January - March 2018 | Potential Signals of Serious Risks/New Safety Information Identified from the FDA Adverse Event Reporting System (FAERS)

Product Name: Trade (Active Ingredient) *or* Product Class	Potential Signal of a Serious Risk / New Safety Information	Additional Information (as of January 31, 2025)
• AccuNeb (albuterol sulfate) inhalation solution • Combivent Respimat (ipratropium bromide and albuterol) inhalation spray • DuoNeb (ipratropium bromide/albuterol sulfate) inhalation solution • ProAir HFA (albuterol sulfate) inhalation aerosol • Proair respiclick (albuterol sulfate) inhalation powder, for oral inhalation use • Proventil HFA (albuterol sulfate) aerosol • Ventolin HFA (albuterol sulfate) inhalation aerosol • Xopenex HFA (levalbuterol tartrate) inhalation aerosol, for oral inhalation use	Albuterol sulfate and serious skin reactions	FDA decided that no action is necessary at this time based on available information.
• Actemra (tocilizumab) injection • Arcalyst (rilonacept) injection • Ilaris (canakinumab) injection • Kevzara (sarilumab) injection • Kineret (anakinra) injection	IL-1 and IL-6 inhibitors and pulmonary hypertension, interstitial lung disease, pulmonary alveolar proteinosis	Updated FDA decided that no action is necessary at this time based on available information.

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HELSINN EXHIBIT 2080
Azurity Pharmaceuticals, Inc. v. Helsinn Healthcare S.A.
IPR2025-00949

Product Name: Trade (Active Ingredient) *or* Product Class	Potential Signal of a Serious Risk / New Safety Information	Additional Information (as of January 31, 2025)
Adempas (riociguat) tablets	Syncope	FDA decided that no action is necessary at this time based on available information.
• Ambien (zolpidem tartrate) tablets • Lunesta (eszopiclone) tablets • Sonata (zaleplon) capsules	Somnambulism, Abnormal Sleep-related event	Updated The "Boxed Warning", "Contraindications", "Warnings", "Precautions", "Warnings and Precautions", "Adverse Reactions", "Patient Counseling Information", and "Medication Guide" sections of the labeling were updated in February 2019 and August 2019 to include information about complex sleep behaviors. Example: Ambien labeling (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/019908s046lbl.pdf) An FDA Drug Safety Communication (https://www.fda.gov/drugs/drug-safety-and-availability/fda-adds-boxed-warning-risk-serious-injuries-caused-sleepwalking-certain-prescription-insomnia) was issued on April 30, 2019.
• Bosulif (bosutinib) tablets • Gleevec (imatinib mesylate) tablets • Iclusig (ponatinib) tablets • Sprycel (dasatinib) tablets • Tasigna (nilotinib) capsules	Thrombotic microangiopathy	Updated The "Adverse Reactions" section of the labeling was updated between August 2018 and November 2018 to include thrombotic microangiopathy. Example: Bosulif labeling (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/203341s015lbl.pdf)
Bridion (sugammadex) injection	Labeling confusion - total strength expression on vial obscured by peel-off sticker intended for syringe	Updated The Bridion applicant revised the peel-off label by moving it from the principal display panel to the side panel and vertically repositioned the barcode.
Bridion (sugammadex) injection	Laryngospasm	Updated FDA decided that no action is necessary at this time based on available information.
Bridion (sugammadex) injection	Bronchospasm	Updated FDA decided that no action is necessary at this time based on available information.

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Product Name: Trade (Active Ingredient) *or* Product Class	Potential Signal of a Serious Risk / New Safety Information	Additional Information (as of January 31, 2025)
• Carnitor (levocarnitine) injection • Carnitor (levocarnitine) oral solution • Carnitor (levocarnitine)tablets • Carnitor SF (levocarnitine) sugar-free oral solution	Hypersensitivity and anaphylaxis	The "Warnings" and "Adverse Reactions" sections of labeling were updated to include hypersensitivity reactions. Carnitor labeling (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/018948s028,019257s014lbl.pdf)
Insulin Pen Products • Apidra (insulin glulisine) injection • Basaglar (insulin glargine) injection • Fiasp (insulin aspart) injection • Humulin (human isophane insulin and human insulin) injectable suspension • Humalog (insulin lispro) injection • Lantus (insulin glargine) injection • Levemir (insulin detemir) injection • Novolog (insulin aspart) injection • Ryzodeg (insulin degludec and insulin aspart) injection • Soliqua (insulin glargine and lixisenatide) injection • Toujeo (insulin glargine) injection • Tresiba (insulin degludec) injection • Xultophy (insulin degludec and liraglutide) injection	Product use error – failure to remove inner needle cover	Updated An FDA Safety Communication was issued on September 27, 2018 (https://wayback.archive-it.org/7993/20201224130048/https:/www.fda.gov/medical-devices/safety-communications/caution-when-using-pen-needles-inject-medicines-fda-safety-communication) (http://www.fda.gov/about-fda/website-policies/website-disclaimer), cautioning patients, caregivers, and health care providers when using pen needles to inject medicines.

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Kinevac (sincalide) for injection	Anaphylaxis, anaphylactic shock, and other hypersensitivity reactions	The "Contraindications," "Warnings," and "Adverse Reactions" sections of labeling were updated to include anaphylaxis and hypersensitivity reactions. Kinevac labeling (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/017697s032lbl.pdf)
Lamictal (lamotrigine) tablets	Hemophagocytic lymphohistocytosis (HLH)	The "Warnings and Precautions" section of labeling has been updated to include hemophagocytic lymphohistocytosis. Lamictal labeling (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020241s057lbl.pdf) Lamictal Drug Safety Communication (/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-warns-serious-immune-system-reaction-seizure-and-mental-health) (April 25, 2018) (/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-warns-serious-immune-system-reaction-seizure-and-mental-health)
Ninlaro (ixazomib) capsules	Product packaging quantity issues (empty unit dose blister cells)	FDA decided that no action is necessary at this time based on available information.
• Noxafil (posaconazole) delayed-release tablets • Noxafil (posaconazole) injection • Noxafil (posaconazole) oral suspension • Sporanox (itraconazole) capsules • Sporanox (itraconazole) injection	Mineralocorticoid excess	Updated The "Adverse Reactions" section of the posaconazole labeling was updated in February 2019 to include pseudoaldosteronism. Noxafil labeling (https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/022003s025,205053s009,205596s008lbl.pdf) For itrazonazole, FDA decided that no action is necessary at this time based on available information.
Propylthiouracil tablets	Fatal cases of antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis	Updated The "Warnings," "Precautions," "Adverse Reactions," and "Medication Guide" sections of the propylthiouracil labeling were updated in September 2018 to include vasculitis. Propylthiouracil labeling (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/006188s026lbl.pdf)

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Product Name: Trade (Active Ingredient) *or* Product Class	Potential Signal of a Serious Risk / New Safety Information	Additional Information (as of January 31, 2025)
• Varubi (rolapitant) tablets • Varubi (rolapitant) injectable emulsion, for intravenous use	Infusion related and hypersensitivity reactions	Updated The Varubi applicant issued a Dear Health Care Provider letter to inform health care providers of the potential risk of anaphylaxis, anaphylactic shock and other serious hypersensitivity reactions associated with use of Varubi (rolapitant) injectable emulsion. Dear Health Care Provider letter (/media/110258/download) The Varubi applicant notified FDA that Varubi injectable emulsion was no longer marketed and requested that approval of the Varubi injectable emulsion application be voluntarily withdrawn. FDA withdrew approval for Varubi in the Federal Register effective January 22, 2021. Withdrawal of Approval (https://www.regulations.gov/document/FDA-2020-N-2272-0001)
Volumen (barium sulfate)	Name confusion with Voluven (hydroxyethyl starch)	Updated The Volumen manufacturer issued an information letter on February 14, 2018, to inform their customers of the potential risk of name confusion. The proprietary name was changed from Volumen to Neulumex (https://www.accessdata.fda.gov/spl/data/0c317cb8-036a-b89f-8049-0e4c38ceabd9/0c317cb8-036a-b89f-8049-0e4c38ceabd9.xml) to address the risk of name confusion.

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