



Highlights of FDA Activities – 9/1/25 – 9/30/25

FDA Drug Safety Communications & Drug Information Updates:

FDA Authorized Blood Pressure Monitors

9/16/25

The FDA issued a safety communication regarding use of unauthorized devices for measurement of blood pressure, including blood pressure monitors, smart watches, rings, or other wearables that claim to measure blood pressure. Health care professionals should counsel patients on the use of FDA-authorized blood pressure monitoring devices. Additional information can be found in the FDA [notice](#), and the FDA [website](#) (FDA’s 510(k) database) can be used to check if a device has been FDA authorized.

Caprelsa (vandetanib) Risk Evaluation and Mitigation Strategy (REMS) Removed

9/25/25

The FDA removed the REMS for vandetanib after determining oncologists have adequate knowledge about managing the heart rhythm related risks associated with the medication and that proper monitoring has been incorporated into standard practice.

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

Dexcom G7 and ONE+ Apps: Urgent Device Correction – Software Error

9/12/25

Dexcom sent customers an Urgent Medical Device Correction Notification for the Dexcom G7 Continuous Glucose Monitoring (CGM) App (for Android, iOS, and watchOS) and the Dexcom ONE+ CGM App (for Android and iOS) due to a software design error that leads to a missed “Sensor Failed” alert when the transmitter encounters a hardware/firmware failure. Users are instructed to update the Apps.

t:slim X2 Insulin Pumps, Tandem Diabetes Care: Recall – Software Update Required

9/15/25

Tandem issued an urgent device correction for certain t:slim X2 insulin pumps that have been found to malfunction due to faulty speaker wiring that can stop insulin delivery. This error is called Malfunction 16 and once it has occurred, pump users should be instructed to use the back-up plan for insulin delivery and blood sugar testing until a replacement unit is provided. The full list of recalled units can be found on the recall [page](#) along with additional instructions for managing the update.

BD Alaris Pump Module model 8100, BD/CareFusion: Recall/Correction – Compatible Infusion Sets

9/15/25

BD and their subsidiary CareFusion issued two urgent recall corrections notifying users of worse performance when the BD Alaris Pump Module model 8100 (pump module) is used with a subset of compatible pump infusion sets. The updated [alert](#) contains additional affected devices and corrective action.

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> |
|-----------------------------------|-----------------------|---|
| agebox iKids Growth Day Formula | Stimulate growth | Ibutamoren ¹ |
| agebox iKids-Growth Night Formula | Stimulate growth | Ibutamoren ¹ |
| FTX Plus | Joint pain | Dexamethasone, diclofenac |
| FLEXI BION | Joint pain | Dexamethasone, diclofenac |
| Me Vale Madre | Migraine, stress pain | Acetaminophen, diclofenac |
| REUMA KING | Joint pain | Dexamethasone, diclofenac, methocarbamol |
| SILANTAN | Joint pain | Meloxicam |

¹Ibutamoren (MK-677) is a growth hormone secretagogue that is not FDA approved. Serious side effects have included increased appetite, water retention, fatigue, muscle pain, alterations in glucose metabolism, insulin sensitivity, and increased potential for congestive heart failure. The long-term risks are not known.

New Product Shortages (per FDA or ASHP)

| | <u>Date Initially Posted</u> |
|---|-------------------------------------|
| Metyrosine capsules | 9/3/25 |
| Hydroxocobalamin solution for Intramuscular Injection | 9/8/25 |
| Ibandronate sodium injection | 9/15/25 |
| Acetazolamide injection | 9/22/25 |

[ASHP Drug Shortages List](#) contains up to-date information on drug shortages

Brand Name or Sole Source Product Discontinuations/Withdrawals

| | <u>Date Posted</u> |
|---|---------------------------|
| Obeticholic acid (Ocaliva, Intercept Pharmaceuticals): withdrawn from market, patients should be transitioned to alternative treatments for primary biliary cholangitis | 9/11/25 |
| Triazolam tablet (Halcion, Pfizer): generics remain available | 9/29/25 |
| Tafamidis meglumine capsule (Vyndaqel, Pfizer): tafamidis (Vyndamax) remains available | 9/29/25 |
| Oseltamivir phosphate capsule, 45 mg (Tamiflu, Genentech); generics remain available | 9/29/25 |

New Drug Approvals:

| <u>Description (See Attached Drug Summaries)</u> | <u>Date Approved</u> |
|---|-----------------------------|
| Elamipretide/Forzinity/Stealth BioTherapeutics | 9/19/25 |
| Imlunestran/Inlurio/Eli Lilly and Company | 9/25/25 |
| Paltusotine/Palsonify/Crinetics | 9/25/25 |
| Remibrutinib/Rhapsido/Novartis | 9/30/25 |

New Indications:

| <u>Description</u> | <u>Date Approved</u> |
|---|-----------------------------|
| Von Willebrand Factor (Recombinant)/Vonvendi/Takeda Pharmaceuticals | 9/5/25 |
| Selumetinib/Koselugo/AstraZeneca | 9/10/25 |
| Beremagene geperpavec-svdt/Vyjuvek/Krysal Biotech | 9/12/25 |
| Ruxolitinib/Opzelura/Incyte | 9/18/25 |
| Evinacumab-dgnb/Evkeeza/Regeneron Pharmaceuticals | 9/25/25 |

| <u>New Dosage Forms or Formulation:</u> | <u>Description</u> | <u>Date Approved</u> |
|--|--|-----------------------------|
| Bimatoprost/Zolymbus/Thea Pharma | Ophthalmic gel: 0.01% in single-dose containers; for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension | 9/9/25 |
| Gemcitabine/Inlexzo/Janssen Biotech | Intravesical system: 225 mg single-dose; treatment of adult patients with Bacillus Calmette-Guerin (BCG)-unresponsive, non-muscle invasive bladder cancer with carcinoma in situ, with or without papillary tumors | 9/9/25 |
| Selumetinib/Koselugo/AstraZeneca | Oral granules: 5 mg and 7.5 mg dose-unit; treatment of NF1 with symptomatic inoperable plexiform neurofibromas in pediatric patients at least 1 year of age | 9/10/25 |
| Bumetanide/Enbumyst/Corstasis Therapeutics | Nasal spray: 0.5 mg/0.1 mL unit dose; treatment of edema associated with congestive heart failure and hepatic and renal disease, including nephrotic syndrome, in adults; it is not intended for chronic use | 9/15/25 |
| Lamotrigine/Subvenite/OWP Pharmaceuticals | Suspension (prepared), 10 mg/ml strength; treatment for epileptic seizures (adjunctive), monotherapy for epilepsy, or bipolar disorder | 9/16/25 |
| Pembrolizumab and berahyaluronidase alfa/Keytruda Qlex/Merck Sharp & Dohme LLC | Injection, single-dose vial: pembrolizumab 395 mg and berahyaluronidase alfa 4800 units/2.4 mL and pembrolizumab 790 mg and berahyaluronidase alfa 9600 units/4.8 mL; indicated for subcutaneous administration by a healthcare provider | 9/19/25 |
| Clotrimazole/Clotic/Carwin Pharmaceutical Associates | Otic solution: 1% in single-dose vial (1.7 mg/0.17 mL); for the treatment of fungal otitis externa due to Aspergillus species and Candida species in adults, instilled twice daily for 14 days; not recommended for use in patients with perforated tympanic membranes | 9/26/25 |

Compiled by:

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| Elamipretide/Forzinity/Stealth BioTherapeutics | |
|---|---|
| Generic Name/Brand Name/Company | Elamipretide/Forzinity/Stealth BioTherapeutics |
| Date of approval | 9/19/25 |
| Drug Class (Mechanism of Action if novel agent) | Mitochondrial cardiolipin binder that localizes to the inner mitochondrial membrane and improves mitochondrial morphology and function |
| Indication | To improve muscle strength in patients with Barth syndrome weighing at least 30 kg |
| Comparative agent – Therapeutic interchange? | None |
| Dosage forms/strengths | Injection: 280 mg/3.5 mL (80 mg/mL) in single-patient use vial |
| Common Dose/sig | 40 mg subcutaneously once daily |
| DEA Schedule | N/A |
| Date of market availability | By the end of 2025 |
| Similar Medication Names | Forxiga |
| Clinical Use Evaluation | |
| Common Adverse Effects | Injection site reactions (100%): erythema (100%), pain (75%), induration (67%), pruritus (67%), bruising (25%), urticaria (25%) |
| Severe Adverse Effects | Serious hypersensitivity reactions |
| 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. | None |
| Used in Pediatric Areas | Indicated in pediatric patients weighing at least 30 kg |
| Renal or Hepatic Dosing | Reduce dose to 20 mg once daily in adults if eGFR less than 30 mL/min and not on dialysis. Insufficient information to recommend dosage for adults on dialysis or pediatric patients with renal impairment. No dosage adjustment in mild to moderate renal impairment or in hepatic impairment. |
| Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized | Contraindications: Serious hypersensitivity to elamipretide or any product ingredients Warnings: Benzyl alcohol toxicity: contains benzyl alcohol—avoid use in neonates Hypersensitivity reactions: if a serious reaction occurs do not administer further doses; mild to moderate reactions may be treated with topical corticosteroids and oral antihistamines |
| Special administration technique or considerations | Administer subcutaneously in the abdomen or outer thigh at the same time each day. Rotate injection sites daily. Discard vials 8 days after first opening. |
| Prepared by | Terri Levien, PharmD |
| Source | Forzinity (elamipretide) [prescribing information]. Needham, MA: Stealth BioTherapeutics Inc; September 2025. |

| Imlunestrant/Inluriyo/Eli Lilly and Company | |
|---|--|
| Generic Name/Brand Name/Company | Imlunestrant/Inluriyo/Eli Lilly and Company |
| Date of approval | 9/25/25 |
| Drug Class (Mechanism of Action if novel agent) | Endocrine therapy (estrogen receptor antagonist) |
| Indication | Adults with ER+, HER2-, ESR1-mutated advanced or metastatic breast cancer with disease progression after treatment with at least one endocrine therapy |
| Comparative agent – Therapeutic interchange? | Fulvestrant (Faslodex) |
| Dosage forms/strengths | Tablets: 200 mg |
| Common Dose/sig | 400 mg by mouth once daily |
| DEA Schedule | N/A |
| Date of market availability | Available |
| Similar Medication Names | Inlexzo, Inlyta, fulvestrant, Lunesta |
| Clinical Use Evaluation | |
| Common Adverse Effects | ≥10%: hemoglobin decrease, musculoskeletal pain, calcium decrease, neutrophil decrease, AST increase, fatigue, diarrhea, ALT increase, triglyceride increase, nausea, platelet decrease, constipation, cholesterol increase, abdominal pain |
| Severe Adverse Effects | Musculoskeletal pain, fatigue, diarrhea, nausea, abdominal pain, hemoglobin decreased, neutrophils decreased, platelets decreased, AST increased, ALT increased |
| Severe Drug-Drug Interactions | Strong CYP3A Inhibitors: avoid concomitant use or decrease imlunestrant dose if concomitant use cannot be avoided. Strong CYP3A Inducers: avoid concomitant use or increase imlunestrant dose if concomitant use cannot be avoided. Avoid P-gp or BCRP substrates as imlunestrant inhibits P-gp and BCRP. |
| Severe Drug-Food Interactions | Exposure and peak concentrations are increased; administration on an empty stomach is recommended |
| Important Labs Values to assess prior to order entry or at point of clinical follow up. | Pregnancy test prior to starting therapy. Select patient son basis of ER-positive, HER2-negative, and ESR1 mutation positive cancer. |
| Used in Pediatric Areas | Safety and efficacy have not been established in pediatric patients |
| Renal or Hepatic Dosing | Reduce dose in patients with moderate (Child Pugh B) or severe (Child Pugh C) hepatic impairment. No dosage adjustments are recommended in mild hepatic impairment or in renal impairment. |
| Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized | Contraindications: none in labeling Embryo-fetal toxicity: Advise females of reproductive potential and male partners of females of reproductive potential to use effective contraception during treatment and for 1 week after the last dose. Lactation: Advise patients not to breastfeed during treatment and for 1 week after the last dose. |
| Special administration technique or considerations | Take on an empty stomach, 2 hours before food or 1 hour after food. Swallow tablets whole. Pre/perimenopausal women and men should receive a GnRH agonist according to clinical practice standards. |
| Prepared by | Hayden Wesley |
| Source | Inluriyo (imlunestrant) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; September 2025. |

| Paltusotine/Palsonify/Crinetics | |
|---|---|
| Generic Name/Brand Name/Company | Paltusotine/Palsonify/Crinetics |
| Date of approval | 9/25/25 |
| Drug Class (Mechanism of Action if novel agent) | Somatostatin receptor agonist |
| Indication | Treatment of adults with acromegaly who had an inadequate response to surgery and/or for whom surgery is not an option |
| Comparative agent – Therapeutic interchange? | Pasireotide |
| Dosage forms/strengths | Tablets: 20 mg, 30 mg |
| Common Dose/sig | Initiate with 40 mg orally once daily (may be temporarily reduced to 20 mg daily based on tolerability); after 2 to 4 weeks, based on IGF-1 levels, titrate to 60 mg once daily |
| DEA Schedule | N/A |
| Date of market availability | Available |
| Similar Medication Names | Palovarotene |
| Clinical Use Evaluation | |
| Common Adverse Effects | >5%: diarrhea, abdominal pain, nausea, decreased appetite, sinus bradycardia, hyperglycemia, palpitations, gastroenteritis |
| Severe Adverse Effects | Cholelithiasis, cardiac conduction abnormalities |
| Severe Drug-Drug Interactions | Paltusotine dosage adjustments may be necessary when administered with strong or moderate CYP3A4 inducers or proton pump inhibitors. Cyclosporine dosage may require adjustment if coadministered. |
| Severe Drug-Food Interactions | Absorption reduced when administered with food; administration on an empty stomach (6 hours after and 1 hour before a meal) is recommended |
| Important Labs Values to assess prior to order entry or at point of clinical follow up. | Blood glucose, thyroid function (TSH, total, and/or free T ₄), vitamin B12 levels |
| Used in Pediatric Areas | Safety and efficacy not established in pediatric patients |
| Renal or Hepatic Dosing | No dosage adjustments in patients with hepatic or renal impairment |
| Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized | Contraindications: none in the labeling Warnings: Cholelithiasis and its complications: monitor Hyperglycemia and hypoglycemia: monitor glucose Cardiovascular abnormalities: bradycardia or conduction abnormalities Hypothyroidism: monitor Steatorrhea and malabsorption of fats Vitamin B12 deficiency: monitor levels |
| Special administration technique or considerations | Take on an empty stomach, at least 6 hours after a meal and at least 1 hour before the next meal. |
| Prepared by | Terri Levien |
| Source | Palsonify (paltusotine) [prescribing information]. San Diego, CA: Crinetics Pharmaceuticals Inc; September 2025. |

| Remibrutinib/Rhapsido/Novartis | |
|---|---|
| Generic Name/Brand Name/Company | Remibrutinib/Rhapsido/Novartis |
| Date of approval | 9/30/25 |
| Drug Class (Mechanism of Action if novel agent) | Bruton's tyrosine kinase inhibitor |
| Indication | Treatment of chronic spontaneous urticaria in adults who remain symptomatic despite H1 antihistamine treatment |
| Comparative agent – Therapeutic interchange? | Omalizumab, dupilumab |
| Dosage forms/strengths | Tablets: 25 mg |
| Common Dose/sig | 25 mg orally twice daily with or without food |
| DEA Schedule | N/A |
| Date of market availability | Available |
| Similar Medication Names | Rapaflo, remifentanyl |
| Clinical Use Evaluation | |
| Common Adverse Effects | Nasopharyngitis (11%), bleeding (9%), headache (7%), nausea (3%), abdominal pain (3%) |
| Severe Adverse Effects | None reported |
| Severe Drug-Drug Interactions | Avoid concomitant use with strong or moderate CYP3A4 inhibitors or inducers Monitor for more frequent adverse reactions with P-gp substrates Consider risks and benefits with concomitant antithrombotic agents |
| Severe Drug-Food Interactions | None known |
| Important Labs Values to assess prior to order entry or at point of clinical follow up. | None |
| Used in Pediatric Areas | Safety and efficacy not established |
| Renal or Hepatic Dosing | Avoid use in mild, moderate, or severe hepatic impairment. No dosage adjustment in mild, moderate, or severe renal impairment. |
| Critical Issues (i.e., contraindications, warnings, etc) that should be emphasized | No labeled contraindications Warnings: Risk of bleeding: monitor, interrupt therapy for 3-7 days pre- and post-surgery Avoid live or live attenuated vaccines |
| Special administration technique or considerations | Swallow tablets whole with water; may take with or without food. |
| Prepared by | Terri Levien |
| Source | Rhapsido (remibrutinib) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2025. |