PERFORMRx℠

Drug Information Update

March 2022

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NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
Istodax	Romidepsin 10 mg/2 mL vial	Celgene/BMS	Treatment of cutaneous T-cell lymphoma (CTCL) in adult patients who have received at least one prior systemic therapy.
Erythrocin Lactobionate	Erythromycin lactobionate 500 mg vial	Hospira/Pfizer	Treatment of infections caused by susceptible strains of the designated organisms in the diseases listed in the prescribing information when oral administration is not possible or when the severity of the infection requires immediate high serum levels of erythromycin.
Lanoxin	Digoxin 62.5 mcg (0.0625 mg) tablet	Concordia	• Heart Failure in Adults • Heart Failure in Pediatric Patients • Atrial Fibrillation in Adults **see prescribing information for detailed description of indications.*
Revlimid	Lenalidomide 5 mg, 10 mg, 15 mg, 25 mg capsule	Celgene	• Multiple myeloma • Myelodysplastic syndromes • Mantle cell lymphoma • Follicular lymphoma • Marginal zone lymphoma **see prescribing information for detailed description of indications.*
Ozobax	Baclofen 5 mg/5 mL solution	Metacel	Treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. Ozobax may also be of some value in patients with spinal cord injuries and other spinal cord diseases.
Vimpat	Lacosamide 50 mg, 100 mg, 150 mg, 200 mg tablet	UCB Pharma	• Treatment of partial-onset seizures in patients 1 month of age and older • Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients 4 years of age and older
Zipsor	Diclofenac potassium 25 mg capsule	Assertio Therapeutics	For relief of mild to moderate acute pain in adult and pediatric patients 12 years of age and older.

NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description	Comments
Takhzyro 300 mg/2 mL (150 mg/mL) subcutaneous syringe	lanadelumab-flyo	New SC syringe presentation	New Dosage Form
Twyneo 0.1 %-3 % topical cream	Tretinoin/benzoyl peroxide	Combination tretinoin & benzoyl peroxide product	New Combination
citalopram 30 mg capsule	citalopram hydrobromide	New citalopram capsule form and strength	New Dosage Form and Strength
Moderna COVID-19 Booster 50 mcg/0.5 mL intramuscular suspension	covid-19 vacc,mrna(moderna)/pf	COVID-19 booster vaccine dose presentation	New Strength
Vasostrict 0.2 unit/mL, 0.4 unit/mL intravenous solution	vasopressin	New dose form and strength presentation	New Dosage Form and Strength
Talzenna 0.5, 0.75 mg capsule	talazoparib tosylate	New strength for dose reduction based on renal impairment	New Strength
Pyrukynd 20, 50 mg tablet	mitapivat sulfate	Pyruvate kinase activator; the first approved disease-modifying therapy for hemolytic anemia in adults with pyruvate kinase (PK) deficiency.	New Entity
Descovy 120 mg-15 mg tablet	emtricitabine/tenofov alafenam	HIV treatment, new strength due to new pediatric population approval	New Strength
Pyrukynd 5 mg tablet	mitapivat sulfate	Pyruvate kinase activator; the first approved disease-modifying therapy for hemolytic anemia in adults with pyruvate kinase (PK) deficiency.	New Entity
Pyrukynd 20 mg (7)-5 mg (7) tablets in a dose pack, 50 mg (7)-20 mg (7) tablets in a dose pack	mitapivat sulfate	Pyruvate kinase activator; the first approved disease-modifying therapy for hemolytic anemia in adults with pyruvate kinase (PK) deficiency.	New Entity

Drug Name	Generic Name	Description	Comments
Releuko 300 mcg/mL, 480 mcg/1.6 mL injection solution	filgrastim-ayow	Biosimilar Neupogen	Biosimilar to Neupogen
Releuko 300 mcg/0.5 mL, 480 mcg/0.8 mL subcutaneous syringe	filgrastim-ayow	Biosimilar Neupogen	Biosimilar to Neupogen
Carvykti 0.5x 10exp6 to 1x 10exp8 cell intravenous suspension	ciltacabtagene autoleucel	New CART immunotherapy for r/r multiple myeloma	New Entity
Herceptin 420 mg intravenous solution	trastuzumab	New Strength; no pricing. Genentech has never marketed this strength and it is not available. FDB added to drug file to identify reference biologic for biosimilars using new attributes.	New Strength; Genentech has never marketed this strength and it is not available. FDB added to drug file to identify reference biologic for biosimilars using new attributes
Ibsrela 50 mg tablet	tenapanor hcl	A sodium/hydrogen exchanger 3 inhibitor indicated for treatment of IBS-C in adults.	New Entity
Rezipres 4.7 mg/mL intravenous solution	ephedrine hcl	Used for clinically important hypotension occurring in the setting of anesthesia	New Route, Dosage Form and Strength
Korsuva 50 mcg/mL intravenous solution	difelikefalin acetate	IV kappa opioid receptor agonist indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD) in adults undergoing hemodialysis	New Entity
Vonjo 100 mg capsule	pacritinib citrate	A JAK2 inhibitor for treatment of intermediate or high-risk primary or secondary myelofibrosis with a platelet count below 50 × 109/L	New Entity

Drug Name	Generic Name	Description	Comments
Akovaz 25 mg/5 mL (5 mg/mL) intravenous syringe	ephedrine sulfate	New strength, dosage form (syringe), used for clinically important hypotension occurring in the setting of anesthesia	New Dosage Form and Strength
rilpivirine ER 900 mg/3 mL (300 mg/mL) IM suspension, extended release	rilpivirine	Component of Cabenuva	New Route, Dosage Form, and Strength; Component of Cabenuva
Megatope 0.5 mCi/mL to 1 mCi/mL intravenous solution	albumin, iodinated i-131	Diagnostic radiopharmaceutical	New Entity
Jeanatope 0.01 mCi/mL to 1 mCi/mL intravenous solution	albumin, iodinated i-125	Diagnostic radiopharmaceutical	New Entity
cabotegravir ER 400 mg/2 mL (200 mg/mL), 600 mg/3 mL (200 mg/mL) IM suspension, extended release	cabotegravir	Component of Cabenuva	New Strength; Component of Cabenuva
rilpivirine ER 600 mg/2 mL (300 mg/mL) IM suspension, extended release	rilpivirine	Component of Cabenuva	New Route, Dosage Form, and Strength; Component of Cabenuva
Antivert 25 mg chewable tablet	meclizine	branded RX version of generically available meclizine	New Branded form of generic product
Soaanz 20, 40, 60 mg tablet	torsemide	505(b)(2) approved torsemide loop diuretic	New Branded form of generic product
Loreev XR 1.5 mg capsule,extended release	lorazepam	Extended release lorazepam product, 505(b)(2) approval pathway	New Strength
Nexiclon XR 0.17 mg tablet,extended release	clonidine hcl	Re-launch; extended release clonidine for treatment of hypertension	Previous NDC obsolete since 10/24/2011

NEW INDICATIONS (EXISTING DRUGS)

†**Bolded** items reflect newly approved indication; ~~strikethrough~~ of removed indication/age limit/etc.

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
Jardiance	empagliflozin 10 mg, 25 mg tablets	Boehringer Ingelheim	A sodium-glucose co-transporter 2 (SGLT2) inhibitor indicated: • as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. • to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. • to reduce the risk of cardiovascular death ~~plus~~ **and** hospitalization for heart failure in adults with heart failure ~~and reduced ejection fraction~~.
Descovy	emtricitabine and tenofovir alafenamide 120 mg-15 mg, 200 mg-25 mg tablets	Gilead	HIV-1 treatment: • in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg. • in combination with other antiretroviral agents other than protease inhibitors that require a CYP3A inhibitor for the treatment of HIV-1 infection in pediatric patients weighing at least **14 kg and less than 35 kg** ~~25 kg and less than 35 kg~~. HIV-1 PrEP: • Indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex. Individuals must have a negative HIV-1 test immediately prior to initiating Descovy for HIV-1 PrEP.
Opdivo	nivolumab injection, 40 mg/4 mL, 100 mg/10 mL, 120 mg/12 mL, 240 mg/24 mL solution in single-dose vials	BMS Primary Care	Non-Small Cell Lung Cancer (NSCLC): • **adult patients with resectable (tumors ≥4 cm or node positive) non-small cell lung cancer in the neoadjuvant setting, in combination with platinum-doublet chemotherapy.**

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			Note: Opdivo has many other approved indications not mentioned here; see full prescribing information for details.
Lynparza	olaparib tablets, 150 mg, 100 mg	AstraZeneca	Breast cancer: • **For the adjuvant treatment of adult patients with deleterious or suspected deleterious gBRCAm human epidermal growth factor receptor 2 (HER2)-negative high risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.** *Note: Lynparza has many other approved indications not mentioned here; see full prescribing information for details.*

RECALLS

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
365 SKINNY High Intensity Capsules, 600 mg, 30-count bottle, BODY BALANCE INTERNACIONAL	Class I	Drugs	Lot 102-26, Exp Dec 2022	Marketed Without an Approved NDA/ANDA: FDA analysis found the product to be tainted with undeclared sibutramine, a previously approved drug that was withdrawn from the US market due to safety concerns.	Je Dois Lavoir LLC
PARAGARD T380A (intrauterine copper contraceptive), 1 unit per carton together with an insertion tuve and solid white rod in a Tyvek polyethylene pouch, Rx Only, Manufactured by Teva Women's Health Inc. a subsidiary of Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 51285-204-01	Class I	Drugs	Lot # 517001,Exp 1/2024	Non-sterility	CooperSurgical, Inc
HYDROmorphone HCl PF 10 mg/50 mL (0.2mg/mL) in NaCl, 50 mL in 50 mL Single Dose Syringe, Rx only, STAQ Pharma, Inc., Denver, CO 80239, NDC: 73177-0104-05.	Class I	Drugs	Lot Number: 21104221A, Expiration date: 05-22-2022	Labeling: Label Mix up; A limited number of syringes containing HYDROmorphone HCl PF were incorrectly labeled as Morphine Sulfate PF with lot number 21104221A	STAQ Pharma, Inc.
Morphine Sulfate PF 25 mg/25mL (1 mg/mL) in NaCl, 25 mL in 30 mL Single Dose Syringe, Rx only, STAQ Pharma, Inc., Denver, CO 80239, NDC: 73177-0105-04.	Class I	Drugs	Lot Number: 21104221A, Expiration date: 05-22-2022	Labeling: Label Mix up; A limited number of syringes containing HYDROmorphone HCl PF were incorrectly labeled as Morphine Sulfate PF with lot number 21104221A	STAQ Pharma, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
MAC DADDY RED Capsules, packaged in 10-count blisters per carton, ASIN B07TLDZLY2, UPC 742137 605191.	Class I	Drugs	Lot # 1230004, Exp. date 03/30/2024	Marketed Without An Approved NDA/ANDA: product was found to contain undeclared tadalafil and/or sildenafil, ingredients found in FDA approved products for the treatment of male sexual enhancement, making these unapproved drugs.	ABC Sales 1 Inc
MAC DADDY PURPLE Capsules, packaged in 10-count blisters per carton, ASIN B08Z63Z4QK, UPC 742137 605764.	Class I	Drugs	Lot # 1230005, Exp. date 03/30/2024	Marketed Without An Approved NDA/ANDA: product was found to contain undeclared tadalafil and/or sildenafil, ingredients found in FDA approved products for the treatment of male sexual enhancement, making these unapproved drugs.	ABC Sales 1 Inc
RED MAMMOTH capsules, 400 mg, packaged in 10-count blisters per carton, ASIN B00KA8FBNI, barcode X001ANE0I5.	Class I	Drugs	Lot # DK1027, Exp. 08/01/2023	Marketed Without An Approved NDA/ANDA: Product was found to contain undeclared sildenafil and tadalafil, ingredients found in FDA approved products for the treatment of male sexual enhancement, making this an unapproved drug.	Celebrate Today
THE RED PILL, EXTRA STRENGTH capsules, 800 mg, packaged in 10-count blisters packaged in a carton, ASIN B0847BSQQ5, Barcode X002G5GMJ1.	Class I	Drugs	Lot # 26436989, Exp. date 10/30/2023	Marketed Without An Approved NDA/ANDA: Product was found to contain undeclared tadalafil, an ingredient found in FDA approved products for the treatment of	Your Favorite Shop

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
				male sexual enhancement, making this an unapproved drug.	
HCG 6,000iu (lyo) Human Chorionic Gonadotropin Inj., For Sub-Q or IM Use Only, Not For IV Use, Vial, Rx Only, Compounded By: Revive Rx 3831 Golf Dr., Houston, TX 77018, NDC: 88888-1739-01.	Class I	Drugs	Lot: 631359 BUD: 05/01/2022	Non-sterility; bacterial contamination identified as Paenibacillus lautus.	Revive Rx LLC dba Revive Rx Pharmacy
RISE UP RED EDITION Capsules, 650 mg, 10-count blisters packaged in a carton, ASIN B08JCWG84D, barcode X002NI8PE1.	Class I	Drugs	Lot # 48658908, Exp. date 09/09/2023	Marketed Without An Approved NDA/ANDA: Product was found to contain undeclared tadalafil, an ingredient found in FDA approved products for the treatment of male sexual enhancement, making this an unapproved drug.	Positive Health
REVITADERM WOUND CARE GEL, (Benzalkonium Chloride in a gel containing transforming growth factor-b), 0.1%, packaged in 29.6 mL (1.0 FL OZ) bottles (NDC 63347-120-02) and 88.7 mL (3.0 FL OZ) tubes (NDC 63347-120-01), Blaine Labs Inc., Santa Fe Springs, CA 90670	Class I	Drugs	Lot/Batch #: BL 2844, Expiration date 2/19/2023	Microbial Contamination of Non-sterile Product; FDA analysis found the product to be contaminated with Bacillus cereus.	Blaine Labs Inc
NaturesPlus Advanced Therapeutics Glucosamine Chondroitin MSM Ultra Rx-Joint Cream, 4 oz tubes, Manufactured for NaturesPlus 548 Broadhollow Road, Melville, NY 11747, USA	Class II	Drugs	Product code 4929, Lot # 23622	MICROBIAL CONTAMINATION OF NON-STERILE PRODUCT: microbial contaminant identified as Pluralibacter gergoviae.	Organics Corporation of America DBA Ambix Laboratories
Moxifloxacin Ophthalmic Solution, USP 0.5% w/v, 3 mL bottle, Sterile, Rx Only, Distributed by: Aurobindo Pharma USA, Inc.,	Class II	Drugs	Lot#: CMF210001, CMF210003, CMF210004, Exp 6/2023	Failed impurities/degradation specifications -Out of Specification (OOS) results of 0.78% to 1.02%;	Aurobindo Pharma USA Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
East Windsor, NJ 08520, Made in India, NDC 65862-840-03				Spec NMT 0.1% for Other Single impurities	
Chlorthalidone Tablets USP 25 mg, Rx Only, 100 Tablets, Sun Pharma, Mfg. by: Fontida Bio Pharm Inc., 1100 Orthodox St. Philadephia, PA 19124, Dist. by: Sun Pharmaceutical Industries, Inc., Cranbury, NJ 08512, NDC 57664-648-88.	Class II	Drugs	Lot #: P0602, Exp. Date 03/2023	Foreign Matter identified as stainless steel microscopic wear particles mixed with punch lubricant oil and silicone particles from the dust cup	SUN PHARMACEUTICAL INDUSTRIES INC
Diazepam Oral Solution (Concentrate), 25 mg per 5 mL (5 mg/mL), 30 mL BOTTLE and DROPPER, Rx Only, Distributed by: Lannett Company, Inc., Philadelphia, PA 19136, NDC 0527-1768-36.	Class II	Drugs	Lot #: 2664A, 2664B, Exp. date 07/2022; 2874A, 2874B, Exp. date 01/2023	Failed Impurities/Degradation Specifications: Out of specification results for related substances.	Lannett Company, Inc.
Alprazolam Tablets, USP 0.25 mg, packaged in a) 100-count bottles (NDC 67253-900-10), b) 500-count bottles (NDC 67253-900-50), and c) 1000-count bottles (NDC 67253-900-11), Rx only, Distributed by: Par Pharmaceutical Chestnut Ridge, NY 10977	Class II	Drugs	Lot #: a) 19C003A, Exp. Date 03/2022; 19G002A, exp. date 07/2022; b) 19C004B, Exp. Date 03/2022; c) 19C048C, Exp. Date 03/2022	cGMP Deviations	ANI Pharmaceuticals, Inc.
Alprazolam Tablets, USP 0.5 mg, packaged in a) 100-count bottles (NDC 67253-901-10), b) 500-count bottles (NDC 67253-901-50), and c) 1000-count bottles (NDC 67253-901-11), Rx only, Distributed by: Par Pharmaceutical Chestnut Ridge, NY 10977	Class II	Drugs	Lot #: a) 19B029A, Exp. Date 02/2022; 19D021A, Exp. Date 04/2022. b) 19A087B, 19A088B, 19A089B, 19A090B, Exp. Date 02/2022; 19A086B, 19A091B, 19B019B, Exp. Date 02/2022. c) 19B020C, 19B021C, 19B027C, 19B028C, Exp. Date 02/2022, 19E056C,	cGMP Deviations	ANI Pharmaceuticals, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			19E057C, Exp. Date 05/2022; 19E059C, Exp. Date 06/2022 19G072C, Exp. Date 07/2022		
Alprazolam Tablets, USP 1.0 mg, packaged in a) 100-count bottles (NDC 67253-902-10), b) 500-count bottles (NDC 67253-902-50), and c) 1000-count bottles (NDC 67253-902-11), Rx only, Distributed by: Par Pharmaceutical Chestnut Ridge, NY 10977	Class II	Drugs	Lot #: a) 19B081A, Exp. Date 02/2022; 19E088A, 19E089A, Exp. Date 05/2022 b) 19A102B, Exp. Date 02/2022; 19D067B, 19D068B, Exp. Date 04/2022; 19D070C, Exp. Date 05/2022. c) 19F045C, 19F046C, Exp. Date 06/2022; 19B082C, 19B083C, Exp. Date 03/2022; 19D069C, Exp. Date 05/2022.	cGMP Deviations	ANI Pharmaceuticals, Inc.
Alprazolam Tablets, USP 2.0 mg, packaged in a) 100-count bottles (NDC 67253-903-10), b) 500-count bottles (NDC 67253-903-50), Rx only, Distributed by: Par Pharmaceutical Chestnut Ridge, NY 10977	Class II	Drugs	Lot #: a) 19C002A, Exp. Date 03/2022; 19E012A, 19E013A, Exp. Date 05/2022. b) 19C100B, Exp. Date 04/2022; 19E001B, 19E002B, Exp. Date 05/2022.	cGMP Deviations	ANI Pharmaceuticals, Inc.
Pyrazinamide Tablets, USP 500 mg, 100-count bottles, Rx only, Manufactured by: ULTRAtab Laboratories, Inc. Highland, NY 12528, Distributed by Par Pharmaceuticals, Chestnut Ridge, NY 10977, NDC 67253-660-10.	Class II	Drugs	Lot #: 19B064A, Exp. Date 03/2022	cGMP Deviations	ANI Pharmaceuticals, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Erythromycin Topical Gel USP, 2%, Net Wt 30 g tube, Rx only, Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310, Distributed by: McKesson Corporation, dba Sky Packaging, 4971 Southridge Blvd., Suite 101, Memphis, TN 38141, NDC 63739-053-66.	Class II	Drugs	Lot: 15724, Exp. 06/2022	Failed Impurities/Degradation Specifications: Lot not meeting specification for Unknown Max Related Compounds.	Teligent Pharma, Inc.
Acetaminophen Oral Suspension Grape Flavor, 160 mg per 5 mL, 16 fl oz (473 mL) per bottle, Distributed by Perrigo, Allegan, MI 49010. NDC: 50941-009-43	Class II	Drugs	Batch: 1AK1031, Exp 12/31/2022	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Children's Pain & Fever Bubblegum Flavored Acetaminophen Suspension (160mg/5ml), 4 fl oz (118 mL) per bottle, Distributed by: Wal-Mart Stores, Inc., Bentonville, AR 72716. NDC: 49035-313-26	Class II	Drugs	Batch: 1BK0784, Exp 12/31/2022; 1CK0997, 1CK1083, Exp 01/31/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Children's Grape Flavored Acetaminophen Oral Suspension (160mg/5ml), 4 FL OZ (118 mL) per bottle, Distributed by: Rugby Laboratories, 17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152. NDC: 0536-1321-97	Class II	Drugs	Batch: 1BK0960, Exp 12/31/2022	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Children's Cherry Flavored Acetaminophen Oral Suspension (160mg/5ml), 4 FL OZ (118 mL) per bottle, Distributed by Perrigo, Allegan, MI 49010. NDC: 45802-203-26	Class II	Drugs	Batch: 1GK0903, Exp 01/31/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Acetaminophen Child Strawberry Oral Suspension (160 mg/5 ml), 4 FL OZ (118 mL) per bottle, Distributed by: Walgreen Co.,	Class II	Drugs	Batch: 1DK0917, 1GK0905, Exp 01/31/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
200 Wilmot Rd., Deerfield, IL 60015. NDC: 0363-0971-26					
Acetaminophen Infant Dye Free Grape Oral Suspension (160mg/5ml), 2 FL OZ (59 mL) per bottle, Distributed by Target Corporation, Minneapolis, MN 55403. NDC: 11673-133-16	Class II	Drugs	Batch: 1CK0907, Exp 01/31/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Infant's Grape Flavored Acetaminophen Oral Suspension (160mg/5ml), 2 FL OZ (59 mL) per bottle, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895. NDC: 59779-946-16	Class II	Drugs	Batch: 1CK1276, 1FK1184, 1GK0821 and 1EK1046, Exp 02/28/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Acetaminophen Child Dye Free Cherry Flavor Oral Suspension (160mg/5ml), 4 FL OZ (118 mL) per bottle, DISTRIBUTED BY THE KROGER CO. CINCINNATI, OHIO 45202. NDC: 30142-818-26	Class II	Drugs	Batch: 1BK1045, Exp 12/31/2022	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Acetaminophen Child Dye Free Cherry Flavor Oral Suspension (160mg/5ml), 4 FL OZ (118 mL) per bottle, Distributed By Perrigo, Allegan, MI 49010. NDC: 0113-8959-26	Class II	Drugs	Batch: 1BK1045, Exp 12/31/2022	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Acetaminophen Child Dye Free Cherry Flavor Oral Suspension (160mg/5ml), 4 FL OZ (118 mL) per bottle, DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202. NDC: 30142-818-26	Class II	Drugs	Batch: 1BK1045, Exp 12/31/2022	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Acetaminophen Child Dye Free Cherry Flavor Oral Suspension (160mg/5ml), 4 FL OZ (118 mL) per bottle, DISTRIBUTED BY: Walmart	Class II	Drugs	Batch: 1BK1045, Exp 12/31/2022	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Inc., Bentonville, AR 72716. NDC: 49035-959-26					
Children's Grape Flavored Acetaminophen Oral Suspension (160mg/5ml), 4 FL OZ (118 mL) per bottle, DISTRIBUTED BY DOLGENCORP, LLC, 100 MISSION RIDGE, GOODLETTSVILLE, TN 37072. NDC: 55910-251-26	Class II	Drugs	Batch: 1CK1001, Exp 12/31/2022	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Children's Grape Flavored Acetaminophen Oral Suspension (160mg/5ml), 4 FL OZ (118 mL) per bottle, Distributed by Target Corp., Minneapolis, MN 55403 NDC: 11673-130-26	Class II	Drugs	Batch: 1CK1146, Exp 02/28/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Children's Grape Flavored Acetaminophen Oral Suspension (160mg/5ml), 4 FL OZ (118 mL) per bottle, Distributed by: Walmart, Inc., Bentonville, AR 72716. NDC: 49035-042-26	Class II	Drugs	Batch: 1BK0962, Exp 12/31/2022, 1CK0999, Exp 01/31/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Acetaminophen Child Strawberry Oral Suspension (160 mg/5 ml), 4 FL OZ (118 mL) per bottle, MADE WITH PRIDE & CARE FOR H-E-B SAN ANTONIO, TX 78204. NDC: 37808-759-26	Class II	Drugs	Batch: 1GK0905, Exp 01/31/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Acetaminophen Child Strawberry Oral Suspension (160 mg/5 ml), 4 FL OZ (118 mL) per bottle, Distributed by Target Corporation, Minneapolis, MN 55403. NDC: 11673-759-26	Class II	Drugs	Batch: 1FK1252, 1GK0905, Exp 01/31/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Acetaminophen Infant Dye Free Grape Oral Suspension (160mg/5ml), 2 FL OZ (59 mL) per bottle, DISTRIBUTED BY THE KROGER	Class II	Drugs	Batch: 1CK1274, Exp 02/28/2023	CGMP Deviations: Products were manufactured with contaminated	Perrigo Company PLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
CO., CINCINNATI, OHIO 45202. NDC: 30142-766-16				excipient that was recalled from the excipient supplier.	
Acetaminophen Infant Dye Free Grape Oral Suspension (160mg/5ml), 2 FL OZ (59 mL) per bottle, DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202. NDC: 30142-766-16	Class II	Drugs	Batch: 1CK1274, Exp 02/28/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Acetaminophen Infant Dye Free Grape Oral Suspension (160mg/5ml), 2 FL OZ (59 mL) per bottle, DISTRIBUTED BY: Wal-Mart Stores, Inc., Bentoneville, AR 72716. NDC: 49035-766-16	Class II	Drugs	Batch: 1CK1274, Exp 02/28/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Infant's Grape Flavored Acetaminophen Oral Suspension (160mg/5ml), 2 FL OZ (59 mL) per bottle, DISTRIBUTED BY: Wal-Mart Stores, Inc., Bentonville, AR 72716. NDC: 49035-946-16	Class II	Drugs	Batches: 1FK1027, 1FK1184, 1EK1046, Exp 02/28/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Acetaminophen Child Bubble Gum Flavored Oral Suspension (160 mg/5 ml), two 4 FL OZ (118 mL) bottles per pack, Distributed by Walmart Inc., Bentonville, AR 72716. NDC: 49035-313-26	Class II	Drugs	Batch: 1BK0794, Exp 12/31/2022, 1BK1035, Exp 01/31/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Children's Pain & Fever Acetaminophen, 160 mg per 5 mL Oral Suspension combo pack. DS SR APAP 160MG CHLD BBGM/DF CHRY/GRP. UPC: 3 70030 11637 9	Class II	Drugs	Batch: 1EV1874, Exp 11/02/2022	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Acetaminophen Child Bubble Gum Flavored Oral Suspension (160 mg/5 ml), 4 FL OZ (118 mL) per bottle, Distributed by Perrigo, Allegan, MI 49010. NDC: 11673-105-26	Class II	Drugs	Batch: 1CK0998, Exp 01/31/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Acetaminophen Child Bubble Gum Flavored Oral Suspension (160 mg/5 ml), 4 FL OZ (118 mL) per bottle, Distributed by Perrigo, Allegan, MI 49010. NDC: 0113-0020-26	Class II	Drugs	Batch: 1CK0963, Exp 12/31/2022	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Maximum Strength Plus Menthol No Drip Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY: AMAZON.COM SERVICES LLC 410 TERRY AVENUE N.SEATTLE, WA 98109. NDC: 72288-703-10	Class II	Drugs	Batch: 1FK1251, Exp 02/28/2023; 1BK0716, Exp 12/31/2022	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Severe Congestion Nasal Spray, No Drip Plus Menthol, Oxymetazoline HCl 0.05% Nasal Decongestant, 1 FL Oz (30 mL) per bottle, Packaged by Perrigo Company for: Big Lots Stores, Inc., P.O. Box 28523, Columbus, OH 43228-0523. NDC: 50594-719-10	Class II	Drugs	Batch: 1BK0827, Exp 12/31/2022	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Severe Congestion Nasal Spray, No Drip Plus Menthol, Oxymetazoline HCl 0.05%, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY FOODHOLD U.S.A., LLC, LANDOVER, MD 20785. NDC 41520-108-10	Class II	Drugs	Batch: 1BK0716, Exp 12/31/2022; 1FK1251, Exp 02/28/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Severe Congestion No Drip Nasal Spray Plus Menthol, Oxymetazoline HCl 0.05%, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY DOLGENCORP, LLC, 100 MISSION RIDGE, GOODLETTSVILLE, TN 37072. NDC 55910-511-10	Class II	Drugs	Batch: 1BK0716, Exp 12/31/2022); 1CK0899, Exp 01/31/2023; 1FK1163, Exp 01/31/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Severe Congestion Nasal Spray, No Drip Plus Menthol, Oxymetazoline HCl 0.05%, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY	Class II	Drugs	Batch: 1BK0716; Exp 12/31/2022); 1FK1251, Exp 02/28/2023	CGMP Deviations: Products were manufactured with contaminated	Perrigo Company PLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
FOODHOLD U.S.A., LLC, LANDOVER, MD 20785. NDC 41520-108-10				excipient that was recalled from the excipient supplier.	
Severe Congestion Nasal Spray, No Drip Plus Menthol, Oxymetazoline HCl 0.05%, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY: RITE AID, 30 HUNTER LANE, CAMP HILL, PA 17011. NDC 11822-6378-1	Class II	Drugs	Batch: 11BK0827, Exp 12/31/2022	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Severe Congestion Nasal Spray, No Drip Plus Menthol, Oxymetazoline HCl 0.05%, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY: BETTER LIVING BRANDS LLC, P.O. BOX 99, PLEASANTON, CA 94566-0009. NDC 21130-813-10	Class II	Drugs	Batch: 1BK0716, Exp 12/31/2022; 1FK1251, 1HK1196, Exp 02/28/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Severe Congestion Nasal Spray, No Drip Plus Menthol, Oxymetazoline HCl 0.05%, 1 FL Oz (30 mL) per bottle, Distributed by SUPERVALU INC., Eden Prairie, MN 55344 USA. NDC 41163-343-10	Class II	Drugs	Batch: 1FK1251, Exp 02/28/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Severe Congestion Nasal Spray, No Drip Plus Menthol, Oxymetazoline HCl 0.05%, 1 FL Oz (30 mL) per bottle, Dist. by Target Corp., Mpls., MN 55403. NDC 11673-935-10	Class II	Drugs	Batch: 1BK0912, Exp 12/31/2022; 1FK1251, Exp 02/28/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Severe Congestion Nasal Spray, No Drip Plus Menthol, Oxymetazoline HCl 0.05%, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY TOPCO ASSOCIATES LLC., ELK GROVE VILLAGE, IL 60007. NDC 36800-907-10	Class II	Drugs	Batch: 1BK0716, Exp 12/31/2022	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Maximum Strength No Drip Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant, 1 FL Oz (30 mL) per bottle,	Class II	Drugs	Batch: 1BK0964R, Exp 01/31/2023	CGMP Deviations: Products were manufactured with contaminated	Perrigo Company PLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
DISTRIBUTED BY: AMAZON.COM SERVICES LLC, 410 TERRY AVENUE N. SEATTLE, WA 9810. NDC 72288-388-10				excipient that was recalled from the excipient supplier.	
Maximum Strength No Drip Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY: AMAZON.COM SERVICES LLC, 410 TERRY AVENUE N. SEATTLE, WA 9810. NDC 72288-388-10	Class II	Drugs	Batch: 1BK0826, Exp 12/31/2022); 1BK0964R, Exp 01/31/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
No Drip Nasal Mist, Oxymetazoline HCl 0.05% Nasal decongestant, 1 FL Oz (30 mL) per bottle, Distributed by: CVS Pharmacy, Inc., One CVS Drive, Woonsocket, RI 02895. NDC 59779-388-10	Class II	Drugs	Batch: 1FK1164, Exp 01/31/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Maxiumum Strength No Drip Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY OLD EAST MAIN CO., 100 MISSION RIDGE, GOODLETTSVILLE, TN 37072. NDC 55910-623-10	Class II	Drugs	Batch: 1BK0826, Exp 12/31/2022); 1FK1232, 1BK0964, Exp 01/31/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Nasal Spray Decongestant, No Drip, Oxymetazoline HCl 0.05%, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202. NDC 30142-388-10	Class II	Drugs	Batch: 1BK0826, Exp 12/31/2022	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Soothing 12 Hour Nasal Decongestant Spray No Drip, Oxymetazoline HCl 0.05%, 1 FL Oz (30 mL) per bottle, Distributed By MAJOR PHARMACEUTICALS, 17177 N Laurel Park	Class II	Drugs	Batch: 1BK0826, Exp 12/31/2022; 1FK1164, Exp 01/31/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Drive, Suite 233 Livonia, MI 48152. NDC 0904-6761-30					
Maximum Strength No Drip Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant, 1 FL Oz (30 mL) per bottle, DIST. BY MEIJER DISTRIBUTION, INC., GRAND RAPIDS, MI 49544. NDC 41250-388-10	Class II	Drugs	Batch: 1FK1164, Exp 01/31/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Maximum Strength No Drip Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202. NDC 30142-388-10	Class II	Drugs	Batch: 1BK0826, Exp 12/31/2022	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Maximum Strength No Drip Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY: RITE AID, 30 HUNTER LANE, CAMP HILL, PA 17011. NDC 11822-6319-1	Class II	Drugs	Batch: 1BK0964, Exp 01/31/2023; 1FK1164, Exp 01/31/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
No Drip Nasal Decongestant, Oxymetazoline HCl 0.05%, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY: BETTER LIVING BRANDS LLC, P.O. BOX 99, PLEASANTON, CA 94566-0009. NDC 21130-801-10	Class II	Drugs	Batch: 1BK0964, Exp 01/31/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
No Drip Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant, 1 FL Oz (30 mL) per bottle, Distributed by SUPERVALU INC., Eden Prairie, MN 55344 USA. NDC 41163-703-10	Class II	Drugs	Batch: 1BK0964, Exp 01/31/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Maximum Strength No Drip Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202. NDC 30142-388-10	Class II	Drugs	Batch: 1BK0826, Exp 12/31/2022	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
No Drip Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY TOPCO ASSOCIATES LLC, ELK GROVE VILLAGE, IL 60007. NDC 36800-388-10	Class II	Drugs	Batch: 1FK1233, Exp 01/31/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
No Drip Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY: Walmart Inc., Bentonville, AR 72716. NDC 49035-388-10	Class II	Drugs	Batch: 1CK0897, 1FK1233, 1FK1232, Exp 01/31/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Sinus Severe, Oxymetazoline HCl 0.05% Nasal Decongestant with Menthol, 1 FL Oz (30 mL) per bottle, DISTRIBUTED BY DOLGENCORP, LLC., 100 MISSION RIDGE, GOODLETTSVILLE, TN 37072. NDC 55910-696-10	Class II	Drugs	Batch: 1BK0931, Exp 12/31/2022; 1CK0900, Exp 01/31/2023; 1HK1196, Exp 02/28/2023	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Maximum Strength Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant with Menthol, 1 FL Oz (30 mL) per bottle, DIST. BY MEIJER DISTRIBUTION, INC., GRAND RAPIDS, MI 49544. NDC 41250-989-10	Class II	Drugs	Batch: 1BK0716, Exp 12/31/2022	CGMP Deviations: Products were manufactured with contaminated excipient that was recalled from the excipient supplier.	Perrigo Company PLC
Maximum Strength Nasal Spray, Oxymetazoline HCl 0.05% Nasal Decongestant with Menthol, 1 FL Oz (30 mL)	Class II	Drugs	Batch: 1BK0716, Exp 12/31/2022	CGMP Deviations: Products were manufactured with contaminated	Perrigo Company PLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
per bottle, DIST. BY MEIJER DISTRIBUTION, INC., GRAND RAPIDS, MI 49544. NDC 41250-989-10				excipient that was recalled from the excipient supplier.	
Premium Nature Instant Hand Sanitizer, (ethyl alcohol 65%), plastic bottles packaged as (a) 2 OZ / 60ML, UPC 8 19192 02865 1; (b) 4 OZ, 118 ML, UPC 8 19192 02826 2; (c) 16 OZ, 473 ML, UPC 8 19192 02874 3; (d) 1 gallon, UPC 8 19192 02830 9; Premium Nature, South Plainfield, NJ.	Class II	Drugs	All lots within expiry and labelled as 'Made in the USA'	Subpotent Drug: FDA analysis has revealed some bottles of these products were sub potent for ethanol.	AMS Packaging Inc
Premium Nature Instant Hand Sanitizer, (ethyl alcohol 70%), plastic bottle packaged as (a) 8 OZ, UPC 8 19192 02866 8; (b) 16 OZ, UPC 8 19192 02874 3; Premium Nature, South Plainfield, NJ.	Class II	Drugs	All lots within expiry and labelled as 'Made in the USA'	Subpotent Drug: FDA analysis has revealed some bottles of these products were sub potent for ethanol.	AMS Packaging Inc
Methylphenidate Hydrochloride Chewable Tablets, 2.5 mg, 100-count bottle, Rx Only, Manufactured for: Rising Pharmaceuticals Inc., Saddle Brook, NJ 07863, NDC 64980-221-01	Class II	Drugs	lot# 25910009, Exp 01/2023	Failed Tablet Specifications: Recall of this drug product was voluntarily initiated by the manufacturer due to a market complaint, which stated that a tablet in the sealed bottle was twice larger in size when compared to the remaining tablets. This complaint is second of its kind.	RISING PHARMACEUTICALS
Prevantics (chlorhexidine gluconate and isopropyl alcohol) Maxi Swabstick, 3.15% w/v and 70% v/v, packaged as a) One Maxi Swabstick, 0.172 fl. Oz. (5.1 mL) Each in a pouch, 30 Individual Maxi Swabsticks per	Class II	Drugs	Lot #: a) 12000315, Exp Feb 2022; 12000700, Exp Mar 2022; 12001112 LE, Exp Jun 2022; 12001214, Exp Jul 2022; 12001362,	cGMP deviations: uncertainty of the adequacy of the validation of the test methods used to manufacture the products.	Professional Disposables International, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
carton, 10 boxes of 30 Individual Swabsticks per case, NDC 10819-4076-4, REORDER NO. S41950; b) One Maxi Swabstick, 0.172 fl. Oz. (5.1 mL) Each in a pouch, 300 Individual Swabsticks per case, NDC 10819-4076-3, REORDER NO. S27350; Professional Disposables International, Inc., Orangeburg, NY 10962-1376.			12001406, Exp Aug 2022; 12001628, Exp Sep 2022; 12001856, Exp Oct 2022; 12002103, Exp Dec 2022; 12002113, 12100024, Exp Jan 2023; 12100226, 12100227, Exp Feb 2023; 12100443, 12100503, Exp Mar 2023; 12100516, 12100517, Exp Apr 2023; 12100748, 12100756, Exp May 2023; b) 12001113 LE, Exp Jun 2022; 12001289, 12001240, Exp Jul 2022; 12002104, Exp Dec 2022; 12100025, Exp Jan 2023; 12100405, Exp Mar 2023; 12100674, Exp Apr 2023; 12100779, Exp May 2023		
Prevantics (chlorhexidine gluconate and isopropyl alcohol) Swab, 3.15% w/v and 70% v/v, packaged as a) One Swab, 0.034 fl. Oz. (1 mL) Each in a pouch, 100 Individual Swabs per carton, 10 boxes of 100 Individual Swabs per case, REORDER NO. B10800, NDC 10819-1080-1; b) One Swab, 0.034 fl. oz. (1 mL) Each in a pouch, 3000 Individual Swabs per case, REORDER NO. B11400, NDC 10819-1080-2; Professional Disposables	Class II	Drugs	Lot #: a) 12000165, 12000166, 12000382, Exp Feb 2022; 12000228, 12000381, 12000383, 12000577, 12000578, 12000579, 12000661, 12000662, Exp Mar 2022; 12000659, 12000660, Exp Apr 2022; 12001060, 12001061, 12001062,	cGMP deviations: uncertainty of the adequacy of the validation of the test methods used to manufacture the products.	Professional Disposables International, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
International, Inc., Orangeburg, NY 10962-1376.			12001100 LE, 12001101 LE, Exp Jun 2022; 12001233, 12001234, 12001235, 12001236, Exp Jul 2022; 12001351, 12001394, 12001395, 12001396, 12001397, 12001398, 12001399, Exp Aug 2022; 12001632,12001633, 12001634, 12001635, 12001636, Exp Sep 2022; 12001637, 12001638, 12001639, 12001640, 12001641, 12001721, 12001791, Exp Oct 2022; 12001792, 12001793, 12001794, 12001962, Exp Nov 2022; 12002039, 12002040, 12100014, 12100015, 12100016, 12100017, 12100035, 12100036, 12100037, 12100074, 12100183, 12100184, Exp Jan 2023; 12100018, 12100185, 12100186, 12100192, 12100193, 12100194, 12100195, 12100241, 12100242, 12100243,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			12100244, 12100245, 12100246, 12100247, 12100277, Exp Feb 2023; 12100312, 12100313, 12100347, 12100348, 12100349, Exp Mar 2023; 12100350, 12100351, 12100543, 12100638, Exp Apr 2023; 12100541, 12100542, 12100639, 12100732, 12100733, 12100753, 12100754, Exp May 2023; 12100755, 12100790, 12100791, 12100824, Exp Jun 2023; b) 12000194, 12000195, Exp Feb 2022; 12000500, 12000570, 12000594, 12000698, Exp Mar 2022; 12001058, 12001059, 12001069, 12001108 LE, 12001109 LE, 12001110 LE, Exp Jun 2022; 12001111 LE, 12001225, 12001226, 12001227, 12001228, 12001229, 12001230, Exp Jul 2022; 12001393, 12001522, Exp Aug 2022; 12001734, 12001735, 12001736,		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			12001737, Exp Oct 2022; 12001854, Exp Nov 2022; 12002033, 12002035, 12002045, 12002046, Exp Dec 2022; 12100019, 12100020, 12100021, 12100022, 12100096, 12100097, 12100098, 12100099, Exp Jan 2023; 12100196, 12100197, 12100251, 12100252, 12100253, 12100254, 12100255, 12100256, 12100257, 12100346, Exp Feb 2023; 12100363,12100364, 12100365, 12100366, Exp Mar 2023; 12100518, 12100519, 12100520, 12100521, Exp Apr 2023; 12100691, 12100693, Exp May 2023		
Prevantics (chlorhexidine gluconate and isopropyl alcohol) Swabstick, 3.15% w/v and 70% v/v, packaged as a) One Swabstick, 0.054 fl. oz. (1.6 mL) Each in a pouch, NDC 10819-4077-1; 50 Individual Swabsticks per carton, 10 boxes of 50 Individual Swabsticks per case, REORDER NO. S40750, NDC 10819-4077-4; b) One Swabstick, 0.054 fl. Oz. (1.6	Class II	Drugs	Lot #: a) 12000203, 12000204, Exp Mar 2022; 12001114 LE, Exp Jun 2022; 12001115 LE, 12001117 LE, Exp Jul 2022; 12001313, 12001407, 12001408, Exp Aug 2022; 12001498,	cGMP deviations: uncertainty of the adequacy of the validation of the test methods used to manufacture the products.	Professional Disposables International, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
mL) Each in a pouch, 500 Individual Swabsticks per case, REORDER NO. S32450, NDC 10819-4077-2; c) One Swabstick, 0.054 fl. Oz. (1.6 mL) Each in a pouch, 500 Individual Swabsticks per case, REORDER NO. S42850, NDC 10819-4077-3; Professional Disposables International, Inc., Orangeburg, NY 10962-1376.			12001499, 12001500, 12001629, 12001630, Exp Sep 2022; 12002070, 12002114, Exp Dec 2022; 12100106, 12100107, 12100223, Exp Feb 2023; 12100224, 12100225, 12100354, 12100513, Exp Mar 2023; 12100514, 12100515, 12100605, 12100628, Exp Apr 2023; 12100629, 12100630, Exp May 2023; b) 12000332, Exp Feb 2022; 12000484, Exp Mar 2022; 12001116 LE, Exp Jul 2022; 12001312, Exp Aug 2022; 12001730, Exp Oct 2022; 12002071, 12100105, Exp Jan 2023; 12100222, Exp Mar 2023; 12100635, 12100636, Exp Jun 2023; c) 12000728, Exp Apr 2022; 12001119 LE, Exp Jul 2022; 12001631, Exp Oct 2022; 12001811, Exp Nov 2022; 12002115, 12002116, Exp Jan 2023; 12100221, Exp Feb 2023; 12100633, Exp May 2023;		

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			12100634, 12100774, 12100817, Exp Jun 2023		
Lung Cleaner (saline eucalyptus) inhaler, 37 oz cans, Manufactured For: The Lung Cleaner LLC Boulder, CO 80302	Class II	Drugs	Lot #: 33748	cGMP deviations	Pharmasol Corporation
70% Isopropyl Alcohol First Aid Antiseptic with Wintergreen, 12 FL. OZ. 355 ML bottle, Distributed By: TSM Brands LLC, 540 Equinox LN, Manalapan, NJ 07726, www.tsmbrands.com, Made in Turkey, UPC 868275965765	Class II	Drugs	Lot#: 39,40,41,42,43,44 and 45	Labeling - product contains undeclared ethyl alcohol	Tsm Brands LLC
Luxury 70% Isopropyl Alcohol, 16 FL. OZ. (1PT) 473 ML bottle, Distributed by: TSM Brands LLC, 540 Equinox Ln, Manalapan, NJ 07726, UPC 868275965734.	Class II	Drugs	Lot#:339,340,341,342,343 ,344,345,346,347,348,349, 350,351,352,353,354,355, 356,357,358,359,360,361, 362,363,364,365,366,367, 368,369,370,371,372,373, 374,375,376,377,378,379, 380,381,382,383,384,385, 386,387,388,389,390,391, 392,393,394,395,396,397, 398 and 399	Labeling - product contains undeclared ethyl alcohol	Tsm Brands LLC
Amlodipine and Olmesartan Medoxomil Tablets, 10 mg /20 mg, 30-count bottles, Rx only, Manufactured for: Macleods Pharma USA, Inc., Plainsboro, NJ 08536, Manufactured by: Macleods Pharmaceuticals, Ltd, Baddi, Himachal Pradesh, INDIA, NDC 33342-192-07.	Class II	Drugs	Lot#: BAD62101A, Exp 2/2024	cGMP deviations	Macleods Pharma Usa Inc

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Olanzapine Tablets, USP 10 mg, 30-count bottles, Rx only, Manufactured for: Macleods Pharma USA , Inc. Plainsboro, NJ 08536, Manufactured by: Macleods Pharmaceuticals Ltd., Baddi, HImachal Pradesh, India, NDC 33342-070-07.	Class II	Drugs	Lot #: BOB42029A, BOB4202B, Exp. Date 09/2022	cGmp Deviations	Macleods Pharma Usa Inc
Dexamethasone Elixir, USP 0.5 mg/5 mL, Net: 8 fl oz (237 mL) bottle, Rx only, Manufactured By: Morton Grove Pharmaceuticals, Inc., Morton Grove, IL 60053, NDC 60432-466-08.	Class II	Drugs	Lot #s: UV1004, UV1005, Exp 6/22; UW1014, UW1015, Exp 1/23; UW1084, Exp 7/23	Failed Impurities/Degradation Specifications: higher than permissible levels of unknown impurities were found in the drug product.	Morton Grove Pharmaceuticals, Inc.
Moxifloxacin Ophthalmic Solution USP 0.5%, 3 mL, Packaged and Distributed By: Direct Rx Dawsonville, GA 30534 Dist. By Aurobindo Pharma USA, Inc. East Windsor, NJ 08520, NDC 72189-076-05	Class II	Drugs	Lot#: 18JA2218 Exp. 6/30/23; 20DE2104 Exp. 6/30/23; 08NO2111 Exp. 6/30/23	Failed impurities/degradation specifications	Direct Rx
Alprazolam Tablets, USP 1mg, Generic for Xanax, Pkg Size: a) 30 tablets per bottle, NDC: 68788-6381-03, b) 60 tablets per bottle, NDC: 68788-6381-06, c) 90 tablets per bottle, NDC: 68788-6381-09, Mfg: Par Pharmaceutical.	Class II	Drugs	Lot #s: a) G2919M, I0619O, F1419J; b) H3019Q; c) F1219N, F1919D, H0219D, I0519R, J0319G, Exp. 03/31/2022.	CGMP deviations	Preferred Pharmaceuticals, Inc.
All Over-The-Counter (OTC) drug products sold by Family Dollar retail stores located in Alabama, Arkansas, Louisiana, Mississippi, Missouri and Tennessee.	Class II	Drugs	All drug products sold by Family Dollar retail stores located in AL, AR, LA, MS, MO, and TN from January 1, 2021 to present.	CGMP Deviations: Potential exposure to rodents and rodent activity in the distribution center.	Dollar Tree Distribution, Inc.
HEB 50% Isopropyl Alcohol First Aid Antiseptic, packaged in 16 FL OZ 91 PT) 473 mL brown bottles with brown colored	Class II	Drugs	Lot: 0546089 Exp. 09/2023	Labeling: Label Mix-Up-The primary label on the front of the bottles have 50% Isopropyl	Vi-Jon, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
closures. Distributed by HEB San Antonio, TX 78204. UPC 0 41220 25111 7				Alcohol affixed to the containers. However, the product inside the bottle is Hydrogen Peroxide, Topical Solution USP with active ingredient Hydrogen Peroxide (stabilized) 3%, 32 FL Ounces. The back label is correct. Product is packaged in dark bottles.	
Zoster Vaccine Live	Class II	Biologics	9LH3Y	Vaccine, placed in glass vials found to have morphology defects, was distributed.	GlaxoSmithKline Biologicals SA
Oxycodone Hydrochloride Oral Solution, USP (C-II), 5 mg/5 mL, Delivers 5 mL per Cup, 1 Tray of 10 Cups, Rx Only, For Institutional Use Only, American Health Packaging, Columbus, OH 43217. UPC (01) 003 60687 406 40 4; Case NDC#: 60687-406-77, Unit Dose NDC#: 60687-406-40	Class II	Drugs	Lot# 1004276, Exp 11/30/2022	Impurity failure at 0-time of the repackaged lot.	American Health Packaging
PALIPERIDONE EXTENDED-RELEASE TABLETS, 9 mg, 100 Tablets per carton (10 x 10 blister packs), Rx only, Manufactured by: Sun Pharmaceutical Industries Ltd., Survey No. 259/15, Dadra-396 191, India. Distributed by: MAJOR PHARMACEUTICALS, 17177 N. Laurel Park Dr., Suite 233, Livonia, MI 48152. NDC: 0904-6937-61	Class II	Drugs	Lot #: N00522, Exp. Date 09/2022; N00618, Exp. Date 11/2022	Failed Dissolution Specifications	The Harvard Drug Group
Alprazolam C-IV 1 mg 60-count bottles, Rx Only, Dist. By: Par Pharmaceutical Chestnut Ridge, NY 10977 Packaged and Distributed	Class II	Drugs	Lot #: 19AU1910 Exp. 5/31/22	CGMP Deviations: The Recall is due to the potential cross-contamination at the contract	Direct Rx

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
By: Direct Rx Dawsonville, GA 30534, NDC 61919-836-60				manufacturer (Ultra Tab Laboratories Inc.)	
Alprazolam C-IV 2 mg, 60-count bottles, Rx Only, Dist. By: Par Pharmaceutical Chestnut Ridge, NY 10977 Packaged and Distributed By: Direct Rx Dawsonville, GA 30534, NDC 72189-0058-60	Class II	Drugs	Lot #: 07NO1901 Exp. 5/31/22	CGMP Deviations: The Recall is due to the potential cross-contamination at the contract manufacturer (Ultra Tab Laboratories Inc.)	Direct Rx
hydrALAZINE HCl Tablets, USP, 10 mg, 100 Tablets per carton (10x10 blister packs), Rx only, Distributed by: MAJOR PHARMACEUTICALS, Livonia, MI 48152 USA. NDC # 0904-6440-61	Class II	Drugs	Lot #: T03755, T03756, Exp. Date 03/2023	Failed Impurities/Degradation Specifications: Out of specification result obtained during routine stability testing for Impurities.	The Harvard Drug Group
0.9% Sodium Chloride Injection USP, 250 mL Excel Container, Rx only, B. Braun Medical Inc., Bethlehem, PA, NDC 0264-7800-20	Class II	Drugs	Lot #: J1E086, J1E204, J1E213, Exp 5/31/2023; J1H137, J1H138, Exp 6/30/2023	Lack of sterility assurance: leaking bags	B. Braun Medical, Inc.
Alprazolam Tablets, USP 1mg, 180-count bottles, Rx only, Manufactured by ULTRAlab Laboratories, Inc., NY; Packaged by GSMS, Inc., CA NDC 60429-504-18.	Class II	Drugs	Lot #: GS027852, Expiry: 06/2022.	CGMP Deviation: Potential cross-contamination with other drug substance during the manufacturing process.	Golden State Medical Supply Inc.
Hydromorphone HCl 2 mg/mL Infusion 250 mL bags, Rx only, Family Pharmacy of Statesville, Inc.	Class II	Drugs	Lot #: 07212020@4 BUD: 10/19/2020; 07212020@4 BUD: 10/30/2020	Lack of Assurance of Sterility	Family Pharmacy of Statesville
Hydromorphone HCl 1 mg/mL 250 mL bags, Rx only, Family Pharmacy of Statesville, Inc.	Class II	Drugs	Lot #: 07272020@2 BUD: 10/25/2020; 07302020@1 BUD: 10/28/2020; 08012020@1 BUD: 10/30/2020	Lack of Assurance of Sterility	Family Pharmacy of Statesville

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Hydromorphone HCl 5 mg/mL Infusion in 250 mL bags, Rx only, Family Pharmacy of Statesville, Inc.	Class II	Drugs	Lot #: 07292020@7 BUD: 8/12/2020	Lack of Assurance of Sterility	Family Pharmacy of Statesville
Hydromorphone HCl 0.1 mg/mL Infusion in 1000 mL bags, Rx only, Family Pharmacy of Statesville, Inc.	Class II	Drugs	Lot #: 08022020@1 BUD: 8/17/2020	Lack of Assurance of Sterility	Family Pharmacy of Statesville
Trimix (Alprostadil/Papaverine/Phentolamine) 20 mcg/30 mg/0.5 mg Injectable 5 mL vials, Rx only, Family Pharmacy of Statesville, Inc.	Class II	Drugs	Lot #: 07212020@ BUD: 9/4/2020	Lack of Assurance of Sterility	Family Pharmacy of Statesville
Trimix (Alprostadil/Papaverine/Phentolamine) 10 mcg/20 mg/1 mg Injectable 5 mL vials, Rx only, Family Pharmacy of Statesville, Inc.	Class II	Drugs	Lot #:07232020@1 BUD: 9/6/2020; 07282020@1 BUD: 9/11/2020; 07282020@2 BUD: 9/11/2020	Lack of Assurance of Sterility	Family Pharmacy of Statesville
Vancomycin14 mg/mL Fortified Ophthalmic Solution in 5 mL bottles, Rx only, Family Pharmacy of Statesville, Inc.	Class II	Drugs	Lot: 07312020@2 BUD: 9/14/2020	Lack of Assurance of Sterility	Family Pharmacy of Statesville
Morphine Sulfate 6 mg/mL Infusion in 250 mL bag, Rx only, Family Pharmacy of Statesville, Inc.	Class II	Drugs	Lot #: 07212020@3 BUD: 10/19/2020; 07292020@2 BUD: 10/27/2020	Lack of Assurance of Sterility	Family Pharmacy of Statesville
Ketamine 50 mg Infusion (LV 1) Solution in 250 mL bags, Rx only, Family Pharmacy of Statesville, Inc.	Class II	Drugs	Lot #: 07212020@1 BUD: 8/4/2020; 07232020@2 BUD: 8/6/2020; 07302020@2 BUD: 8/13/2020	Lack of Assurance of Sterility	Family Pharmacy of Statesville
Lorazepam 1 mg/mL Infusion Solution in 250 mL bags, Rx only, Family Pharmacy of Statesville, Inc.	Class II	Drugs	Lot #: 07312020@6 BUD: 8/7/2020	Lack of Assurance of Sterility	Family Pharmacy of Statesville

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Methylcobalamin 1 mg/mL Injectable in 1 mL syringes, Rx only, Family Pharmacy of Statesville, Inc.	Class II	Drugs	Lot #: 07282020@3 BUD: 8/11/2020	Lack of Assurance of Sterility	Family Pharmacy of Statesville
Fentanyl 150 mcg/mL Infusion Solution in 250 mL bags, Rx only, Family Pharmacy of Statesville, Inc.	Class II	Drugs	Lot #: 07312020@5 BUD: 8/14/2020	Lack of Assurance of Sterility	Family Pharmacy of Statesville
Sermorelin Acetate Lyophilized powder for reconstitution, Multi-Dose 9 mg per vial, Each ML contains: 5% Mannitol USP, Sterile Water for Injection USP, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0059-00	Class II	Drugs	Lots: D44026 Exp. 4/26/22; F42104 Exp. 6/4/22	Sub Potent	Olympia Compounding Pharmacy dba Olympia Pharmacy
NAD+ Nicotinamide Adenine Dinucleotide, Lyophilized powder for reconstitution, Multi-Dose 500 mg per vial, Each ML contains: 0.288% Sodium Phosphate Monobasic USP, 0.42% Sodium Phosphate Dibasic USP, 5% Mannitol USP, Sterile Water for Injection USP, Rx Only, Olympia Pharmaceuticals 6700 Conroy Rd., Ste. 155, Orlando, FL 32835 NDC: 73198-0083-00	Class II	Drugs	Lot: D24005 Exp. 4/5/22; C41008 Exp. 3/8/22	Product found to be Sub Potent or Exceeded reconstitution time	Olympia Compounding Pharmacy dba Olympia Pharmacy
Sincalide Lyophilized powder for reconstitution Each ML contains: Mannitol 170mg, Arginine 30mg, Lysine 15mg, Potassium Phosphate 9mg, Methionine 4mg, Edetate Disodium Dihydrate 2mg, Polysorbate mcg, Water for Injection, Multiple Dose Injection 5 mcg Vial, Rx Only, Olympia Compounding Pharmacy Compounded by: Olympia Pharmacy Conroy	Class II	Drugs	Lot: D24001 Exp. 4/1/22	Super Potent and Failed Reconstitution Time	Olympia Compounding Pharmacy dba Olympia Pharmacy

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Rd., Ste. 155, Orlando, FL 32835, NDC 73198-0082-00 Revised Label: Sincalide Lyophilized powder for reconstitution, 5mcg per multi dose vial, Each ML contains: 16.7% Mannitol, 3% Arginine, 1.5% Lysine, 0.9% Potassium Phosphate, 0.4% Methionine, 0.2% Edetate Disodium Dihydrate, 0.004% Sodium Metabisulfate, 0.0005% Polysorbate. Water for injection. Rx only, Olympia Pharmaceuticals NDC 73198-0082-00					
ROCK TOWN - DISTILLERY - HAND SANITIZER, Alcohol Antiseptic 70%, Topical Solution packaged in a) 375 mL (12.7 fl. oz.), NDC 74492-0002-1; b) 3785 mL/1 gallon NDC 74492-0002-2; c) 236 mL/8 oz. NDC 74492-0002-3; d) 473 mL/16 oz. NDC 74492-0002-4; Made in USA Rock Town Distillery, 1201 Main Street Little Rock, Arkansas 72202	Class II	Drugs	No lot number or expiration date.	CGMP Deviations: FDA analysis found product to contain acetal and acetaldehyde above specification limits.	Rock Town Distillery, Inc.
Norepinephrine Bitartrate Injection 4mg per 250 mL in 0.9% Sodium Chloride, 4 mg, 250 mL excel bag, Rx only, Athenex Pharma Solutions, LLC, Clarence, NY, 14031, NDC 76154-474-15	Class II	Drugs	Lot #: F2101628, F2101629, F2101630, F2101631, Exp 4/28/22; F2101632, F2101633, Exp 4/29/22; F2101795, F2101796, Exp 5/27/22	Defective container	Athenex Pharma Solutions, LLC
Norepinephrine Bitartrate Injection 16 mg per 250 mL added to 0.9% Sodium Chloride, 16 mg, 250 mL excel bag, Rx only, Athenex Pharma Solutions, LLC, Clarence, NY, 14031, NDC 76154-476-15	Class II	Drugs	Lot #: F2101634, Exp 3/30/22; F2101665, F2101666, Exp 4/02/22; F2101788, F2101789, Exp 4/26/22; F2101811,	Defective container	Athenex Pharma Solutions, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			F2101812, F2101815, Exp 4/29/22		
Norepinephrine Bitartrate Injection 8 mg per 250 mL in 0.9% Sodium Chloride, 8 mg, 250 mL excel bag, Rx only, Athenex Pharma Solutions, LLC, Clarence, NY, 14031, NDC 76154-475-15	Class II	Drugs	Lot #: F2101639, F2101642, F2101644, F2101645, Exp 4/30/22; F2101674, F2101675, F2101676, Exp 5/05/22; F2101790, F2101791, F2101792, F2101793, F2101794, Exp 5/26/22; F2101813, Exp 5/29/22	Defective container	Athenex Pharma Solutions, LLC
Phenylephrine HCl Injection 40 mg per 250 mL in 0.9% Sodium Chloride, 40 mg, 250 mL excel bag, Rx only, Athenex Pharma Solutions, LLC, Clarence, NY, 14031, NDC 76154-493-15	Class II	Drugs	Lot #: F2101651, Exp 5/30/22	Defective container	Athenex Pharma Solutions, LLC
Phenylephrine HCl Injection 50 mg per 250 mL in 0.9% Sodium Chloride, 50 mg, 250 mL excel bag, Rx only, Athenex Pharma Solutions, LLC, Clarence, NY, 14031, NDC 76154-494-15	Class II	Drugs	Lot #: F2101652, F2101653, Exp 5/30/22; F2200111, Exp 7/27/22	Defective container	Athenex Pharma Solutions, LLC
Phenylephrine HCl Injection in 0.9% Sodium Chloride, 20 mg, 250 mL excel bag, Rx only, Athenex Pharma Solutions, LLC, Clarence, NY, 14031, NDC 76154-491-15	Class II	Drugs	Lot #: F2101654, Exp 5/30/22; F2101834, Exp 7/03/22; F2200110, Exp 7/27/22	Defective container	Athenex Pharma Solutions, LLC
Epinephrine Injection 8 mg per 250 mL in 0.9% Sodium Chloride, 8mg, 250 mL excel bag, Rx only, Athenex Pharma Solutions, LLC, Clarence, NY, 14031, NDC 76154-814-15	Class II	Drugs	Lot #: F2101780, F2101781, Exp 6/21/22	Defective container	Athenex Pharma Solutions, LLC

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Betamethasone Dipropionate Lotion USP, 0.05%* (Augmented), packaged in a) 30 mL (29 grams) bottles, NDC 52565-023-29; b) 60 mL (58 grams) bottles, NDC 52565-023-59, Rx Only, Teligent Pharma, Inc., Buena, NJ 08310	Class II	Drugs	Batch: a) 15998, Exp. 3/31/2022; b) 16104, Exp. 4/30/2022; 16133, Exp. 5/31/2022; 16391, Exp. 8/31/2022; 15440, Exp. 9/30/2022	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Clobetasol Propionate Cream USP, 0.05%, packaged in a) 15 grams tube, NDC 52565-051-15; b) 30 grams tube, NDC 52565-051-30; c) 45 grams tube, NDC 52565-051-45; d) 60 grams tube, NDC 52565-051-60; Rx only, Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310.	Class II	Drugs	Batch: a) 15803, Exp. 7/31/2022; 16237, Exp. 11/30/2022; b) 15803, Exp. 7/31/2022; 16388, Exp. 2/28/2023; c) 15605, Exp. 7/31/2022; 16237, Exp. 11/30/2022; 16388, Exp. 2/28/2023; d) 15605, Exp. 7/31/2022; 15860, Exp. 8/31/2022; 16001, Exp. 9/30/2022; 16237, Exp. 11/30/2022; 16344, Exp. 1/31/2023; 16294, Exp. 2/28/2023; 16474, Exp. 2/28/2023; 16543, Exp. 2/28/2023.	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Clobetasol Propionate Cream USP, 0.05% (Emollient), packaged in a) 15 grams tube, NDC 52565-094-15; b) 30 grams tube, NDC 52565-094-30; c) 45 grams tube, NDC 52565-094-45; d) 60 grams tube, NDC 52565-094-60, Rx only, Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310.	Class II	Drugs	Batch: a) 15377, Exp. 3/31/2022; 15927, Exp. 9/30/2022; 16130, Exp. 11/30/2022; b) 15117, Exp. 2/28/2022; 16028, Exp. 9/30/2022; 16945, Exp. 5/31/2023; c) 15377, Exp. 3/31/2022; 15927,	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Exp. 9/30/2022; 16683, Exp. 5/31/2022; d) 15116, Exp. 2/28/2022; 15117, Exp. 2/28/2022; 16130, Exp. 11/30/2022; 16228, Exp. 11/30/2022; 16348, Exp. 1/31/2023		
Clobetasol Propionate Lotion, 0.05%, packaged in a) 2 fl. oz. (59 mL) bottles, NDC 52565-055-02; b) 4 fl. oz. (118 mL) bottles, NDC 52565-055-04, Rx Only, Manufactured by: Teligent Pharma, Inc., Buena, New Jersey 08310.	Class II	Drugs	Batch: a) 15599, Exp. 4/30/2022; 16108, Exp. 10/31/2022; 16471, Exp. 2/28/2023; 16680, Exp. 3/31/2023; b) 15120, 15126, 15592, Exp. 2/28/2022; 15599, Exp. 4/30/2022; 16108, 16145, Exp. 10/31/2022; 16261, Exp. 12/31/2022; 16456, 16471, Exp. 2/28/2023; 16552, 16680, Exp. 3/31/2023	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Clobetasol Propionate Ointment USP, 0.05%, packaged in a) 15 grams tube, NDC 52565-039-15; b) 30 grams tube, NDC 52565-039-30; c) 45 grams tube, NDC 52565-039-45; d) 60 grams tube, NDC 52565-039-60, Rx only, Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310.	Class II	Drugs	Batch: a) 15856, Exp. 8/31/2022; 17026, Exp. 6/30/2023; b) 15856, Exp. 8/31/2022; 17026, Exp. 6/30/2023; 17046, Exp. 6/30/2023; c) 15856, Exp. 8/31/2022; d) 15856, Exp. 8/31/2022; 17026, Exp. 6/30/2023	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Clobetasol Propionate Gel, 0.05%, packaged in a) 15 grams tube, NDC 52565-082-15; b) 30 grams tube, NDC 52565-082-30; c) 60 grams tube, NDC 52565-082-60, Rx Only, Teligent Pharma, Inc., Buena, NJ 08310.	Class II	Drugs	Batch: a) 15063, Exp. 2/28/2022; 15928, Exp. 9/30/2022; 16432, Exp. 2/28/2023; 16769, Exp. 4/30/2023; b) 15243, Exp. 2/28/2022; 16628, Exp. 3/31/2023; c) 15064, 15286, 15287, Exp. 2/28/2022; 16173, Exp. 11/30/2022; 16628, Exp. 3/31/2023	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Desonide Ointment, 0.05%, packaged in a) 15 g tubes, NDC 52565-038-15; b) 60 g tubes, NDC 52565-038-60, Rx Only, Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310.	Class II	Drugs	Batch: a) 15495, Exp. 4/30/2022; 16955, Exp. 5/31/2023; b) 15249, 15250, 15446, Exp. 3/31/2022; 15495, Exp. 4/30/2022; 16377, Exp. 1/31/2023	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Desoximetasone Ointment USP, 0.05%, Net Wt. 100 grams tubes, Rx only, Manufactured for: SOLA Pharmaceuticals, Baton Rouge, LA 70810, NDC 70512-037-10.	Class II	Drugs	Batch: 15996, 15997, Exp. 9/30/2022	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Desoximetasone Ointment USP, 0.05%, packaged in a) 100 grams tubes, NDC 52565-045-99; b) 60 grams tubes, NDC 52565-045-60, Rx only, Manufactured by: Teligent Pharma, Inc., Buena, New Jersey 08310.	Class II	Drugs	Batch: a) 15196, Exp. 2/28/2022; 16605, Exp. 3/31/2023; b)15190, Exp. 2/28/2022; 16660, Exp. 4/30/2023; 17037, Exp. 6/30/2023; 17163, Exp. 8/31/2023	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Desoximetasone Ointment USP, 0.25%, packaged in a) 100 grams tubes, NDC 52565-030-99; b) 60 grams tubes, NDC 52565-030-60; c) 15 grams tubes, NDC 52565-030-15, Rx Only, Teligent Pharma, Inc., Buena, New Jersey 08310.	Class II	Drugs	Batch: a) 15496, Exp. 4/30/2022; 16347, Exp. 1/31/2023; b) 15496, Exp. 4/30/2022; 16298, Exp. 1/31/2023; c) 15496, Exp. 4/30/2022; 16298, Exp. 1/31/2023	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Diclofenac Sodium Topical Solution USP, 1.5% w/w, 5 fl. oz. (150 mL) bottle, Rx only, Teligent Pharma, Inc., Buena, New Jersey 08310, NDC 52565-002-05.	Class II	Drugs	Batch: 15066, 15389 Exp. 3/31/2023; 15437, Exp. 12/31/2023; 16823, Exp. 4/30/2024; 16825, 16826, Exp. 4/30/2024	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Diclofenac Sodium Topical Solution USP, 1.5% w/w, 5 fl. oz. (150 mL) bottles, Rx Only, Manufactured for: SOLA Pharmaceuticals, Baton Rouge, LA 70810, NDC 70512-025-05.	Class II	Drugs	Batch: 15384, Exp. 3/31/2023; 15646, Exp. 5/31/2023; 15971, Exp. 9/30/2023; 16206, 16226, Exp. 11/30/2023; 16268, Exp. 12/31/2023; 16342, 16343, Exp. 1/31/2024; 16503, 16504, Exp. 3/31/2024; 16632, Exp. 4/30/2024; 16715, 16731, Exp. 5/31/2024	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Diflorasone Diacetate Ointment USP, 0.05%, Net Wt 60 g tubes, Rx only, Manufactured for: SOLA Pharmaceuticals, LLC Baton Rouge, LA 70809, NDC 70512-031-60.	Class II	Drugs	Batch: 15800, Exp. 7/31/2022; 15876, 15904, 15917, 15922, Exp. 8/31/2022; 16202, 16203, Exp. 11/30/2022.	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Econazole Nitrate Cream, 1%, packaged in a) 15 grams tubes, NDC 52565-022-15; b) 85	Class II	Drugs	Batch: a) 16410, 16438, Exp. 1/31/2023; 16882,	cGMP deviations: all products within expiry are being recalled	Teligent Pharma, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
grams tubes, NDC 52565-022-85; c) 30 grams tubes, NDC 52565-022-30, Rx Only, Manufactured by: Teligent Pharma, Inc., Buena, New Jersey 08310.			Exp. 4/30/2023; b) 15349, Exp. 2/28/2022; 16410, 16438, Exp. 1/31/2023; 16882, Exp. 4/30/2023; c) 16410, 16438, Exp. 1/31/2023	because the firm is discontinuing its stability study program.	
Fluocinonide Cream USP, 0.1%, 120 grams tube, Rx Only, Manufactured by: Teligent Pharma, Inc., Buena, New Jersey 08310, NDC 52565-079-11.	Class II	Drugs	Batch: 15288, Exp. 3/31/2022; 16065, Exp. 10/31/2022; 16430, 16431, Exp. 2/28/2023; 16675, Exp. 3/31/2023	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Fluocinonide Gel USP, 0.05%, packaged in a) 15 g tubes, NDC 52565-054-15; b) 60 g tubes, NDC 52565-054-60; c) 30 g tubes, NDC 52565-054-30, Rx Only, Teligent Pharma, Inc., Buena, NJ 08310.	Class II	Drugs	Batch: a) 15122, Exp. 2/28/2022; 15475, Exp. 3/31/2022; b) 15119, Exp. 2/28/2022; 15122, Exp. 2/28/2022; 15380, Exp. 3/31/2022; c) 15380, Exp. 3/31/2022	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Fluocinonide Topical Solution USP, 0.05%, packaged in a) 20 mL bottles, NDC 52565-025-20; b) 60 mL bottles, NDC 52565-025-59, Rx only, Teligent Pharma, Inc., Buena, New Jersey 08310.	Class II	Drugs	Batch: 17138, Exp. 2/28/2023	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Gentamicin Sulfate Cream USP, 0.1%, packaged in a) 15 g tubes, NDC 52565-085-15, b) 30 g tubes, NDC 52565-085-30, Rx Only, Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310.	Class II	Drugs	Batch: a) 15342, 15343, 16686, Exp. 3/31/2023; b) 15259, 15260, Exp. 3/31/2022; 15282, Exp. 4/30/2022; 15283, Exp. 5/31/2022; 15725, 15745,	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			15764, Exp. 6/30/2022; 16066, Exp. 10/31/2022		
Gentamicin Sulfate Ointment USP 0.1%, packaged as a) 15 grams tube, NDC 52565-090-15; b) 30 grams tube, NDC 52565-090-30, Rx Only, Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310.	Class II	Drugs	Batch: a) 16878, 16912, Exp. 5/31/2023; b)16878, Exp. 5/21/2023	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Halobetasol Propionate Ointment, 0.05%, Net Wt. 50 grams tube, Rx only, Manufactured for: SOLA Pharmaceuticals, Baton Rouge, LA 70809, NDC 70512-033-50.	Class II	Drugs	Batch: 15128, Exp. 2/28/2022; 15721, Exp. 6/30/2022; 16171, Exp. 10/31/2022; 16819, Exp. 4/30/2023; 17124, Exp. 7/31/2023	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Halobetasol Propionate Ointment, 0.05%, packaged as a) 15 g tubes, NDC 52565-073-15; b) 50 g tubes, NDC 52565-073-51, Rx Only, Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310.	Class II	Drugs	Batch: a) 15280, Exp. 2/28/2022; 16539, Exp. 3/31/2023; 16907, Exp. 5/31/2023; b) 15381, Exp. 3/31/2022; 15382, 15501, 15523, Exp. 4/30/2022; 15812, Exp. 7/31/2022; 15972, 16034, 16037, Exp. 9/30/2022; 16105, 16143, Exp. 10/31/2022; 16539, 16746, 16747, Exp. 3/31/2023; 16906, Exp. 5/31/2023; 16962, 17041, Exp. 6/30/2023; 17110, Exp. 7/31/2023	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Hydrocortisone Butyrate Lotion 0.1%, 4 fl. oz. (118 mL) bottle, Rx only, Distributed by: Mayne Pharma, Greenville, NC 27834, NDC 51862-159-04.	Class II	Drugs	Batch: 15435, Exp. 3/31/2022; 16960, Exp. 5/31/2023	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Halobetasol Propionate Ointment, 0.05%, Net Wt. 50 grams tube, Rx Only, Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310, Distributed by: McKesson Corporation, dba Sky Packaging, 4971 Southridge Blvd., Suite 101, Memphis, TN 38141, NDC 63739-998-67.	Class II	Drugs	Batch: 15720, Exp. 6/30/2022; 16449, 16450, Exp. 2/28/2023	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Hydrocortisone Butyrate Lotion, 0.1%, packaged in a) 2 fl oz (59 mL) bottles, NDC 52565-087-02; b) 4 fl oz (118 mL) bottles, NDC 52565-087-04, Rx only, Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310.	Class II	Drugs	Batch: a) 16293, Exp. 1/31/2023; 16436, 16451, Exp. 2/28/2023; b) 15105, Exp. 2/28/2022; 15290, 15291, 15292, Exp. 3/31/2022; 16293, Exp. 1/31/2023; 16436, 16451, 16472, Exp. 2/28/2023	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Lidocaine Cream, 4%, packaged in a) Net Wt. 15 grams tubes, NDC 52565-122-15; b) Net Wt. 30 grams tubes, NDC 52565-122-30; c) 5 x 5 gram tubes, NDC 52565-122-07; Manufactured by: Teligent Pharma, Inc. Buena, New Jersey 08310; Manufactured by: Teligent Pharma, Inc., Buena, New Jersey 08310.	Class II	Drugs	Batch: a) 15192, Exp. 2/28/2022; 16278, Exp. 1/31/2023; b) 15124, 15192, Exp. 2/28/2022; 15296, 15336, 15337, 15439, Exp. 3/31/2022; 16278, Exp. 1/31/2023; 16603, 16664, Exp. 3/31/2023;17023, Exp. 6/30/2023; c) 15067, Exp.	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			2/28/2022; 16664, Exp. 3/31/2023		
Lidocaine Ointment USP, 5%, Net Wt 35.44 g (1 1/4 oz) tube, Rx Only, Teligent Pharma, Inc., Buena, New Jersey 08310, NDC 52565-008-14.	Class II	Drugs	Batch: 16389, Exp. 2/29/2024; 16452, Exp. 2/29/2024	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Nystatin and Triamcinolone Acetonide Ointment, USP, packaged in a) 15 grams tubes, NDC 52565-042-15; b) 30 grams tubes, NDC 52565-042-30; c) 60 grams tubes, NDC 52565-042-60, Rx Only, Manufactured by: Teligent Pharma, Inc., Buena, NJ 08310.	Class II	Drugs	Batch: a) 15125, Exp. 2/28/2022; 15385, Exp. 3/31/2022; 15613, Exp. 5/31/2022; 16027, Exp. 9/30/2022; 16204, Exp. 11/30/2022; 16376, Exp. 1/31/2023; 16707, Exp. 3/31/2023; b) 15385, Exp. 3/31/2022; 15752, Exp. 6/30/2022; 15346, Exp. 9/30/2022; 16188, Exp. 11/30/2022; 16567, Exp. 2/28/2023; 16730, Exp. 4/30/2023; c)15752, Exp. 6/30/2022; 16188, Exp. 11/30/2022	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Triamcinolone Acetonide Ointment USP, 0.5%, Net Wt. 15 grams tube, Rx Only, Teligent Pharma, Inc., Buena, New Jersey 08310, NDC 52565-048-15.	Class II	Drugs	Batch: 15608, Exp. 5/31/2022; 16026, Exp. 9/30/2022; 16224, Exp. 11/30/2022	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Triamcinolone Acetonide Cream USP, 0.1%, packaged in a) 15 grams tubes, NDC 52565-056-15; b) 30 grams tubes, NDC 52565-056-30; c) 80 grams tubes, NDC 52565-056-80, d)	Class II	Drugs	Batch: a) 15123, Exp. 2/28/2022; 15875, Exp. 8/31/2022; 16115, Exp. 10/31/2022; b) 15123,	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
1 lb (454 g) jars, NDC 52565-056-26; Rx Only, Teligent Pharma, Inc., Buena, New Jersey 08310.			15201, Exp. 2/28/2022; 15477, Exp. 4/30/2022; 15897, Exp. 8/31/2022; 16090, Exp. 10/31/2022; 16374, Exp. 1/31/2023; 16676, Exp. 3/31/2023; 17109, Exp. 7/31/2023; c) 15241, Exp. 2/28/2022; 16610, Exp. 3/31/2023; d) 15121, 15127, 15191, 15201, 15278, Exp. 2/28/2022;15386, 15567, Exp. 4/30/2022; 15875, Exp. 8/31/2022; 16050, 16051, 16115, Exp. 10/31/2022; 16165, 16201, Exp. 11/30/2022; 16609, 16610, 16624, Exp. 3/31/2023; 16700, Exp. 4/30/2023; 16732, Exp. 5/31/2023; 17081, 17108, Exp. 7/31/2023		
Triamcinolone Acetonide Lotion USP, 0.025%, 60 mL (60 grams) bottle, Rx only, Teligent Pharma, Inc., Buena, New Jersey 08310, NDC 52565-010-59.	Class II	Drugs	Batch: 14796, Exp. 12/31/2022; 14797, Exp. 1/31/2023; 14534, 15571, 15572, Exp. 4/30/2023; 15746, 15756, Exp. 6/30/2023; 15982, Exp. 9/30/2023; 16043, 16144, 16149, Exp. 10/31/2023;	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			16433, 16434, Exp. 2/29/2024; 16656, 16679, Exp. 3/31/2024; 16784, Exp. 5/31/2024		
Triamcinolone Acetonide Ointment USP, 0.1%, packaged in a) 15 grams tubes, NDC 52565-014-15; b) 80 grams tubes, NDC 52565-014-80; c) 1 lb (454 g) jars, NDC 52565-014-26; Rx only, Teligent Pharma, Inc., Buena, New Jersey 08310.	Class II	Drugs	Batch: a) 15000, Exp. 1/31/2023; 15591, Exp. 4/30/2023; 15946, Exp. 9/30/2023; b) 14674, Exp. 11/30/2022; 14760, 14798, Exp. 12/31/2022; 14896, Exp. 1/31/2023; 15000, Exp. 1/31/2023; 15591, Exp. 4/30/2023; 15802, 15833, Exp. 7/31/2023; 15872, Exp. 8/31/2023; 15946, Exp. 9/30/2023; 16069, Exp. 10/31/2023; 16199, Exp. 11/30/2023; 16429, Exp. 2/29/2024; 16608, 16712, Exp. 3/31/2024; 17080, Exp. 7/31/2024; c)15065, Exp. 2/28/2023; 15072, Exp. 2/28/2023; 15436, Exp. 3/31/2023; 15810, Exp. 7/31/2023; 15877, Exp. 8/31/2023; 15974, Exp. 9/30/2023; 16045, Exp. 10/31/2023; 16269, Exp. 12/31/2023; 16270,	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
			Exp. 12/31/2023; 16566, Exp. 3/31/2024; 16713, Exp. 3/31/2024; 17042, Exp. 6/30/2024; 17068, Exp. 7/31/2024		
Clobetasol Propionate Cream USP, 0.05%, packaged in 60 grams tube, Rx only, Manufactured for SOLA Pharmaceuticals, Baton Rouge, LA 70809; NDC 70512-028-60.	Class II	Drugs	Batch: 16001 Exp. 9/30/2022; 16089 Exp. 11/30/2022	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Diflorasone Diacetate Ointment USP, 0.05%, Net Wt 60 g tubes, Rx only, Manufactured by: Teligent Pharm, Inc., Buena, New Jersey 08310, NDC 52565-063-60.	Class II	Drugs	Batch: 15876, Exp 8/31/2022; 16205, Exp. 11/30/2022	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Gentamicin Sulfate Cream USP, 0.1%, packaged in 30 grams tubes, Rx Only, Manufactured for: SOLA Pharmaceuticals, LLC, Baton Rouge, LA 70810, NDC 70512-036-30.	Class II	Drugs	Batch: 15725, Exp. 6/30/2022; 16113, Exp. 10/31/2022	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Hydrocortisone Butyrate Lotion, 0.1%, 4 fl oz (118 mL) bottle, Rx only, Manufactured for: SOLA Pharmaceuticals, Baton Rouge, LA 70809, NDC 70512-032-04.	Class II	Drugs	Batch: 16896, 16897 Exp. 5/31/2023	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Lidocaine Cream 4%, Net Wt. 30 grams tube, Distributed by: RUGBY LABORATORIES, 17177 N. Laurel Park Dr., Suite 233, Livonia, MI 48152, NDC 0536-1281-28.	Class II	Drugs	Batch: 15722, Exp. 6/30/2022; 16274, Exp. 12/31/2022; 16947, Exp. 5/31/2023; 17140, Exp. 8/31/2023	cGMP deviations: all products within expiry are being recalled because the firm is discontinuing its stability study program.	Teligent Pharma, Inc.
Lidocaine Ointment USP, 5%, Net Wt 35.44 g (1 1/4 Oz) tube, Rx Only, Manufactured for:	Class II	Drugs	Batch: 16695, Exp 4/30/2024	cGMP deviations: all products within expiry are being recalled	Teligent Pharma, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Hi-Tech Pharmacal Co., Inc., Amityville, NY 11701, NDC 50383-341-35.				because the firm is discontinuing its stability study program.	
Diclofenac Sodium Topical Solution 1.5%, 150 mL, Rx only, Packaged and Distributed by: Direct Rx Dawsonville, GA 30534 Mfg. For SOLA Pharmaceuticals Baton Rouge, LA, NDC 61919-675-05	Class II	Drugs	Lot #: 24MA2010 Exp. 1/31/2023	Defective Container: Leaking containers.	Direct Rx
TheraTears Extra (sodium carboxymethylcellulose) 0.25% Lubricant Eye Drops, 30 Sterile Single-Use Vials per box, Akorn Consumer Health, A Division of Akorn, Inc., Ann Arbor, MI 48105. NDC 58790-010-30	Class II	Drugs	Lot #: 913012, 913013, 913014, Exp. Date 1/31/2023	Lack of Assurance of Sterility	Akorn, Inc.
Azacitidine, 1,00mg/Vial, One Single-dose Vial, Rx Only, Mfd. By: Dr. Reddy's Laboratories Limited, Visakhapatnam - 530 046, India, NDC 43598-305-62	Class III	Drugs	Lot #: H200101, H200102, H200099, H200100 & H200106, Exp 8/1/2023; H210015, H210014 & H210013, Exp 11/1/2023; H210086, Exp 12/1/2023; H210130, Exp 1/1/2024; H210171, H210172, H210173, H210174, Exp 2/1/2024; H210196 & H210197, Exp 3/1/2024; H210283 & H210282, Exp 4/1/2024; H210382, H210381, H210419 & H210420, Exp 7/1/2024, H210445, Exp 8/1/2024.	Failed stability specifications	Dr. Reddy's Laboratories, Inc.

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Azacitidine, 100mg/vial, One Single-dose Vial, Rx Only, Mfd. By: Dr. Reddy's Laboratories Limited, Visakhapatnam - 530 046, India, NDC 43598-465-62	Class III	Drugs	Lot#: H200107, Exp 8/1/2023; H200154, Exp 9/1/2023; H210020, Exp 11/1/2023; H210055, Exp 12/1/2023; H210129, Exp 1/1/2024, H210288, Exp 4/1/2024.	Failed stability specifications	Dr. Reddy's Laboratories, Inc.
Bortezomib, 3.5 mg/vial, Single-Dose Vial, Rx Only, Mfd. By: Dr. Reddy's Laboratories Limited, Visakhapatnam - 530 046, India, NDC 43598-865-60	Class III	Drugs	Lot # H210233, Exp 3/1/2023	Failed stability specifications	Dr. Reddy's Laboratories, Inc.
Norepinephrine bitartrate 16 mg in 250 mL NaCl 0.9%, packaged in IV bags, Rx only, BayCare Central Pharmacy 7802 E. Telecom Parkway Temple Terrace, FL 33637 (813) 901-6392	Class III	Drugs	Lot #: Nore1620220111, Nore1620220113, Nore1620220118, Nore1620220125, Nore1620220127, Nore1620220202, Exp 3/31/22	Subpotent drug	BayCare Integrated Service Center, LLC /dba BayCare Central Pharmacy
Sapropterin Dihydrochloride Powder for Oral Solution, 100 mg, 30 individual packets per carton, Rx Only, Dr. Reddy's, Distributor: Dr. Reddy's Laboratories Inc., Princeton, NJ 08540, Made in India, NDC: 43598-477-11 (packet), 43598-477-30 (carton).	Class III	Drugs	T2100891, Exp. 02/28/2024	Subpotent Drug: Out-of-specification results observed in Assay in sapropterin dihydrochloride powder 100mg.	Dr. Reddy's Laboratories, Inc.
Formula F9, Papaverine 0.9 mg/mL, Phentolamine 0.1 mg/mL, PGE 20 mcg/mL, Atropine 0.01 mg/mL, Multi-Dose 10 mL vial, Each ML contains: 0.5% Chlorobutanol NF, 0.005% Edetate Disodium Dihydrate USP, 2.74% Benzyl Alcohol NF, 5% Mannitol USP,	Class III	Drugs	Lot: D41C19 Exp. 4/19/22	Sub Potent	Olympia Compounding Pharmacy dba Olympia Pharmacy

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
1% Sodium Metabisulfite NF, 1% Ethyl Alcohol USP, Sterile Water for Injection USP, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155, Orlando, FL 32835. NDC 73198-0004-10					
T-105, Papaverine 30 mg/mL Phentolamine 1 mg/mL PGE 10 mcg/mL packaged as a) 5 mL Multi-dose NDC 73198-0005-05; b) 10 mL Multi-dose NDC 73198-0005-10; Each ML contains: 0.5% Chlorobutanol NF, 0.0005% Edetate Disodium Dihydrate USP, 1.84% Benzyl Alcohol NF, 5% Mannitol USP, 1% Sodium Metabisulfite NF, 0.5% Ethyl Alcohol USP, Sterile Water for Injection USP, Rx Only, Olympia Pharmaceuticals, 6700 Conroy Rd., Ste. 155, Orlando, FL 32835.	Class III	Drugs	Lots: a) E41F10 Exp. 5/10/22; b) E41G10 Exp. 5/10/22	Super Potent	Olympia Compounding Pharmacy dba Olympia Pharmacy
SB-4, Papaverine 30mg/mL, Phentolamine 3mg/mL, Alprostadil 40mcg/mL, packaged in a) 5 mL Multi-dose vial NDC 73198-0023-05; b) 10 mL Multi-dose vial NDC 73198-0023-10, Each ML contains: 0.5% Chlorobutanol NF, 0.0005% Edetate Disodium Dihydrate USP, 1.84% Benzyl Alcohol NF, 5% Mannitol USP, 1% Sodium Metabisulfite NF, 2% Ethyl Alcohol USP, Sterile Water for Injection USP, Rx Only, Olympia Pharmaceuticals, Conroy Rd., Ste. 155, Orlando, FL 32835	Class III	Drugs	Lots: a) E41C18 Exp. 5/18/22; b) E41D18 Exp. 5/18/22	Sub Potent	Olympia Compounding Pharmacy dba Olympia Pharmacy
Hydroxocobalamin B12 1mg/mL, Multi-Dose 30 mL vial, Each ML contains: 0.82% Sodium Chloride USP, 0.9% Benzyl Alcohol NF,	Class III	Drugs	Lot: E47025 Exp. 5/21/22	Sub Potent	Olympia Compounding Pharmacy dba

Product Description	Classification	Product Type	Code Info	Reason for recall	Recalling Firm
Sterile Water for Injection USP, Rx Only, Olympia Pharmaceuticals Conroy Rd., Ste. 155, Orlando, FL 32835 NDC 73198-0080-30					Olympia Pharmacy

*Please refer to FDA website for further information at: http://www.fda.gov/Safety/Recalls/default.htm

CURRENT DRUG SHORTAGES

Below is the list of drugs listed by the FDA as currently in shortage. Please refer to the FDA website for more information at: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

Generic Name or Active Ingredient

Acetazolamide Injection
Amifostine Injection
Amino Acids
Amoxapine Tablets
Amphetamine Oral Suspension, Extended Release
Atropine Sulfate Injection
Azacitidine for Injection
Azithromycin (Azasite) Ophthalmic Solution 1%
Bacteriostatic 0.9% Sodium Chloride Injection
Bacteriostatic Water for Injection
Belatacept (Nulojix) Lyophilized Powder for Injection
Bumetanide Injection
Bupivacaine Hydrochloride and Epinephrine Injection
Bupivacaine Hydrochloride Injection
Calcium Disodium Versenate Injection
Calcium Gluconate Injection
Cefazolin Injection
Cefixime Oral Capsules
Cefotaxime Sodium Injection
Cefotetan Disodium Injection
Chlordiazepoxide Hydrochloride Capsules
Chloroprocaine Hydrochloride Injection
Conivaptan Hydrochloride (Vaprisol) in 5% Dextrose Plastic Container
Continuous Renal Replacement Therapy (CRRT) Solutions
Cortisone Acetate Tablets
Cyclopentolate Ophthalmic Solution
Cysteamine Hydrochloride Ophthalmic Solution
Cytarabine Injection
Dacarbazine Injection
Desmopressin Acetate Nasal Spray
Dexamethasone Sodium Phosphate Injection
Dexmedetomidine Injection
Dextrose 10% Injection
Dextrose 25% Injection
Dextrose 5% Injection
Dextrose 50% Injection
Diflunisal Tablets
Digoxin Injection

Disopyramide Phosphate (Norpace) Capsules
Dobutamine Hydrochloride Injection
Dopamine Hydrochloride Injection
Echothiophate Iodide (Phospholine Iodide) Ophthalmic Solution
Enalaprilat Injection
Epinephrine Injection, 0.1 mg/mL
Epinephrine Injection, Auto-Injector
Fentanyl Citrate (Sublimaze) Injection
Floxuridine for Injection
Fluvoxamine ER Capsules
Furosemide Injection
Gemifloxacin Mesylate (Factive) Tablets
Gentamicin Sulfate Injection
Guanfacine Hydrochloride Tablets
Heparin Sodium and Sodium Chloride 0.9% Injection
Hydrocortisone Tablets
Hydromorphone Hydrochloride Injection
Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert
Imipenem and Cilastatin for Injection
Isoniazid Injection
Ketamine Injection
Ketoprofen Capsules
Ketorolac Tromethamine Injection
Leucovorin Calcium Lyophilized Powder for Injection
Leuprolide Acetate Injection
Lidocaine Hydrochloride (Xylocaine) and Dextrose Injection Solution-Premix Bags
Lidocaine Hydrochloride (Xylocaine) Injection
Lidocaine Hydrochloride (Xylocaine) Injection with Epinephrine
Lipid Injection
Lithium Oral Solution
Lorazepam Injection
Mannitol Injection
Mepivacaine Hydrochloride Injection
Methyldopa Tablets
Methylprednisolone Acetate Injection
Metronidazole Injection
Midazolam Injection
Morphine Sulfate Injection
Multi-Vitamin Infusion (Adult and Pediatric)
Nefazodone Hydrochloride Tablets
Nizatidine Capsules
Ondansetron Hydrochloride Injection
Paclitaxel Injection (protein-bound particles)
Pantoprazole Sodium for Injection
Parathyroid Hormone (Natpara) Injection
Pentostatin Injection

Physostigmine Salicylate Injection
Potassium Acetate Injection
Potassium Chloride Concentrate Injection
Promethazine (Phenergan) Injection
Propofol Injectable Emulsion
Protamine Sulfate Injection
Rifampin Injection
Rifapentine Tablets
Ropivacaine Hydrochloride Injection
Sclerosol Intrapleural Aerosol
Sincalide (Kinevac) Lyophilized Powder for Injection
Sodium Acetate Injection
Sodium Bicarbonate Injection
Sodium Chloride 0.9% Injection Bags
Sodium Chloride 23.4% Injection
Sodium Chloride Injection USP, 0.9% Vials and Syringes
Sodium Phosphates Injection
Sterile Water for Injection
Streptozocin Powder for Injection
Sulfasalazine Tablets
Tacrolimus Capsules
Technetium Tc 99m Sulfur Colloid Injection
Technetium Tc99m Succimer Injection (DMSA)
Teprotumumab-trbw
Thiothixene Capsules
Tocilizumab Injection
Triamcinolone Acetonide Injectable Suspension
Triamcinolone Hexacetonide Injectable suspension
Valproate Sodium Injection
Varenicline Tartrate (Chantix) Tablets
Vecuronium Bromide for Injection
Vitamin A Palmitate (Aquasol A) Injection