeling. Warnings: Differentiation syndrome: patients treated with ivosidenib have experienced symptoms of differentiation syndrome, which can be fatal if not treated. QTc interval prolongation: monitor electrocardiograms and electrolytes; reduce dose or withhold, then resume dose or permanently discontinue ivosidenib if QTc interval prolongation occurs. Guillain-Barré syndrome: monitor for signs and symptoms of new motor and/or sensory findings; permanently discontinue ivosidenib in patients who are diagnosed with Guillain-Barré syndrome.
Special administration technique or considerations	Avoid taking ivosidenib with a high fat meal. Do not split or crush ivosidenib tablets.

Prepared by	Sunao Tamukai
Source	Tibsovo (ivosidenib) [prescribing information]. Cambridge, MA: Agios Pharmaceuticals, Inc.; July 2018.

Tafenoquine / Krintafel / GlaxoSmithKline	
Generic Name / Brand Name / Company	Tafenoquine / Krintafel / GlaxoSmithKline
Date of approval	7/20/18
Drug Class (Mechanism of Action if novel agent)	8-aminoquinolone antimalarial
Indication	Radical cure (prevention of relapse) of *Plasmodium vivax* malaria in patients aged 16 years and older who are receiving an appropriate antimalarial therapy for acute *P. vivax* infection. Not indicated for the treatment of acute *P. vivax* malaria.
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths. Common Dose/sig	Tablets: 150 mg Dose: 300 mg (two 150-mg tablets taken together) as a single dose
DEA Schedule	Not applicable
Date of market availability	Unknown
Similar Medication Names	Chloroquine, primaquine
Clinical Use Evaluation	
Common Adverse Effects	>5%: dizziness, nausea, vomiting, headache, and decreased hemoglobin.
Severe Adverse Effects	Hemolytic anemia related to G6PD deficiency, methemoglobinemia, and psychiatric effects.
Severe Drug-Drug Interactions	Avoid coadministration with drugs that are substrates of organic cation transporter-2 (OCT2) or multidrug and toxin extrusion (MATE) transporters.
Severe Drug-Food Interactions	Must be taken with food, preferably a high-fat, high calorie meal to increase systemic absorption.
Important Labs Values to assess prior to order entry or at point of clinical follow up.	G6PD testing must be performed before prescribing this medication due to the risk of hemolytic anemia. Pregnancy testing for females of reproductive potential.
Used in Pediatric Areas	Safety and effectiveness have not been established in patients younger than 16 years of age.
Renal or Hepatic Dosing	Has not been studied in renal or hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications include G6PD deficiency or unknown G6PD status, breastfeeding by a lactating woman when the infant is found to be G6PD deficient or if G6PD status is unknown, and known hypersensitivity reactions to tafenoquine, other 8-aminoquinolones, or any component of the medication formulation. Warnings for hemolytic anemia (related to G6PD deficiency), G6PD deficiency in pregnancy or lactation, methemoglobinemia, psychiatric effects, and hypersensitivity reactions. Due to the long half-life (15 days), psychiatric effects and hypersensitivity reactions may be delayed in onset or duration.
Special administration technique or considerations	Coadminister on the first or second day with appropriate antimalarial therapy for the acute *P. vivax* malaria. Administer with food.
Prepared by	Hannah Sanchez
Source	Krintafel (tafenoquine) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; July 2018.

Elagolix / Orilissa / AbbVie	
Generic Name / Brand Name / Company	Elagolix / Orilissa / AbbVie
Date of approval	7/24/18
Drug Class (Mechanism of Action if novel agent)	Gonadotropin-releasing hormone (GnRH) receptor antagonist
Indication	Management of moderate to severe pain associated with endometriosis
Comparative agent – Therapeutic interchange?	GnRH receptor agonists
Dosage forms/strengths. Common Dose/sig	Tablets: 150 mg and 200 mg. Dose: 150 mg once daily for up to 24 months or 200 mg twice daily for up to 6 months.
DEA Schedule	Not applicable
Date of market availability	Anticipated availability in August 2018.
Similar Medication Names	None
Clinical Use Evaluation	
Common Adverse Effects	>5%: hot flashes, night sweats, headache, nausea, insomnia, amenorrhea, anxiety, arthralgia, depression-related adverse reactions and mood changes
Severe Adverse Effects	Bone loss, suicidal ideation, and liver injury
Severe Drug-Drug Interactions	Elagolix may decrease plasma concentrations of drugs that are substrates of CYP3A and may increase plasma concentrations of drugs that are substrates of P-gp (e.g., digoxin). Co-administration of elagolix with drugs that inhibit OATP1B1 may increase elagolix plasma concentrations. Concomitant use of elagolix and strong OATP1B1 inhibitors (e.g., cyclosporine and gemfibrozil) is contraindicated. Concomitant use of elagolix 200 mg twice daily and strong CYP3A inhibitors for more than 1 month is not recommended. Limit concomitant use of elagolix 150 mg once daily and strong CYP3A inhibitors to 6 months. Co-administration of elagolix with drugs that induce CYP3A may decrease elagolix plasma concentrations.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Pregnancy test prior to initiation. Assess bone mineral density in women with additional risk factors for bone loss.
Used in Pediatric Areas	Safety and effectiveness have not been established in pediatric patients
Renal or Hepatic Dosing	No dosage adjustment of elagolix is required for women with any degree of renal impairment or with mild hepatic impairment (Child-Pugh A). Only the 150 mg once daily regimen is recommended for women with moderate hepatic impairment (Child-Pugh B) and the duration of treatment should be limited to 6 months. Elagolix is contraindicated in women with severe hepatic impairment (Child-Pugh C).
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in pregnancy, known osteoporosis, severe hepatic impairment (Child-Pugh C), or administered with strong organic anion transporting polypeptide (OATP) 1B1 inhibitors. Warnings for bone loss, reduced ability to recognize pregnancy, suicidal ideation and mood disorders, hepatic transaminase elevations, and potential for reduced efficacy with estrogen-containing contraceptives.
Special administration technique or considerations	Exclude pregnancy before initiating therapy or start therapy within 7 days from the onset of menses. Take at the same time each day, with or without food. Limit duration of use because of bone loss.
Prepared by	Hannah Sanchez
Source	Orilissa (elagolix) [prescribing information]. North Chicago, IL; AbbVie Inc.; Revised July 2018.

Fish Oil Triglycerides / Omegaven / Fresenius Kabi USA	
Generic Name / Brand Name / Company	Fish Oil Triglycerides / Omegaven / Fresenius Kabi USA
Date of approval	7/27/18
Drug Class (Mechanism of Action if novel agent)	Supplement that provides a biologically utilizable source of calories and essential fatty acids.
Indication	A source of calories and fatty acids in pediatric patients with parenteral nutrition-associated cholestasis (PNAC). It is not indicated for the prevention of PNAC. It has not been demonstrated that the clinical outcomes observed in patients treated with this medication are a result of the omega-6:omega 3 fatty acid ratio of the product.
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths. Common Dose/sig	Injectable emulsion: 5 g/50 mL and 10 g/100 mL in a single-dose bottle. Recommended daily dose (and maximum dose) in pediatric patients is 1 g/kg/day. Recommended dose depends on age, energy expenditure, clinical status, body weight, tolerance, ability to metabolize, and consideration of additional energy sources given to the patient. For information on infusion rate when initiating dosing in patients with elevated triglyceride levels, see full prescribing information. Recommended duration for infusion is between 8 and 24 hours, depending on clinical situation.
DEA Schedule	Not applicable
Date of market availability	Unknown; has been available through an expanded access protocol
Similar Medication Names	None
Clinical Use Evaluation	
Common Adverse Effects	>15%: vomiting, agitation, bradycardia, apnea, and viral infection
Severe Adverse Effects	Risk of death in preterm infants due to pulmonary lipid accumulation, risk of infections, fat overload syndrome, and hypertriglyceridemia, aluminum toxicity (in comorbid renal impairment).
Severe Drug-Drug Interactions	Prolonged bleeding time has been reported in patients taking antiplatelet agents or anticoagulants and oral omega-3 fatty acids. Periodically monitor bleeding time in patients receiving fish oil triglycerides and concomitant antiplatelet agents or anticoagulants.
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Initiate when conjugated bilirubin levels are 2 mg/dL or greater. Routinely monitor serum triglycerides, fluid and electrolyte status, blood glucose, liver and kidney function, coagulation parameters, and complete blood count including platelets throughout treatment. Monitor for laboratory evidence of essential fatty acid deficiency is also recommended.
Used in Pediatric Areas	Yes; efficacy established in studies enrolling infants 3 to 42 weeks of age, including preterm neonates.
Renal or Hepatic Dosing	No dose adjustment required on the basis of renal or hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindications include known hypersensitivity to fish or egg protein or to any of the active ingredients or excipients, severe hemorrhagic disorders, and severe hyperlipidemia or severe disorders of lipid metabolism with serum triglycerides greater than 1,000 mg/dL. Monitor for pulmonary lipid accumulation (signs and symptoms of pleural or pericardial effusion), hypersensitivity reactions, infection, fat overload syndrome, refeeding syndrome, hypertriglyceridemia, and aluminum toxicity.
Special administration technique or considerations	For infusion into a central or peripheral vein. May be infused directly from the bottle with a vented infusion set or admixed in a parenteral nutrition container. Use a 1.2 micron in-line filter during administration. Recommended infusion duration is 8 to 24 hours; complete infusion within 12 hours when using a Y-connector and within 24 hours when

	used as part of an admixture. Prior to administration, correct severe fluid and electrolyte disorders and measure serum triglycerides to establish a baseline level. Administer until direct or conjugated bilirubin levels are less than 2 mg/dL or until the patient no longer requires peripheral nutrition. In patients with elevated triglycerides, consider other reasons for hypertriglyceridemia (e.g., renal disease, other drugs). If triglycerides remain at elevated levels, consider a reduced dose of 0.5 g to 0.75 g/kg/day with an incremental increase to 1 g/kg/day. Contains 0.15 to 0.3 mg/ml dl-alpha-tocopherol; consider when determining need for additional vitamin E supplementation.
Prepared by	Hannah Sanchez
Source	Omegaven (fish oil triglycerides) [prescribing information]. Graz, Austria; Fresenius Kabi; July 2018.

Lusutrombopag / Mulpleta / Shionogi Inc	
Generic Name / Brand Name / Company	Lusutrombopag / Mulpleta / Shionogi Inc
Date of approval	7/31/18
Drug Class (Mechanism of Action if novel agent)	Thrombopoietin receptor agonist
Indication	For the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.
Comparative agent – Therapeutic interchange?	Avatrombopag (Doptelet)
Dosage forms/strengths. Common Dose/sig	Tablets: 3 mg Dose: 3 mg orally once daily with or without food for 7 days.
DEA Schedule	Not applicable
Date of market availability	Early September 2018
Similar Medication Names	Avatrombopag, eltrombopag
Clinical Use Evaluation	
Common Adverse Effects	>3%: headache
Severe Adverse Effects	Thrombotic and thromboembolic complications
Severe Drug-Drug Interactions	None known
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Obtain a platelet count prior to initiation of therapy and not more than 2 days before the procedure.
Used in Pediatric Areas	Safety and effectiveness have not been established.
Renal or Hepatic Dosing	No dose adjustment in patients with renal or hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No contraindications in prescribing information. Warnings include thrombotic or thromboembolic complications in patients with chronic liver disease.
Special administration technique or considerations	Begin lusutrombopag dosing 8-14 days prior to a scheduled procedure. Patients should undergo their procedure 2-8 days after the last dose.
Prepared by	Hannah Sanchez
Source	Mulpleta (lusutrombopag) [prescribing information]. Florham Park, NJ; Shionogi Inc.; July 2018.