



## Highlights of FDA Activities – 3/1/25 – 3/31/25

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

**Spectrum Infusion Pumps, Baxter Healthcare: Recall – Missing Motor Mounting Screws** 3/5/25

Baxter Healthcare recalled the Sigma Spectrum Infusion System V6 Platform (product code: 35700BAX) and Spectrum IQ Infusion System with Dose IQ Safety Software (product code: 3570009), recommending they be removed from use and returned for inspection and reservicing. Missing motor mounting screws have affected pump performance and been associated with one serious injury.

**Acne Products: Recall - Benzene Contamination** 3/11/25

La Roche-Posay Effaclar Duo Dual Action Acne Treatment (Lot #MYX46W); Walgreens Acne Control Cleanser (Lot #23 09328); Proactiv Emergency Blemish Relief Cream Benzoyl Peroxide 5% (Lot #V3305A, V3304A); Proactiv Skin Smoothing Exfoliator (Lot #V4204A); SLMD Benzoyl Peroxide Acne Lotion (Lot #2430600); Walgreens Tinted Acne Treatment Cream (Lot #49707430); Zapzyt Acne Treatment Gel were recalled for elevated levels of benzene.

**Immune Globulin Intravenous (IGIV) & Immune Globulin Subcutaneous (IGSC): Recall - Hypersensitivity Reactions** 3/11/25

Select lots of IGIV and IGSC solutions from several manufacturers (Grifols, ADMA Biologics, Octapharma) were recalled due to an increase in observed hypersensitivity reactions and allergic reactions. The recalled lots, and their respective manufacturers, can be viewed on the FDA [site](#).

**Levetiracetam in 0.75% Sodium Chloride Injection, Dr. Reddy's: Recall - Mislabeling** 3/13/25

Levetiracetam in 0.75% Sodium Chloride Injection, 1000 mg/100 mL (10 mg/mL) single-dose infusion bags (Batch/Lot No: A1540076) were recalled because the infusion bags were incorrectly labeled as Levetiracetam in 0.82% Sodium Chloride Injection 500 mg/100 mL single-dose bag whereas the aluminum overwrap correctly identifies the product.

**ProPort Plastic Implantable Ports, Smiths Medical: Recall - Separation** 3/20/25

Smiths Medical recalled ProPort Plastic Implantable Ports due to a manufacturing defect that may result in separation at the seal between port housing and port reservoir and subsequent patient injury. The complete list of port ID numbers and lots can be found [here](#). Products from these lots should not be used and patients who may have received products from this lots should be closely monitored.

**BD Alaris Systems Manager, BD Care Coordination Engine Infusion Adapter: Recall - Correction** 3/21/25

Becton, Dickinson and Company corrected software for these systems after receiving reports that the systems may experience delayed system response and backlogging of automated programming requests and then upload outdated automated programming requests which could differ from the parameters of the current infusion.

### 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.

<u>Product</u>	<u>Promoted Use</u>	<u>Undeclared Ingredient(s) or Contaminants</u>
Zaarah Herbals products (Bhringraj Powder, Gurmar Powder, Vasaka Powder, Rasayan Churan)*	Supplements	Lead and arsenic
Vitality*	Male enhancement	Sildenafil and tadalafil

\*recalled

**New Product Shortages**

Bacitracin ophthalmic ointment

**Date Initially Posted**

3/3/25

**Brand Name or Sole Source Product Discontinuations/Withdrawals****Date Posted**

Dapagliflozin/Saxagliptin (Qtern, AstraZeneca) Tablet; individual components remain available, generic combination products have tentative approval	3/3/25
Acyclovir (Zovirax, Actavis) Ointment; generics remain available	3/3/25
Glipizide (Glucotrol XL, Pfizer) extended-release tablet; generics remain available	3/17/25
Travoprost (Travatan Z, Sandoz) ophthalmic solution; generics remain available	3/18/25
Montelukast (Singulair, Organon) granule 4 mg; generics remain available	3/24/25

**New Drug Approvals:****Description (See Attached Drug Summaries)****Date Approved**

Revakinagene taroretcel-lwey/Encelto/ Neurotech Pharmaceuticals, Inc.	An allogeneic encapsulated cell-based gene therapy indicated for the treatment of adults with idiopathic macular telangiectasia type 2	3/5/25
Gepotidacin/Blujepa/GSK	A triazaacenaphthylene bacterial type II topoisomerase inhibitor antimicrobial for treatment of uncomplicated urinary tract infections in female adult or pediatric patients 12 years and older	3/25/25
Fitusiran/Qfitlia/Sanofi	Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years and older with hemophilia A or hemophilia B, with or without factor VIII or IX inhibitors	3/28/25

**New Indications:****Description****Date Approved**

Tislelizumab-jsgr/Tevimbra/BeiGene	In combination with platinum-containing chemotherapy for the first-line treatment of adults with unresectable or metastatic esophageal squamous cell carcinoma whose tumors express PD-L1	3/4/25
Furosemide/Furoscix/scPharmaceuticals	Treatment of edema in adult patients with chronic kidney disease including the nephrotic syndrome	3/6/25
Empagliflozin and metformin/Synjardy and Synjardy XR/Boehringer Ingelheim	Indicated in adults with type 2 diabetes mellitus to reduce the risk of sustained decline in eGFR, end-stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease at risk of progression	3/7/25
Glucagon/Gvoke/Xeris Pharmaceuticals	Intravenous use as a diagnostic aid during radiologic examinations to temporarily inhibit movement of the gastrointestinal tract in adults	3/14/25
Glucagon/Baqsimi/Amphastar Pharmaceuticals	Indication expanded to include use in patients 1 years and older with severe hypoglycemia associated with diabetes	3/17/25
Guselkumab/Tremfya/Janssen Biotech	Treatment of adults with moderately to severely active Crohn's disease	3/20/25
Iptacopan/Fabhalta/Novartis	Treatment of adults with complement 3 glomerulopathy to reduce proteinuria	3/20/25
Vutrisiran/Amvuttra/Alnylam	Treatment of wild-type or hereditary transthyretin-mediated amyloid cardiomyopathy	3/20/25

<b><u>New Indications (continued):</u></b>	<b><u>Description</u></b>	<b><u>Date Approved</u></b>
Darunavir and cobicistat/Prezcobix/Janssen	Indication expanded to include treatment of HIV 1 infection in pediatric patients weighing at least 25 kg to less than 40 kg	3/21/25
Cabozantinib/Cabometyx/Exelixis Inc	Treatment of adult and pediatric patients 12 years and older with previously treated, unresectable, locally advanced or metastatic, well-differentiated pancreatic or extra-pancreatic neuroendocrine tumors	3/26/25
Durvalumab/Imfinzi/AstraZeneca	In combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by single agent durvalumab as adjuvant treatment following radical cystectomy for the treatment of muscle invasive bladder cancer	3/28/25
Lutetium L 177 vipivotide tetraxetan/Pluvicto/Novartis	Treatment of prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer who have been treated with androgen receptor pathway inhibitor therapy and are considered appropriate to delay taxane-based chemotherapy	3/28/25

<b><u>New Dosage Forms or Formulation:</u></b>	<b><u>Description</u></b>	<b><u>Date Approved</u></b>
Epinephrine/Neffy/ARS Pharm Operation	Nasal spray: 1 mg/0.1 mL; for use in patients weighing 15 kg to less than 30 kg	3/5/25
Losartan potassium/Arbli/Scienture, LLC.	Suspension: 10 mg/mL in 165 mL bottle; for treatment of hypertension in patients 6 years and older, reduce risk of stroke in patients with hypertension and left ventricular hypertrophy, and treatment diabetic nephropathy in patients with type 2 diabetes and history of hypertension	3/13/25
Chlorthalidone/Hemiclor/PRM Pharma	Tablet: 12.5 mg; treatment of hypertension	3/17/25
Gallium Ga 68 gozetotide/Gozellix/Telix Pharmaceuticals	Kit containing gallium Ga 68 gozetotide 25 mcg in a multiple-dose vial, plus vial containing acetate buffer and ampule containing ascorbic acid stabilizer; radioactive diagnostic agent indicated for positron emission tomography of prostate-specific membrane antigen positive lesions in men with prostate cancer	3/21/25
Tesamorelin/Egrifta WR/Teratechnologies Inc	Injection: tesamorelin 11.6 mg as lyophilized powder in single-patient use vial; for reduction of excess abdominal fat in adults with HIV who have lipodystrophy	3/25/25
Diazoxide choline/Vykat XR/Soleno Therapeutics, Inc.	Extended-release tablets: 25 mg, 75 mg, 150 mg; for the treatment of hyperphagia associated with Prader-Willi syndrome	3/26/25

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<b>Revakinagene taroretcel-lwey/Encelto/Neurotech Pharmaceuticals, Inc.</b>	
Generic Name / Brand Name / Company	Revakinagene taroretcel-lwey/Encelto/Neurotech Pharmaceuticals, Inc.
Date of approval	3/5/25
Drug Class (Mechanism of Action if novel agent)	Allogenic encapsulated gene therapy; secretes recombinant human ciliary neurotrophic factor (rhCNTF)
Indication	Treatment of adults with idiopathic macular telangiectasia type 2
Comparative agent – Therapeutic interchange?	None
Dosage forms/strengths	Intravitreal implant containing 200,000-400,000 allogeneic retinal pigment epithelial cells (expressing rhCNTF).
Common Dose/sig	One implant (single-dose), each affected eye
DEA Schedule	N/A
Date of market availability	June 2025
Similar Medication Names	Enalapril, Enbrel, Enlon
<b>Clinical Use Evaluation</b>	
Common Adverse Effects	≥2%: conjunctival hemorrhage, delayed dark adaptation, foreign body sensation, eye pain, suture-related complications, miosis, conjunctival hyperemia, eye pruritus, ocular discomfort, vitreous hemorrhage, blurred vision, headache, dry eye, eye irritation, cataract progression or formation, vitreous floaters, severe vision loss, eye discharge, anterior chamber cell, iridocyclitis
Severe Adverse Effects	Severe vision loss, infectious endophthalmitis, retinal tears and/or detachment, vitreous hemorrhage, implant extrusion, cataract formation, suture related complications, and delayed dark adaptation
Severe Drug-Drug Interactions	None identified.
Severe Drug-Food Interactions	None known.
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None required
Used in Pediatric Areas	Safety and effectiveness have not been established
Renal or Hepatic Dosing	No special dosing instructions; systemic levels are below level of detection
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with ocular or periocular infections or known hypersensitivity to endothelial serum free media (Endo-SFM). Patients should be monitored for vision loss, infectious endophthalmitis, retinal tear and/or detachment, vitreous hemorrhage, implant extrusion, cataracts, or suture related complications. Pertinent to future MRI exposure: advise patients to provide implant card and that their implant may be relevant in this situation. Delayed dark adaptation may hinder driving, navigating in the dark, and in transition from bright to dark environments. Patients are advised to use sunglasses in bright environments to aid in adaptation. Patients should be advised not to drive or use machinery until their ophthalmologist informs them their vision has recovered to an acceptable level.
Special administration technique or considerations	This is a surgical implant cell-based gene therapy, administered by a single surgical intravitreal procedure performed in an operating room by an ophthalmologist. Post operative wound care includes use of a topical antibiotic for 7 days and a steroid drop taper of prednisolone acetate for 28 days. The implant should be removed if vitrectomy with a complete gas fill or silicone fill is required or if infectious endophthalmitis occurs.
Prepared by	Hayden Wesley, Pharm.D.
Source	Encelto (revakinagene taroretcel-lwey) [prescribing information]. Cumberland, RI: Neurotech Pharmaceuticals, Inc.; March 2025.

<b>Gepotidacin/Blujepa/GlaxoSmithKline</b>	
Generic Name / Brand Name / Company	Gepotidacin/Blujepa/GlaxoSmithKline
Date of approval	3/25/25
Drug Class (Mechanism of Action if novel agent)	Triazaacenaphthylene bacterial type II topoisomerase inhibitor antibacterial
Indication	Treatment of female adult and pediatric patients 12 years of age and older weighing at least 40 kg with uncomplicated urinary tract infections (uUTI) caused by the following susceptible microorganisms: <i>Escherichia coli</i> , <i>Klebsiella pneumoniae</i> , <i>Citrobacter freundii</i> complex, <i>Staphylococcus saprophyticus</i> , and <i>Enterococcus faecalis</i> .
Comparative agent – Therapeutic interchange?	Nitrofurantoin, trimethoprim-sulfamethoxazole, fosfomycin, pivmecillinam
Dosage forms/strengths	Tablets: 750 mg
Common Dose/sig	1500 mg (two 750 mg tablets) orally twice daily for 5 days
DEA Schedule	N/A
Date of market availability	Second half of 2025
Similar Medication Names	Bludigo, gepirone
<b>Clinical Use Evaluation</b>	
Common Adverse Effects	>1%: diarrhea, nausea, abdominal pain, flatulence, headache, soft feces, dizziness, vomiting, vulvovaginal candidiasis
Severe Adverse Effects	QTc prolongation, dysarthria, anaphylaxis, <i>Clostridioides difficile</i> infection (CDI)
Severe Drug-Drug Interactions	Avoid coadministration with strong CYP3A4 inhibitors, strong CYP3A4 inducers, or drugs with a narrow therapeutic window that are metabolized by CYP3A4. Caution with succinylcholine-type neuromuscular blocking agents, systemic anticholinergic medications, or non-depolarizing neuromuscular blockers, and with digoxin.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Serum electrolytes if administered to patients at risk for QTc prolongation.
Used in Pediatric Areas	Adult dose used in patients 12 years and older weighing at least 40 kg. Safety and effectiveness have not been established in patients less than 12 years of age or weighing less than 40 kg.
Renal or Hepatic Dosing	Avoid use in severe renal impairment or severe hepatic impairment.
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	Contraindicated in patients with history of severe hypersensitivity to gepotidacin. Warnings: QTc prolongation has been observed; avoid in patients with history of QTc interval prolongation or pre-existing cardiac disease, patients taking antiarrhythmic agents, or other agents that may prolong the QTc interval, and in conditions which may increase exposure (with strong CYP3A inhibitors, severe hepatic or renal impairment). Acetylcholinesterase inhibition may occur; monitor for cholinergic effects. Hypersensitivity reactions and CDI have been reported. There is no data in pregnancy; a pregnancy exposure registry will be established.
Special administration technique or considerations	Administer after a meal to reduce gastrointestinal intolerance.
Prepared by	Terri Levien, PharmD
Source	Blujepa (gepotidacin) [prescribing information]. Durham, NC: GlaxoSmithKline; March 2025.

<b>Fitusiran/Qfitlia/Sanofi</b>	
Generic Name / Brand Name / Company	Fitusiran/Qfitlia/Sanofi
Date of approval	3/28/25
Drug Class (Mechanism of Action if novel agent)	Antithrombin-directed small interfering ribonucleic acid
Indication	Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years and older with hemophilia A or hemophilia B, with or without factor VIII or IX inhibitors
Comparative agent – Therapeutic interchange?	Concizumab, emicizumab, marstacimab
Dosage forms/strengths	Injection: 50 mg/0.5 mL single-dose pen, 20 mg/0.2 mL single-dose vial
Common Dose/sig	Starting dose: 50 mg subcutaneously once every 2 months
DEA Schedule	N/A
Date of market availability	Available
Similar Medication Names	Filgrastim, Ofirmev
<b>Clinical Use Evaluation</b>	
Common Adverse Effects	>10%: viral infection, nasopharyngitis, bacterial infection
Severe Adverse Effects	Liver injury, thrombotic events, cholecystitis
Severe Drug-Drug Interactions	Hypercoagulability with concomitant use of clotting factor concentrate (CFC) or bypassing agent (BPA)
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Antithrombin prior to administration and to guide dosing, liver tests at baseline and then monthly for at least 6 months and after dose increases, and periodically thereafter
Used in Pediatric Areas	Safety and effectiveness not established in patients younger than 12 years
Renal or Hepatic Dosing	No dosage adjustment recommended based on renal function. Avoid use in hepatic impairment (Child-Pugh Class A, B, or C).
Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized	No contraindications. Boxed warning: thrombotic events and acute and recurrent gallbladder disease Warnings: thrombotic events have occurred during treatment; if a thrombotic event occurs interrupt therapy and manage as clinically indicated. Acute and recurrent gallbladder disease has occurred; monitor for symptoms and consider interruption or discontinuation of fitusiran. Consider alternative treatments in patients with history of symptomatic gallbladder disease. Monitor for hepatotoxicity; liver test elevations may require dose interruption or discontinuation.
Special administration technique or considerations	Monitor AT activity and maintain between 15 to 35% by adjusting dose and/or frequency of administration. Companion diagnostic available to patients to measure AT levels, which are used to guide dose adjustments. Patients may continue prior CFC or BPA prophylaxis for the first 7 days of fitusiran treatment, but such treatments should be discontinued to later than 7 days after the initial fitusiran dose. If breakthrough bleeding occurs after 7 days from the first dose, bleeds should be managed with a reduced dose and frequency of CFC/BPA to minimize risk of thrombotic events.
Prepared by	Terri Levien, PharmD
Source	Qfitlia (fitusiran) [prescribing information]. Cambridge, MA: Genzyme Corporation; March 2025.