February 2020 Drug Update

CastiaRx™ BELIEVE IN BETTER

New Drug Approvals

Approval Date	Label Name	Generic Name	Strength	Dosage Form	Use	Launch
01/31/2020	**Palforzia®**	peanut (arachis hypogaea) allergen powder-dnfp	0.5 mg 1 mg 10 mg 20 mg 100 mg	Capsule	Peanut Allergy	1/31/2020
01/31/2020	**Palforzia®**	Peanut (arachis hypogaea) allergen powder-dnfp	300 mg	Sachet	Peanut Allergy	01/31/2020

Newly Available Brand Drugs

Approval Date	Label Name	Generic Name	Strength	Dosage Form	Use	Launch
07/23/2019	**Ruxience®**	rituximab-pwr	100 mg/10 mL 500 mg/50 mL	Injection	Lymphoma	02/03/2020
02/20/2019	**Esperoct®**	antihemophilic factor (recombinant), glycopegylated-exei	500 units 1,000 units 1,500 units 2,000 units 3,000 units	Injection	Bleeding control	02/03/2020
01/23/2020	**Tazverik®**	tazemetostat	200 mg	Tablet	Sarcoma	02/04/2020
10/04/2019	Quzyttir®	cetirizine hcl	10 mg/mL	Injection	Antihistamine	02/04/2020
11/14/2019	Fetroja®	cefiderocol	1 g	IV Solution	Antibiotic	02/24/2020
03/12/2019	Trazimera®	trastuzumab-qyyp	420 mg	IV Solution	Breast and Gastric Cancer	02/24/2020

*Specialty medications are listed in **bold** type

First Time Generic Approvals

Label Name	Generic Name	Strength	Dosage Form	Use
Moxeza	moxifloxacin	0.5%	Ophthalmic Solution	Antibiotic

New Uses

Drug Name or Class	Previous Use	New Use
Trulicity (dulaglutide)	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	To reduce heart related risks in adults with or without established cardiovascular disease.
Nerlynx (neratinib)	For the extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer, to follow adjuvant trastuzumab-based therapy.	For use in adult patients in combination with capecitabine for advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 based regimens in the metastatic setting.
Invokamet, Invokamet XR (canagliflozin/metformin)	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus and to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease.	To reduce the risk of end-stage kidney disease, doubling of serum creatinine, cardiovascular death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria.

Safety Updates and Recalls

Drug Name or Class	Use	Description	Impact
Belviq®, Belviq XR®	Weight Loss	The FDA requested the withdrawal from the market because a safety clinical trial showed an increased occurrence of cancer.	Consumers should stop taking the medication and talk to their health care professional about alternatives. The

*Specialty medications are listed in **bold** type

			patient is to dispose of their medication at a drug take back location or in the household trash mixed with an unappealing substance.
phenytoin oral suspension USP, 125 mg/5 mL Taro Pharmaceuticals	Seizures	The reason for the recall is that product from two lots of phenytoin oral suspension may not re-suspend when shaken, as instructed for administration, which could result in under or overdosing.	Consumers with questions regarding this recall can contact Taro by calling 1-866-705-1553 or by e-mail at TaroPVUS@taro.com, Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.
ranitidine 150 mg tablets Amneal Pharmaceuticals, LLC	Stomach Acid Reducer	Voluntary recall of eleven lots due to the potential of N-Nitrosodimethylamine (NDMA) amounts above levels established by the FDA.	Consumers who have ranitidine tablets, USP which are being recalled should stop using the product or with questions regarding this recall can contact Inmar Pharmaceuticals Services by 800-967-5952 (option 1).

*Specialty medications are listed in **bold** type

References:

1. U.S. Food and Drug Administration. Novel Drug Approvals for 2020. Available at: https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2020. Updated February 27, 2020. Accessed February 27, 2020.
2. U.S. Food and Drug Administration. Drugs@FDA: FDA Approved Drug Products. Available at: https://www.accessdata.fda.gov/scripts/cder/daf/. Updated February 27, 2020. Accessed February 27, 2020.
3. U.S. National Library of Medicine. DailyMed. https://dailymed.nlm.nih.gov/dailymed/. Accessed February 27, 2020.
4. FDA requests the withdrawal of the weight-loss drug Belviq, Belviq XR (locaserin) from the market. U.S. FDA MedWatch. Available at: https://www.fda.gov/drugs/fda-drug-safety-podcasts/fda-requests-withdrawal-weight-loss-drug-belviq-belviq-xr-lorcaserin-market. Updated February 27, 2020. Accessed February 27, 2020.
5. Taro Pharmaceuticals U.S.A. Issues Voluntary Nationwide Recall of Phenytoin Oral Suspension USP, 125 mg/5 mL Due to Possible Underdosing or Overdosing. U.S. FDA MedWatch. Available at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/taro-pharmaceuticals-usa-issues-voluntary-nationwide-recall-phenytoin-oral-suspension-usp-125-mg5ml. Updated February 27, 2020. Accessed February 27, 2020.
6. American Health Packaging Issues Voluntary Nationwide Recall of Ranitidine Tablets, USP 150 mg, 100 Count Unit Dose Blisters Due to the Detection of N-nitrosodimethylamine (NDMA) Impurity. U.S. FDA MedWatch. Available at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/american-health-packaging-issues-voluntary-nationwide-recall-ranitidine-tablets-usp-150-mg-100-count?utm_campaign=FDA%20MedWatch%20Ranitidine%20Tablets%2C%20150%20mg%20by%20American%20Health%20Packaging&utm_medium=email&utm_source=Eloqua. Updated February 27, 2020. Accessed February 27, 2020.

*Specialty medications are listed in **bold** type