PERFORMRx℠

Drug Information Update

July 2021

TABLE OF CONTENTS

NEWLY AVAILABLE GENERICS 2
NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS 3
NEW INDICATIONS (EXISTING DRUGS) 6
RECALLS 11
FDA DRUG SAFETY COMMUNICATIONS 39
CURRENT DRUG SHORTAGES 45

NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
formoterol fumarate 20 mcg/2 mL nebulization solution	Perforomist	Teva, Mylan	For the long-term, twice daily (morning and evening) administration in the maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.
foscarnet 6,000 mg/250 mL IV plastic bag	Foscavir	Sagent	• For the treatment of CMV retinitis in patients with acquired immunodeficiency syndrome (AIDS). Combination therapy with Foscarnet Sodium Injection and ganciclovir is indicated for patients who have relapsed after monotherapy with either drug. • For the treatment of acyclovir-resistant mucocutaneous HSV infections in immunocompromised patients.
ferumoxytol 510 mg/17mL IV vial	Feraheme	Sandoz	For the treatment of iron deficiency anemia (IDA) in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron or who have chronic kidney disease (CKD).
varenicline 0.5, 1 mg oral tablet	Chantix	Apotex	For use as an aid to smoking cessation treatment. *Note: This generic is imported from Canada due to shortages in the U.S. It is not a full launch of a generic product.
sulfacetamide sodium/ sulfur 9.8%-4.8% medicated pad	Plexion	KMM	For use in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description	Comments
Dupixent 200 mg/1.14 mL SQ pen injector	Dupilumab	New pen formulation	New Dosage Form
Neonatal-DHA 29 mg-1 mg-200 mg-500 mg oral tablet combination pack	Pnv No. 175/Iron/Fa/Dha/Algal	New formulation of prenatal vitamin	New Formulation
Ayvakit 25, 50 mg oral tablets	Avapritinib	A kinase inhibitor newly indicated for Advanced Systemic Mastocytosis (AdvSM).	New Strength
Nymalize 60 mg/10 mL oral solution	Nimodipine	A calcium channel blocker used to reduce ischemic deficits after rupture of subarachnoid hemorrhage; new package size.	New Dosage Form
Azstarys 26.1 mg-5.2 mg, 39.2 mg-7.8 mg, 52.3 mg-10.4 mg oral capsules	Serdexmethylphenidate /Dexmethylphenidate	A central nervous system (CNS) stimulant indicated for the treatment of ADHD in patients 6 years of age and older. Combination IR and long-acting (serdexmethylphenidate) for prolonged duration of action.	New Entity and New Combination
Kloxxado 8 mg/actuation nasal spray	Naloxone HCl	An opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression, for adults and pediatric patients.	New Strength
Fluad Quad 2021-2022 IM syringe	Flu Vacc Qs2021(65up)/Mf59c/Pf	Influenza Virus Vaccines	New Entity
Afluria Quad 2021-22 (6-35mo) 30 mcg(7.5 mcgx4)/ 0.25 mL IM syringe	Flu Vacc Qs 2021-2022 (6-35mos)/Pf	Influenza Virus Vaccines	New Entity

Drug Name	Generic Name	Description	Comments
Afluria Quad 2021-22 (3yr Up) 60 mcg (15 mcg x4)/0.5 mL IM syringe	Flu Vacc Qs 2021-2022 36mos Up/Pf	Influenza Virus Vaccines	New Entity
Flucelvax Quad 2021-2022 60 mcg (15 mcg x 4)/0.5 mL IM vial	Flu Vac Qs 21-22 (2yr Up) Cell	Influenza Virus Vaccines	New Entity
Flucelvax Quad 2021-2022 60 mcg (15 mcg x 4)/0.5 mL IM syringe	Flu Vac Qs 21-22(2yr Up)Cel/Pf	Influenza Virus Vaccines	New Entity
Brexafemme 150 mg oral tablet	Ibrexafungerp citrate	A triterpenoid antifungal indicated for the treatment or adult and post-menarchal pediatric females with vulvovaginal candidiasis.	New Entity
Prevnar 20 0.5 mL IM syringe	Pneumoc 20-Val Conj-Dip Crm/Pf	Pneumococcal 20-valent conjugate vaccine	New Entity
Neonatal Plus 27 mg-1 mg oral tablet	Pnv No.154/Iron Fum/Folic Acid	Prenatal Vitamin Preparations	New Formulation
Neonatal Fe 90 mg-120 mg-12 mcg-1 mg oral tablet	Iron,Carb/Vit C/Vit B12/Folic	Iron Replacement	New Formulation
Rylaze 10 mg/0.5 mL IM vial	Asparaginase Erwinia-Rywn	Asparaginase product used in chemotherapy regimens for acute lymphoblastic leukemia and lymphoblastic lymphoma in patients allergic to e. coli-derived asparaginase products.	New Entity
Kerendia 10, 20 mg oral tablet	Finerenone	A non-steroidal mineralocorticoid receptor antagonist (MRA) indicated to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in	New Entity

Drug Name	Generic Name	Description	Comments
		adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D).	
Xofluza 80 mg oral tablet	Baloxavir Marboxil	An influenza virus polymerase acidic endonuclease inhibitor. New strength for patients weighing at least 80 kg.	New Strength
Tirosint-Sol 37.5 mcg/mL, 44 mcg/mL, 62.5 mcg/mL oral solution	Levothyroxine Sodium	L-thyroxine (T4) oral solution.	New Strength
Neonatal Complete 29 mg-1 mg oral tablet	Pnv No.175/Iron Fum/Folic Acid	Prenatal Vitamin Preparations	New Formulation
Silatrix 1 g/10 g mucus membrane gel	Sucralfate Malate, Polymerized	Oral gel for treatment of various types of oral lesions	New Dosage Form

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†
Pradaxa	dabigatran etexilate capsules, 75 mg, 110 mg, 150 mg	Boehringer Ingelheim	Direct thrombin inhibitor indicated: • To reduce the risk of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation • For the treatment of deep venous thrombosis (DVT) and pulmonary embolism (PE) in adult patients who have been treated with a parenteral anticoagulant for 5-10 days • To reduce the risk of recurrence of DVT and PE in adult patients who have been previously treated • For the prophylaxis of DVT and PE in adult patients who have undergone hip replacement surgery • **For the treatment of venous thromboembolic events (VTE) in pediatric patients aged 3 months to less than 12 years of age who have been treated with a parenteral anticoagulant for at least 5 days** • **To reduce the risk of recurrence of VTE in pediatric patients aged 3 months to less than 12 years of age who have been previously treated**
Noxafil	posaconazole injection, 300 mg/16.7 mL vial; delayed-release tablets, 100 mg; oral suspension, 40 mg/mL	Schering	An azole antifungal indicated as follows: • **Noxafil injection and Noxafil delayed-release tablets are indicated for the treatment of invasive aspergillosis in adults and pediatric patients 13 years of age and older**.

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			• Noxafil is indicated for the prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy as follows: o **Noxafil injection: adults and pediatric patients ≥ 2 years of age** o **Noxafil delayed-release tablets: adults and pediatric patients ≥ 2 years of age who weigh > 40 kg** o **Noxafil oral suspension: adults and pediatric patients ≥ 13 years of age** o **Noxafil PowderMix* for delayed-release oral suspension: pediatric patients ≥ 2 years of age who weigh ≤ 40 kg** • Noxafil oral suspension is indicated for the treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole **in adult and pediatric patients aged 13 years and older**. **Not currently marketed*
Toviaz	fesoterodine fumarate extended-release tablets, 4 mg, 8 mg	Pfizer	• Overactive bladder (OAB) in adults with symptoms of urge urinary incontinence, urgency, and frequency. • **Neurogenic detrusor overactivity (NDO) in pediatric patients ≥ 6 years of age and weighing > 25 kg.**
Epclusa	sofosbuvir/velpatasvir 200 mg-50 mg, 400 mg-100 mg oral tablets	Gilead	A hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, and velpatasvir, an HCV NS5A inhibitor, and is indicated for the treatment of adults and pediatric patients **3 years of age and older** with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection: • without cirrhosis or with compensated cirrhosis

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			• with decompensated cirrhosis for use in combination with ribavirin
Solosec	secnidazole oral granules, 2 g packets	Lupin	• Treatment of bacterial vaginosis in adult women. • **Treatment of trichomoniasis in adults.**
Keytruda	pembrolizumab injection, 100 mg/4 mL solution in a single-dose vial	Merck	Cutaneous Squamous Cell Carcinoma (cSCC): Treatment of patients with recurrent or metastatic cSCC **or locally advanced cSCC** that is not curable by surgery or radiation. **Note: Keytruda has many other indications not presented here because there were no changes*
Darzalex Faspro	daratumumab and hyaluronidase-fihj injection, 1800 mg daratumumab and 30,000 units hyaluronidase per 15 mL solution in a single dose vial	Janssen Biotech	A combination of daratumumab, a CD38-directed cytolytic antibody, and hyaluronidase, an endoglycosidase, indicated for the treatment of adult patients with: • multiple myeloma in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant • multiple myeloma in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy • multiple myeloma in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant • multiple myeloma in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			• **multiple myeloma in combination with pomalidomide and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor** • multiple myeloma as monotherapy, in patients who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent. • light chain (AL) amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone in newly diagnosed patients. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
Prograf	tacrolimus capsules, 0.5 mg, 1 mg, 5 mg; injection, 5 mg/mL; for oral suspension, 0.2 mg, 1 mg unit-dose packets containing granules	Astellas Pharma	For the prophylaxis of organ rejection in adult and pediatric patients receiving allogeneic liver, kidney, heart, or **lung transplants**, in combination with other immunosuppressants.
Octagam	immune globulin (Human) 10% IV vial	Octapharma USA	An immune globulin intravenous (human) liquid preparation indicated for the treatment of: • Chronic immune thrombocytopenic purpura (ITP) in adults • **Dermatomyositis (DM) in adults**
Padcev	enfortumab vedotin-ejfv 20, 30 mg IV vial	Astellas, Seagen	A Nectin-4-directed antibody and microtubule inhibitor conjugate indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer who:

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			• have previously received a programmed death receptor-1 (PD-1) or • programmed death-ligand 1 (PD-L1) inhibitor and platinum-containing chemotherapy, or • **are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy.**

RECALLS

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Krazy Night capsule, packaged in a) 1-count per blister card and b) 10-count boxes, Manufactured by: SUM MARKETING LLC, Made in USA UPC 746695241860	Class I	Drugs	All lots within expiry.	Marketed Without An Approved NDA/ANDA: Products found to contain undeclared tadalafil and/ or sildenafil and vardenafil making them unapproved drugs for which the safety and efficacy have not been established and therefore subject to recall.	Ummzy, LLC
Shogun-X capsules, 10-count boxes, Manufactured by Power Life Distributors, Made in USA, UPC 118122030185	Class I	Drugs	All lots within expiry.	Marketed Without An Approved NDA/ANDA: Products found to contain undeclared tadalafil and/ or sildenafil and vardenafil making them unapproved drugs for which the safety and efficacy have not been established and therefore subject to recall.	Ummzy, LLC
Thumbs up 7 Red 70K capsules, 10-count boxes,	Class I	Drugs	All lots within expiry.	Marketed Without An Approved NDA/ANDA: Products found to contain	Ummzy, LLC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Distributed Ummzy LLC, Made in USA, UPC 617135894680.				undeclared tadalafil and/ or sildenafil and vardenafil making them unapproved drugs for which the safety and efficacy have not been established and therefore subject to recall.	
Shogun-X 7000 capsule, packaged in a) 1-count blister card and b) 10-count box, Nuri Trading LLC	Class I	Drugs	all lots within expiry	Marketed Without An Approved NDA/ANDA: Product found to be tainted with undeclared tadalafil and sildenafil, two FDA approved drugs making them unapproved drugs for which the safety and efficacy have not been established and therefore subject to recall.	Nuri Trading LLC
Thumbs Up 7 Black 25K capsule, packaged in a) 1-count blister card and b) 10-count box, Nuri Trading LLC	Class I	Drugs	all lots within expiry	Marketed Without An Approved NDA/ANDA: Product found to be tainted with undeclared tadalafil, an FDA approved drug making this an unapproved drug for which the safety and efficacy has not

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
				been established and therefore subject to recall.	
Thumbs Up 7 White 11K capsule, packaged in a) 1-count blister card and b) 10-count box, Nuri Trading LLC	Class I	Drugs	all lots within expiry	Marketed Without An Approved NDA/ANDA: Product found to be tainted with undeclared tadalafil sildenafil, and vardenafil, FDA approved drugs making them an unapproved drug for which the safety and efficacy have not been established and therefore subject to recall.	Nuri Trading LLC
69MODE Blue 69 capsule, packaged in 10-count box, Nuri Trading LLC	Class I	Drugs	all lots within expiry	Marketed Without An Approved NDA/ANDA: Product found to be tainted with undeclared tadalafil and sildenafil, two FDA approved drugs making it an unapproved drug for which the safety and efficacy have not been established and therefore subject to recall.	Nuri Trading LLC
Ulta beauty Fresh Lemon Citron Frais, 70% Alcohol Hand Sanitizer Spray, Net Wt.	Class I	Drugs	Lots #: 20357A, 20358B, 20363C, Exp 12/1/2022	Chemical contamination: product found to be contaminated with methanol	Scentsational Soaps & Candles Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
100.55/3.4 fl. oz., UPC 717897092017				(wood alcohol), benzene and acetaldehyde.	
SS Coconut Breeze Scented Sanitizer, Alcohol Antiseptic 70%, Non-sterile Topical Solution, 3.38 FL. OZ. (100 mL), a) Black and White Collection; b) Photo Real Collection	Class I	Drugs	Lot #: 20252	Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.	Scentsational Soaps & Candles Inc
SS Eucalyptus Mint Scented Sanitizer, Alcohol Antiseptic 70%, Non-sterile Topical Solution, 3.38 FL. OZ. (100 mL), a) Black and White Collection; b) Photo Real Collection	Class I	Drugs	Lot #: 20248	Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.	Scentsational Soaps & Candles Inc
SS Lavender & Herbs Scented Sanitizer, Alcohol Antiseptic 70%, Non-sterile Topical Solution, 3.38 FL. OZ. (100 mL) a) Black and White Collection; b) Photo Real Collection	Class I	Drugs	Lots #: a) 20253, b) 20252	Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.	Scentsational Soaps & Candles Inc
SS Lemon Zest Scented Sanitizer, Alcohol Antiseptic 70%, Non-sterile Topical Solution, 3.38 FL. OZ. (100 mL)	Class I	Drugs	Lot #: 20255	Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.	Scentsational Soaps & Candles Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
a) Black and White Collection; b) Photo Real Collection					
SS Tangerine & Guava Scented Sanitizer, Alcohol Antiseptic 70%, Non-sterile Topical Solution, 3.38 FL. OZ. (100 mL) a) Black and White Collection; b) Photo Real Collection	Class I	Drugs	Lot #: 20254	Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.	Scentsational Soaps & Candles Inc
Goose Creek Hand Sanitizer aloe Blueberry Limeade, Anti-Bacterial Spray, 3.38 FL. OZ. (100 mL), Goose Creek www.GooseCreekCandle.com, 1498 S. Wallace Wilkinson Blvd. Liberty, KY 42539, UPC 8 14630 02049 5	Class I	Drugs	Lot #: 20258	Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.	Scentsational Soaps & Candles Inc
Goose Creek Hand Sanitizer aloe Limoncello, Anti-Bacterial Spray, 3.38 FL. OZ. (100 mL),Goose Creek www.GooseCreekCandle.com, 1498 S. Wallace Wilkinson Blvd. Liberty, KY 42539, UPC 8 18489 01333 2	Class I	Drugs	Lot #: 20258	Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.	Scentsational Soaps & Candles Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Goose Creek Hand Sanitizer aloe Beach Dreams, Anti-Bacterial Spray, 3.38 FL. OZ. (100 mL), Goose Creek www.GooseCreekCandles.com , 1498 S. Wallace Wilkinson Blvd. Liberty, KY 42539, UPC 8 18489 01336 3	Class I	Drugs	Lot #: 20258	Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.	Scentsational Soaps & Candles Inc
Goose Creek Hand Sanitizer aloe Grape Soda, Anti-Bacterial Spray, 3.38 FL. OZ. (100 mL), Goose Creek www.GooseCreekCandle.com, 1498 S. Wallace Wilkinson Blvd., Liberty, KY 42539, UPC 8 18489 01328 8	Class I	Drugs	Lot #: 20258	Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.	Scentsational Soaps & Candles Inc
Goose Creek Hand Sanitizer aloe Champagne Bubbles, Anti-Bacterial Spray, 3.38 FL. OZ. (100 mL), Goose Creek www.GooseCreekCandle.com, 1498 S. Wallace Wilkinson Blvd., Liberty, KY 42539, UPC 8 18489 01334 9	Class I	Drugs	Lot #: 20258	Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.	Scentsational Soaps & Candles Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Goose Creek Hand Sanitizer aloe Dragonfruit Splash, Anti-Bacterial Spray, 3.38 FL. OZ. (100 mL), Goose Creek www.GooseCreekCandle.com, 1498 S. Wallace Wilkinson Blvd., Liberty, KY 42539, UPC 8 18489 01332 5	Class I	Drugs	Lot #: 20258	Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.	Scentsational Soaps & Candles Inc
Goose Creek Hand Sanitizer aloe Marshmallows, Anti-Bacterial Spray, 3.38 FL. OZ. (100 mL), Goose Creek www.GooseCreekCandle.com, 1498 S. Wallace Wilkinson Blvd., Liberty, KY 42539, UPC 8 18489 01331 8	Class I	Drugs	Lot #: 20258	Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.	Scentsational Soaps & Candles Inc
Goose Creek Hand Sanitizer aloe Melon Picnic, Anti-Bacterial Spray, 3.38 FL. OZ. (100 mL), Goose Creek www.GooseCreekCandle.com, 1498 S. Wallace Wilkinson Blvd., Liberty, KY 42539, UPC 8 14630 02424 0	Class I	Drugs	Lot #: 20259	Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.	Scentsational Soaps & Candles Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Goose Creek Hand Sanitizer aloe Optimistic Vibes, Anti-Bacterial Spray, 3.38 FL. OZ. (100 mL), Goose Creek www.GooseCreekCandle.com, 1498 S. Wallace Wilkinson Blvd., Liberty, KY 42539, UPC 8 14630 02234 5	Class I	Drugs	Lot #: 20259	Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.	Scentsational Soaps & Candles Inc
Goose Creek Hand Sanitizer aloe Red, White & Blue Anti-Bacterial Spray, 3.38 FL. OZ. (100 mL), Goose Creek www.GooseCreekCandle.com, 1498 S. Wallace Wilkinson Blvd., Liberty, KY 42539, UPC 8 14630 02045 7	Class I	Drugs	Lot #: 20259	Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.	Scentsational Soaps & Candles Inc
Goose Creek Hand Sanitizer aloe Watermelon Lemonade, Anti-Bacterial Spray, 3.38 FL. OZ. (100 mL), Goose Creek www.GooseCreekCandle.com, 1498 S. Wallace Wilkinson Blvd., Liberty, KY 42539, UPC 814630 02423 3	Class I	Drugs	Lot #: 20259	Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.	Scentsational Soaps & Candles Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Goose Creek Hand Sanitizer aloe Tropical Daydream, Anti-Bacterial Spray, 3.38 FL. OZ. (100 mL), Goose Creek www.GooseCreekCandle.com, 1498 S. Wallace Wilkinson Blvd., Liberty, KY 42539, UPC 8 18489 01335 6	Class I	Drugs	Lot #: 20260	Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.	Scentsational Soaps & Candles Inc
Coconut Stand CoCo TKO Hand Sanitizer, Totally Knocks Out 99.9% of Germs, 3.4 FL. OZ. (100.55 mL), Distributed by: Beauty Sparks LLC St. Petersburg, FL 33711	Class I	Drugs	Lot #: 20260	Chemical contamination: product found to be contaminated with methanol (wood alcohol), benzene and acetaldehyde.	Scentsational Soaps & Candles Inc
Durisan Antimicrobial Solutions (benzalkonium chloride) Hand Sanitizer, listed as 0.1% or 0.13%, Alcohol-Free, packaged in a) 18 mL Net Content 0.61 fl oz credit card size container, (UPC 8 52379 00614 1); b) 50 mL Net Content 1.69 oz bottle, (UPC 8 52379 00634 9 and 8 52379 00612 7); c) 118 mL Net	Class I	Drugs	Lots: DHS030920A1-A, DHS030920A2-S, DHS030920A3-S, Exp. 4/9/2022; DHS031020A4-S, DHS031020A5-S, DHS031020A6-S, DHS031020A7-S, DHS031020A8-S, Exp. 4/10/2022;	Microbial Contamination of Non-Sterile Products: firm's internal testing found certain lots of the product to be contaminated with Burkholderia contaminans and/or yeast and mold.	Sanit Technologies, LLC dba Durisan

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Content 4 oz bottle, (UPC 8 52379 00634 9 and 8 52379 00612 9); d) 236.58 mL Net Content 8 oz bottle, (UPC 8 52379 00635 6); e) 250 mL Net Contents 8.45 oz (UPC 8 52379 00611 0); f) 300 mL Net Content 10 oz bottle, (UPC 8 52379 00697 4); g) 550 mL Net Content 18.59 oz bottle, (UPC 8 52379 00620 2) ; h) 1000 mL Net Content 33.81 oz kidney bottle dispensing 0.4 or 0.8 each actuation, (UPC 8 50008 48507 7 and 8 52379 00610 3); and i) 1 Gallon Net Content 128 oz bottle, (UPC 8 52379 00621 9); Sanit Technologies, LLC 7810 25th Court East, Unit 106 Sarasota, Florida 34243			DHS031120A1-S, DHS031120A2-S, DHS031120A3-S, DHS031120A4-S, DHS031120A5-S, DHS031120A6-S, Exp.4/11/2022; DHS051420A1-S, Exp. 6/14/2022; DHS052020A1-S, DHS052020B1-S, DHS052020C1-S, Exp. 6/20/2022; DHS052220B1-S, Exp. 6/22/2022; DHS052620B1-S, Exp. 6/26/2022; DHS052720C1-S, DHS052720D1-S, Exp. 6/27/2022, DHS052820B1-S, DHS052820C1-S, DHS052820D1-S, Exp. 6/28/2022; DHS060120A1-S,		

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			Exp. 7/1/2022; DHS060220A1-S, DHS062220C-S, Exp. 7/22/2022		
Durisan Antimicrobial Solutions (benzalkonium chloride) Hand Sanitizing Wipes, 0.13%, 160-count canister; Sanit Technologies, LLC, 7810 25th Court East, Sarasota, Florida 34243, UPC 8 52379 00631 8.	Class I	Drugs	Lots: DHS031020A4-S, DHS031020A6-S, Exp. 4/10/2022	Microbial Contamination of Non-Sterile Products: firm's internal testing found certain lots of the product to be contaminated with Burkholderia contaminans and/or yeast and mold.	Sanit Technologies, LLC dba Durisan
Poseidon Platinum 3500 capsule, 1-count per blister card, Distributed by: Poseidon, Made in the USA, UPC 0 95842 05876 0	Class I	Drugs	All lots distributed 07/01/2019 through 09/28/2020.	Marketed Without An Approved NDA/ANDA: Product found to contain undeclared sildenafil and tadalafil making them unapproved drugs for which the safety and efficacy have not been established and therefore subject to recall.	Yamtun7
Prairie Wolf Distillery Alcohol Antiseptic 80%, Topical Solution Hand Sanitizer, packaged in a) (16.9oz) 500 mL (UPC 8 60003 31899 7, NDC:	Class I	Drugs	All lots	Hand sanitizer packaged in bottles that resemble beverage containers.	Prairie Wolf Spirits

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
73891-100-14); and b) (20oz) 591 mL (UPC 8 60003 65984 7 NDC: 73891-100-15) bottles, Prairie Wolf Distillery, Guthrie, Oklahoma					
Limar Hand Sanitizer, Isopropyl Alcohol 70%, Cont. 4 oz bottles, Manufactured in Dominican Republic: by Ardil Comercial S.R.L., Santo Domingo, Dominican Republic UPC 7 487040 301587	Class I	Drugs	Batch Number # 079932-4611-05-J, exp. date May 2022	Labeling Not Elsewhere Classified: Hand sanitizer packaged in containers resembling drinking water bottles.	Ardil Comercial S.R.L.
Topotecan Injection 4 mg/4mL (1 mg/mL), Single-Dose vial, Teva Pharmaceuticals USA, Inc. North Whales, PA 19454, Carton NDC# 0703-4714-01, Vial NDC# 0703-4714-71	Class I	Drugs	Lot # 31328962B, exp. date 04/2022	Presence of Particulate Matter: Complaint received of a glass particle observed inside the vial. The vial was returned to Teva for further analysis where two other particulates were found and identified as one (1) grey silicone particle and one (1) translucent, colorless cotton fiber.	Teva Pharmaceuticals USA
Premium OrgaZEN 7000 capsule, 1-count per blister card, distributed by: Nutra Vita	Class I	Drugs	all lots	Marketed without an approved NDA/ANDA: Products found to contain	NSNY Distributor Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Co, Santa Fe Springs, CA, Made in USA , UPC 0 40232 32555 7				undeclared sildenafil and/ or tadalafil	
Ginseng Power 5000 capsule, 1- count per blister card, GS Natural Co, Los Angeles, CA 90010, UPC 0 40232 18144 3	Class I	Drugs	all lots	Marketed without an approved NDA/ANDA: Products found to contain undeclared sildenafil and/ or tadalafil	NSNY Distributor Inc
DiBAR LABS Hand Sanitizer (ethyl alcohol 70%), 8 FL OZ. (236.5 mL), Distributed by S.E.N.D. LLC, Anthony, NM 88021, Imported by Dibar Labs, LLC, Sugar Land, TX 77479, Made in Mexico,77479, NDC 73009-0001-08 UPC 8 53090 00301 3.	Class I	Drugs	Lot # LDHSN050920 T1, LDHSN051020 DESC, LDHSN051020 T2, EXP 05/2022	Chemical Contamination: FDA analysis found 3 lots of DiBAR hand Sanitizer to be below the label claim for ethanol content and to contain methanol.	DIBAR NUTRICIONAL S DE RL DE CV
PremierZEN Gold 7000 capsule, 1-count blister card, packaged in 12 cards per box (UPC 7 28175 42183 2), Distributed by: New Premier Group, Los Angeles, CA 90006	Class I	Drugs	All lots remaining within expiry.	Marketed without an approved NDA/ANDA - Product found to be tainted with Sildenafil and Tadalafil.	Miracle 8989
PremierZEN Platinum 8000 capsule, 1-count blister card (UPC 7 28175 42185 6),	Class I	Drugs	All lots remaining within expiry.	Marketed without an approved NDA/ANDA -	Miracle 8989

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
packaged in 12 cards per box (UPC 7 28175 42183 2), Distributed by: New Premier Group, Los Angeles, CA 90006				Product found to be tainted with Sildenafil and Tadalafil.	
maXXzen Platinum 12000 capsule, 1-count blister card (UPC 7 18122 04072 8), Distributed by: Maxx Inc, Los Angeles, CA 90028	Class I	Drugs	All lots remaining within expiry.	Marketed without an approved NDA/ANDA - Product found to be tainted with Sildenafil and Tadalafil.	Miracle 8989
Compounded Lyophilized Semorelin/Ipamorelin 3 mg For subcutaneous or intramuscular injection, Rx Only, Compounded by: Innoveix Addison, TX 75001 800-370-1910	Class II	Drugs	Lot #: SIP215 Exp. 01/14/2022, SIP220 Exp. 01/23/2022, SIP210 Exp. 12/15/2021	Lack of Assurance of Sterility	Innoveix Pharmaceuticals Inc
Compounded Lyophilized AOD-9604, 3 mg For subcutaneous or intramuscular injection, Rx Only, Compounded by: Innoveix Addison, TX 75001 800-370-1910	Class II	Drugs	Lot #: AOD205 Exp. 11/09/2021; AOD210 Exp. 11/18/2021; AOD215 Exp. 12/15/2021; AOD220 Exp. 01/20/2022.	Lack of Assurance of Sterility	Innoveix Pharmaceuticals Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Durisan Antimicrobial Solutions (benzalkonium chloride) Hand Sanitizer, listed as 0.1% or 0.13%, Alcohol-Free, packaged in a) 18 mL Net Content 0.61 fl oz credit card size container, (UPC 8 52379 00614 1); b) 50 mL Net Content 1.69 oz bottle, (UPC 8 52379 00634 9 and 8 52379 00612 7); c) 118 mL Net Content 4 oz bottle, (UPC 8 52379 00634 9 and 8 52379 00612 9); d) 236.58 mL Net Content 8 oz bottle, (UPC 8 52379 00635 6); e) 250 mL Net Contents 8.45 oz (UPC 8 52379 00611 0); f) 300 mL Net Content 10 oz bottle, (UPC 8 52379 00697 4); g) 550 mL Net Content 18.59 oz bottle, (UPC 8 52379 00620 2) ; h) 1000 mL Net Content 33.81 oz kidney bottle dispensing 0.4 or 0.8 each actuation, (UPC 8 50008	Class II	Drugs	Lots: DHS041519A1-S, DHS041519A2-S, DHS041519A3-S, DHS041519A4-S, DHS041519A5-S, DHS041519A6-S, Exp. 5/15/2021; DHS042919AR1-S, Exp. 5/29/2021; DHS043019AR1-S, Exp. 5/30/2021; DHS050319A4-S, Exp. 6/03/2021; DHS053019A1-S, DHS053019A2-S, DHS053019A4-S, DHS053019A5-S, DHS053019A6-S, Exp. 6/30/2021; DHS070219A1-S, DHS070219A2-S, DHS070219A3-S, DHS070219A4-S, DHS070219A5-S,	CGMP Deviations: lots recalled due to CGMP deviations because they were manufactured under the same conditions as product lots found to be contaminated.	Sanit Technologies, LLC dba Durisan

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
48507 7 and 8 52379 00610 3); and i) 1 Gallon Net Content 128 oz bottle, (UPC 8 52379 00621 9); Sanit Technologies, LLC 7810 25th Court East, Unit 106 Sarasota, Florida 34243			DHS070219A6-S, DHS070219AB-S, Exp. 8/2/2021; DHS080219A1-S, Exp. 9/2/2021; DHS091819A1-S, Exp 10/18/2021; DHS032820B1-S, Exp 4/28/2022; DHS051520A1R1-S, Exp. 6/15/2022; DHS052020A1R1-S, DHS052020B1R1-S, DHS052020CR1-S, Exp. 6/20/2022; DHS052220A1R1-S, Exp. 6/22/2022; DHS052720C1R1-S, Exp 6/27/2022; DHS052920A1R1-S, DHS052920B1R1-S, DHS052920C1R1-		

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			S, Exp 6/29/2022; DHS060320C1R1-S, Exp. 7/3/2022; DHS060520C1R1-S, DHS060520F1R1-S, Exp. 7/5/2022; DHS060820E1R1-S, Exp. 7/8/2022; DHS061220A1R1-S, Exp. 7/12/2022; DHS061920B1R1-S, Exp. 7/19/2022; DHS062320B1R1-S, Exp. 7/23/2022; DHS062420B1R1-S, Exp. 7/24/2022; DHS081120A1-S, Exp. 9/11/2022; DHS081220A1R1-S, Exp 9/12/2022; DHS081420B1-S, DHS081420B3-S, DHS081420B6-S, DHS081420B8-S,		

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			Exp. 9/14/2022; DHS081720A3-S, DHS081720A5-S, Exp. 9/17/2022		
Durisan Antimicrobial Solutions (benzalkonium chloride) Hand Sanitizing Wipes, 0.13%, packaged in 80-count canister (UPC 8 52379 00632 5), b) 160-count canister (UPC 8 52379 00631 8), and c) 240-count canister (UPC 8 52379 00633 2); Sanit Technologies, LLC, 7810 25th Court East, Sarasota, Florida 34243.	Class II	Drugs	DHS041519A1-S, DHS041519A2-S, DHS041519A3-S, DHS041519A4-S, DHS041519A5-S, DHS041519A6-S, Exp. 5/15/2021; DHS042919AR1-S, Exp. 5/29/2021; DHS043019AR1-S, Exp. 5/30/2021; DHS050319A4-S, Exp. 6/03/2021; DHS053019A1-S, DHS053019A2-S, DHS053019A4-S, DHS053019A5-S, DHS053019A6-S, Exp. 6/30/2021; DHS070219A1-S, DHS070219A2-S,	CGMP Deviations: lots recalled due to CGMP deviations because they were manufactured under the same conditions as product lots found to be contaminated.	Sanit Technologies, LLC dba Durisan

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			DHS070219A3-S, DHS070219A4-S, DHS070219A5-S, DHS070219A6-S, DHS070219AB-S, Exp. 8/2/2021; DHS080219A1-S, Exp. 9/2/2021; DHS091819A1-S, Exp 10/18/2021; DHS032820B1-S, Exp 4/28/2022; DHS051520A1R1-S, Exp. 6/15/2022; DHS052020A1R1-S, DHS052020B1R1-S, DHS052020CR1-S, Exp. 6/20/2022; DHS052220A1R1-S, Exp. 6/22/2022; DHS052720C1R1-S, Exp 6/27/2022; DHS052920A1R1-S,		

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			DHS052920B1R1-S, DHS052920C1R1-S, Exp 6/29/2022; DHS060320C1R1-S, Exp. 7/3/2022; DHS060520C1R1-S, DHS060520F1R1-S, Exp. 7/5/2022; DHS060820E1R1-S, Exp. 7/8/2022; DHS061220A1R1-S, Exp. 7/12/2022; DHS061920B1R1-S, Exp. 7/19/2022; DHS062320B1R1-S, Exp. 7/23/2022; DHS062420B1R1-S, Exp. 7/24/2022; DHS081120A1-S, Exp. 9/11/2022; DHS081220A1R1-S, Exp 9/12/2022; DHS081420B1-S,		

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			DHS081420B3-S, DHS081420B6-S, DHS081420B8-S, Exp. 9/14/2022; DHS081720A3-S, DHS081720A5-S, Exp. 9/17/2022		
Solifenacin Succinate Tablets, 10 mg, 30-count bottles, Rx Only, Manufactured by: Cipla Ltd., Verna, Goa, India Manufactured for Cipla USA, Inc. 1560 Sawgrass Corporate Parkway, Suite 130, Sunrise, FL, 33323, NDC 69097-261-02.	Class II	Drugs	Lot #: GG90819, Exp. Date 06/2021	CGMP Deviations	CIPLA
NIFEdipine EXTENDED-RELEASE TABLETS, USP 30 mg Rx only packaged as a) 100 count unit dose carton, NDC 0904-7080-61; b) 50 count unit dose carton, NDC 0904-7080-06: Distributed by: Ingenus Pharmaceuticals, LLC Orlando, FL 32839-6408 Distributed by: Major Pharmaceuticals 17177	Class II	Drugs	Lots: a)N00418 Exp. 09/2022, b) N00417 Exp. 09/2022	Failed Dissolution Specification: Out of specification for dissolution during routine stability testing.	The Harvard Drug Group

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
N Laurel Park Dr., Suite 233 Livonia, MI 48152 USA					
Buprenorphine and Naloxone Sublingual Film 2mg/0.5mg, 30 pouches each containing 1 sublingual film, Distributed by: Alvogen, Inc. Pine Brook, NJ 07058 USA, NDC 47781-355-03	Class II	Drugs	Lot #: 36924, Exp 6/2021	Subpotent drug: Out of specification for assay of naloxone and buprenorphine (low)	Alvogen, Inc
Xolair (omalizumab) Injection, 150 mg/1 mL, 1 prefilled syringe, Rx Only, For Subcutaneous Use. Single-Dose Prefilled Syringe. Product of France, Manufactured by: Genentech, Inc. A Member of the Roche Group, South San Francisco, CA 9480-4990. NDC: 50242-215-01	Class II	Drugs	Lot No.: 3352758, Exp. Date Aug 2021; Lot No.: 3352759, Exp. Date Aug 2021	Failed Stability Specifications: Out of Specification results of Polysorbate 20 (PS20) content were detected at the 12 month testing time point.	Genentech Inc
Xylocaine-MPF with Epinephrine 1:200,000, (Lidocaine HCl and Epinephrine Injection, USP), 1%, 300 mg/30 mL, (10 mg/mL), 30 mL Single Dose Vial, 25 Vials per Tray, Rx only, Fresenius Kabi USA, LLC,	Class II	Drugs	Batch, expiry: Batch 6123435, exp 01/2022; 6124730, 6124731, exp 07/2022	Low out of specification results for epinephrine assay.	Fresenius Kabi USA LLC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Lake Zurich, IL 60047. Vial NDC 63323-487-07, Tray NDC 63323-487-37					
DiBAR LABS Hand Sanitizer, (ethyl alcohol 70%), packaged as a) 16 FL OZ (473.1 mL) bottle, NDC 73009-001-16, UPC 8 53090 00302 0 and b) 8 FL OZ (236.5 mL) bottle, NDC 73009-0001-08, UPC 8 53090 00301 3; Distributed by: S.E.N.D, LLC., Anthony, NM 88021; Imported by: Dibar Labs, LLC., Sugar Land, TX 77479, Made in Mexico.	Class II	Drugs	All lots	CGMP Deviations: Other lots and products of hand sanitizer recalled because they were manufactured under the same conditions as the product lots found to contain methanol.	DIBAR NUTRICIONAL S DE RL DE CV
ProtectoRx (ethyl alcohol 70%), packaged in a) 2 FL OZ (59 mL), NDC 75408-002-01 and b) 16 FL OZ (473.2 mL), NDC 75408-002-02 bottles, Imported by: Dibar Labs, LLC., Sugar Land, TX 77479; Distributed by: PR Trading LLC, PO Box 19647, San Juan, PR 00910, Made in Mexico.	Class II	Drugs	All lots.	CGMP Deviations: Other lots and products of hand sanitizer recalled because they were manufactured under the same conditions as the product lots found to contain methanol.	DIBAR NUTRICIONAL S DE RL DE CV

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
ADVANCE HAND SANITIZER, (ethyl alcohol 70%), 16 FL OZ (473.2 mL), Imported by: Dibar Labs, LLC,.Sugar Land, TX 77479, Distributed by: Lifetime Health Services, Pharr, TX 78577, Made in Mexico, NDC; 79284-005-00. UPC 8 60004 06470 1	Class II	Drugs	All lots	CGMP Deviations: Other lots and products of hand sanitizer recalled because they were manufactured under the same conditions as the product lots found to contain methanol.	DIBAR NUTRICIONAL S DE RL DE CV
QiYu Hand Sanitizer (ethyl alcohol 75% (v/v)), 16.9 FL OZ (500 ML) bottles, Manufactured by: Guangzhou Minghui Cosmetics Co., Ltd, Baiyun District, Guanzhou, China Distributed by HoYu (US) Logistics Inc UPC 6 926645 716288	Class II	Drugs	Lot # Q20200320, exp. date 03/19/2022	Subpotent	HOYU(US) LOGISTICS INC
Diflorasone Diacetate Ointment USP, 0.05%, packaged in a)15 g (NDC 52565-063-15) and b) 30 g (NDC 52565-063-30) tubes, Rx only, Manufactured by:	Class II	Drugs	Lot #: 16264, Exp Date Nov 2022	Presence of Foreign Substance: Foreign particles observed during routine stability testing.	Teligent Pharma, Inc.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Teligent Pharma, Inc, Buena, NJ 08310.					
DermOtic Oil (fluocinolone acetonide oil) 0.01% Ear Drops 20 mL bottles, Rx only, Manufactured by: Hill Dermaceuticals, Inc. Sanford, FL 32773 for: Royal Pharmaceuticals Manasquan, NJ 08736, NDC 68791-103-20	Class II	Drugs	Lot #: 19K036D, 19L039E Exp. 05/21; 20A001E, 20A003D, 20A003E, Exp. 07/21; 20C013G Exp. 09/21; 20E025F, 20E025G, 20E025H Exp. 12/21; 20H041D, 20H041F Exp. 02/22; 20J043E Exp. 03/22; 20K050F Exp. 04/22; 20L055E Exp. 06/22; 21C015E, 21C018E Exp. 09/22	Presence of Foreign Substance: Potential for broken glass within the glass pipette of the dropper.	Hill Dermaceuticals, Inc.
Metformin Hydrochloride Extended-Release Tablets, USP 750 mg, 100 Tablets, Rx only, Manufactured by: Cadila	Class II	Drugs	Lot M915601 & M915602, Oct 2021	CGMP Deviations: Detection of N-Nitrosodimethylamine (NDMA) levels in excess of the Acceptable Daily Intake Limit.	VIONA PHARMACEUTICALS INC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Healthcare Ltd. Ahmedabad, India. Distributed by: Viona Pharmaceuticals Inc. Cranford, NJ 07016 NDC 72578-036-01					
Erythromycin Topical Solution USP, 2% 60 mL, Rx Only, Teligent Pharma, Inc., Buena, NJ 08310, NDC 52565-027-59	Class III	Drugs	Lot 14180	Failed Impurities/Degradation Specifications	Teligent Pharma, Inc.
Erythromycin Topical Gel, 2%, Net Wt. (a) 30 g,(NDC 52565-033-30) (b) 60 g,(NDC 52565-033-60) Rx Only, Manufactured by: Teligent Pharma, Inc. , Buena, NJ 08310,	Class III	Drugs	1) NDC 52565-033-30 Lot 14010, Exp July 2021; 2) NDC 52565-033-60 Lot 13865, Exp June 2021; Lot 14011, Exp July 2021.	Failed Impurities/Degradation Specifications	Teligent Pharma, Inc.
Acetaminophen EXTRA STRENGTH Pain Reliever / Fever Reducer, Enteric Coated, 50 Coated Tablets/ 500 mg each, Distributed by Amerisource Bergen, 1300 Morris Drive, Chesterbrook, PA, 19087, NDC 46122-649-71	Class III	Drugs	Lot # P120999, Exp 07/31/2022	Labeling: Not Elsewhere Classified The primary label contains the words "enteric coated" but the tablet is not enteric coated and should only say 'coated tablet'	LNK International, Inc.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
LEUKINE (Sargramostim) for Injection, 250 mcg/ vial, 5mL vials, 5 (250 mcg vials) per box, Rx only, Mfd by Partner Therapeutics, Inc. Lexington, MA 02421, NDC 71837-5843-5	Class III	Drugs	Lot #: E8023E, exp. date 11/30/2022	FAILED STABILITY SPECIFICATION: Out-of-specification (OOS) result observed for Leukine (sargramostim) at the 27-month stability timepoint.	Partner Therapeutics Inc
B-Force, Homeopathic, 1 Fl Oz (30 mL) bottle, Distributed by: BioActive Nutritional, Inc., Melbourne, FL 32935, NDC 43857-0576-1	Class III	Drugs	Lot: Z61917	Superpotent	Grato Holdings, Inc.
Mephyton (Phytonadione) 5 mg tablets, 100-count tablets, Rx Only, Manufactured for: Valeant Pharmaceuticals North America, LLC, Bridgewater, NJ, 08807, USA, NDC 0187-1704-05.	Class III	Drugs	Lot #: 19D012P, Exp Date 07/2021; 20D096P, Exp Date 10/2022	Failed Impurities/Degradation Specifications	Bausch Health Companies, Inc.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Phytonadione Tablets, 5 mg, 30-count ablets, Rx only, Manufactured for: Oceanside Pharmaceuticals, a division of Valeant Pharmaceuticals North America LLC, Bridgewater, NJ 08807 USA, NDC 68682-170-30	Class III	Drugs	Lot #:19D013P, Exp Date 07/2021; 20D099P, Exp Date 10/2022	Failed Impurities/Degradation Specifications	Bausch Health Companies, Inc.

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

FDA DRUG SAFETY COMMUNICATIONS

[07/20/2021] FDA requests removal of strongest warning against using cholesterol-lowering statins during pregnancy; still advises most pregnant patients should stop taking statins

What safety information is FDA announcing?
The U.S. Food and Drug Administration (FDA) is requesting removal of its strongest warning against using cholesterol-lowering statin medicines in pregnant patients. Despite the change, most patients should stop statins once they learn they are pregnant. We have conducted a comprehensive review of all available data and are requesting that statin manufacturers make this change to the prescribing information as part of FDA's ongoing effort to update the pregnancy and breastfeeding information for all prescription medicines.

Patients should not breastfeed when taking a statin because the medicine may pass into breast milk and pose a risk to the baby. Many can stop statins temporarily until breastfeeding ends. However, patients requiring ongoing statin treatment should not breastfeed and instead use infant formula or other alternatives.

What is FDA doing?
We are requesting revisions to the information about use in pregnancy in the prescribing information of the entire class of statin medicines. These changes include removing the contraindication against using these medicines in all pregnant patients. A contraindication is FDA's strongest warning and is only added when a medicine should not be used because the risk clearly outweighs any possible benefit. Because the benefits of statins may include prevention of serious or potentially fatal events in a small group of very high-risk pregnant patients, contraindicating these drugs in all pregnant women is not appropriate.

FDA expects removing the contraindication will enable health care professionals and patients to make individual decisions about benefit and risk, especially for those at very high risk of heart attack or stroke. This includes patients with homozygous familial hypercholesterolemia and those who have previously had a heart attack or stroke. Statins are safe to use in patients who are not pregnant but may become pregnant.

What are statins and how can they help me?
Statins are a class of prescription medicines that have been used for decades to lower low-density lipoprotein (LDL-C or "bad") cholesterol in the blood. Statins work by reducing the amount of cholesterol made by the liver and helping the liver remove cholesterol already in the blood. Statins also can lower the risk for heart attack and stroke in those who have heart disease or risk factors for it. These medicines may help stabilize the plaques that can build up inside blood vessel walls, which can interfere with blood flow to the heart and brain, leading to heart attack and stroke.

Medicines in the statin class include atorvastatin, fluvastatin, lovastatin, pitavastatin, pravastatin, rosuvastatin, and simvastatin. They are marketed as single-ingredient products and in combination with other medicines (See FDA-Approved Statin Medicines below). They are available as brand-name and generic products.

What should patients do?
Patients taking statins should notify your health care professionals if you become pregnant or suspect you are pregnant. Your health care professional will be able to advise whether you should stop taking the medicine during pregnancy and whether you may stop your statin temporarily while breastfeeding. Patients who are at high risk of heart attack or stroke who require statins after giving birth should not breastfeed and should use alternatives such as infant formula.

What should health care professionals do?
Health care professionals should discontinue statin therapy in most pregnant patients, or they can consider the ongoing therapeutic needs of the individual patient, particularly those at very high risk for cardiovascular events during pregnancy. Because of the chronic nature of cardiovascular disease, treatment of hyperlipidemia is not generally necessary during pregnancy. Discuss with patients whether they may discontinue statins temporarily while breastfeeding. Advise those who require a statin because of their cardiovascular risk that breastfeeding is not recommended because the medicine may pass into breast milk.

We hope the revised language in the prescribing information will help reassure health care professionals that statins are safe to prescribe in patients who can become pregnant, and help them reassure patients with unintended statin exposure in early pregnancy or before pregnancy is recognized that the medicine is unlikely to harm the unborn baby.

What did FDA review?
When FDA approved the first statin in 1987, the medicine came with our strongest warning recommending against use during pregnancy and breastfeeding. This was based on several factors. These were safety signals from animal data at drug exposures higher than human doses, potential concern that lowering cholesterol may negatively affect the unborn baby or infant, and the perspective that short-term use during pregnancy and breastfeeding did not provide a substantial benefit to the mother. All statins approved subsequently have carried the same warning.

Since then, multiple randomized trials and meta-analyses have demonstrated the benefit of statin therapy on the prevention of cardiovascular events. In addition, data from published observational studies of statin use in pregnant women have not identified a drug-associated risk of major birth defects when controlling for other risks such as diabetes and are insufficient to determine if there is a drug-associated risk of miscarriage.1-15 Overall, animal data suggest limited potential of statins to cause birth defects or miscarriage and limited potential to affect nervous system development in an unborn baby. However, because statins decrease the body's ability to make cholesterol and possibly other substances, it is possible these medicines could harm an unborn baby when taken by a pregnant mother (See Data Summary for more details).

How do I report side effects from statins?
To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving statins or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

How can I get new safety information on medicines I'm prescribing or taking?
You can sign up for email alertsExternal Link Disclaimer about Drug Safety Communications on medicines or medical specialties of interest to you.

FDA-Approved Statin Medicines

Brand Name	Active Ingredient(s)
Lipitor	atorvastatin
Caduet	atorvastatin and amlodipine
Lescol XL	fluvastatin
Altoprev	lovastatin
Livalo	pitavastatin
Zypitamag	pitavastatin
Pravachol	pravastatin
Crestor	rosuvastatin
Ezallor Sprinkle	rosuvastatin
Roszet	rosuvastatin and ezetimibe
Zocor	simvastatin
Flolipid	simvastatin
Vytorin	simvastatin and ezetimibe

Facts about Statins

- Statins are a class of medicines used to lower cholesterol in the blood. Statins work by reducing the amount of cholesterol made by the liver and by helping the liver remove cholesterol already in the blood.
- Statins also can lower the risk for heart attack and stroke in patients who have heart disease or risk factors for it. These medicines may help stabilize the plaques that can build up inside blood vessel walls, which can interfere with blood flow to the heart and brain, leading to heart attack and stroke.
- Common side effects of statins include headache, nausea, muscle pain, diarrhea, and constipation.

Additional Information for Patients

- FDA is requesting that manufacturers of cholesterol-lowering statins remove FDA's strongest warning in the current prescribing information, which states that statins should never be used in

patients during pregnancy. However, most patients should still stop statins once they learn they are pregnant.

- Inform your health care professional if you become pregnant or suspect you are pregnant while taking a statin medicine. Your health care professional will be able to advise whether you should stop taking the medicine.
- Statins are safe to use if you are not pregnant but can become pregnant. If you are taking a statin before you know you are pregnant, it is unlikely to harm your unborn baby.
- Discuss with your health care professional if you are breastfeeding or plan to do so. Breastfeeding is not recommended in patients taking a statin. Your health care professional can help you determine whether it will be better for you to stop the statin temporarily while breastfeeding or whether you need to continue taking it and so should not breastfeed. If ongoing statin treatment is necessary, infant formula and other alternatives are available.
- Always consult with your health care professional about the use of all medicines during pregnancy or while breastfeeding.
- Talk to your health care professional if you have any questions or concerns about your statin medicine.
- To help FDA track safety issues with medicines, report side effects from statins or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.
- You can sign up for email alertsExternal Link Disclaimer about Drug Safety Communications on medicines or medical specialties of interest to you.

Additional Information for Health Care Professionals

- FDA is requesting that manufacturers of cholesterol-lowering statins remove the contraindication included in the current prescribing information stating these medicines should never be used in patients during pregnancy.
- Health care professionals should discontinue statin therapy in most pregnant patients. Alternatively, health care professionals should consider the ongoing therapeutic needs of the individual patient, especially patients at very high risk of cardiovascular events during pregnancy, such as patients with homozygous familial hypercholesterolemia or those with established cardiovascular disease.
- Statins are safe to prescribe in patients who are not pregnant but may become pregnant. Reassure patients who have an unintended exposure to statins in early pregnancy that it is unlikely to cause harm to the developing fetus.
- Treatment of hyperlipidemia is not generally necessary during pregnancy. Atherosclerosis is a chronic process and the temporary discontinuation of lipid-lowering drugs during pregnancy should have little impact on the outcome of long-term therapy of primary hyperlipidemia for most patients.
- There is insufficient evidence to determine whether statins can cause miscarriage.
- Observational studies have not identified an increase in birth defects associated with statin use during pregnancy after adjusting for potential confounders. Animal data suggest limited potential for statins to cause malformations, and limited potential to affect the developing nervous system or cause embryofetal death. Nevertheless, statins decrease the synthesis of cholesterol and possibly other biologically active substances derived from cholesterol. Therefore, statins may cause fetal harm when administered to pregnant patients. Counsel pregnant women of this potential risk.
- Some statins have been shown to pass into human milk and may cause harm to the breastfed infant based on the mechanism of action.

- Advise patients who can become pregnant to inform their health care professionals of a known or suspected pregnancy, or if they are breastfeeding or plan to do so, to discuss whether their statin should be discontinued.
- To help FDA track safety issues with medicines, report adverse events involving statins or other medicines to the FDA MedWatch program, using the information in the "Contact Us" box at the bottom of this page.
- You can sign up for email alertsExternal Link Disclaimer about Drug Safety Communications on medicines or medical specialties of interest to you.

Data Summary

FDA reviewed data from case series and prospective and retrospective observational cohort studies over decades of use of statins in pregnant women.[1-15] Multiple larger, well-designed, and controlled observational studies did not find an increase in major birth defects associated with use of statins during pregnancy. The most recent 2015 Medicaid cohort linkage study of 1,152 statin-exposed pregnant women compared to 886,996 controls did not find a significant teratogenic effect from maternal use of statins in the first trimester of pregnancy, after adjusting for potential confounders.[2] Propensity score-based methods were used to control for maternal age, diabetes, hypertension, obesity, and alcohol and tobacco use. The relative risk of congenital malformations between the group with statin use and the group with no statin use in the first trimester was 1.07 (95% confidence interval (CI) 0.85 to 1.37) after controlling for confounders, particularly pre-existing diabetes. There were also no statistically significant increases in any of the organ-specific malformations assessed after accounting for confounders. In the majority of pregnancies, statin treatment was initiated prior to pregnancy and was discontinued at some point in the first trimester when pregnancy was identified. Study limitations included reliance on physician coding to define the presence of a malformation, lack of control for certain confounders such as body mass index, use of prescription dispensing as verification for the use of a statin, and lack of information on non-live births.

Published data from prospective and retrospective observational cohort studies with statin use in pregnant women are insufficient to determine if there is a drug-associated risk of miscarriage. Many older studies did not report or discuss the rate of miscarriage; however, three studies included miscarriage in their analyses and did not find an increased risk once adjustments were made for confounders.3, 9, 10 In 2009, McGrogan et al.[8] reported an adjusted risk ratio for terminations of 2.48 (95% CI 1.65-3.73). However, this study did not differentiate between elective terminations and miscarriage, and an increased rate of elective terminations would be expected in a study of pregnant women exposed to a drug contraindicated during pregnancy. In a meta-analysis of six small observational studies of statin exposure in pregnant women, Zarek et al.[4] reported a risk ratio of miscarriage of 1.35 (95% CI 1.04-1.75). However, many of the studies included in the analysis, which were older and included the McGrogan 2009 study, did not control for multiple confounders that are known to increase the risk of miscarriage. In 2017, McGrogan et al.[1] published a retrospective cohort study specifically looking at fetal loss as a primary outcome. The authors compared 281 statin-exposed pregnant women versus 2,643 controls. The cohorts were matched for maternal age, diabetes mellitus, hypertension and body mass index, and free text was used to help identify type of loss (i.e., miscarriage vs. elective termination). They found a miscarriage rate of 25% in statin-exposed versus 21% for controls. The adjusted hazard ratio was 1.64 (95% CI 1.1-2.46). Although there was an attempt to control for the presence of diabetes, the authors acknowledged there might still be some confounding because the study was not controlled for the type or severity of diabetes, which can influence rate of

miscarriage. They also acknowledged the possibility of residual misclassification regarding smoking and alcohol use based on changed behavior patterns during pregnancy.

FDA also re-reviewed nonclinical data from statin development programs. The totality of the data suggests a limited potential for statins to cause malformations or embryofetal lethality, and limited potential to affect nervous system development during human embryofetal development and during the pre- and post-natal period.

References

1. McGrogan A, Snowball J, Charlton RA. Statins during pregnancy: a cohort study using the General Practice Research Database to investigate pregnancy loss. Pharmacoepidemiol Drug Saf 2017;26:843-52.
2. Bateman BT, Hernandez-Diaz S, Fischer MA, Seely EW, Ecker JL, Franklin JM, et al. Statins and congenital malformations: cohort study. BMJ 2015;350:h1035.
3. Winterfeld U, Allignol A, Panchaud A, Rothuizen LE, Merlob P, Cuppers-Maarschalkerweerd B, et al. Pregnancy outcome following maternal exposure to statins: a multi-centre prospective study. BJOG 2013;120:463-71.
4. Zarek J, Delano KE, Nickel C, Laskin CA, Koren G. Are statins teratogenic in humans? Addressing the safety of statins in light of potential benefits during pregnancy. Expert Rev Obstet Gynecol 2013;8:513-24.
5. Schir E et al. Safety of statins in pregnancy. Société Française de Pharmacologie et de Thérapeutique Abstracts 2012; 26(Suppl 1):106.
6. Toleikyte I, Retterstøl K, Leren TP, Iversen PO. Pregnancy outcomes in familial hypercholesterolemia: a registry-based study. Circulation 2011;124:1606-14.
7. Colvin L, Slack-Smith L, Stanley FJ, Bower C. Linking a pharmaceutical claims database with a birth defects registry to investigate birth defect rates of suspected teratogens. Pharmacoepidemiol Drug Saf 2010;19:1137-50.
8. McGrogan A, Snowball J, de Vries CS. Statins and pregnancy outcomes: A cohort study in the GPRD. Pharmacoepidemiol Drug Saf 2009;18(Suppl 18):S75-6.
9. Paulus WE et al. Statin treatment in hypercholesterolemic mothers during early pregnancy. Geburtshilfe Und Frauenheilkunde 2008;68:S130.
10. Taguchi N, Rubin ET, Hosokawa A, Choi J, Ying AY, Moretti ME, et al. Prenatal exposure to HMG-CoA reductase inhibitors: effects on fetal and neonatal outcomes. Reprod Toxicol 2008;26:175-7.
11. Petersen EE, Mitchell AA, Carey JC, Werler MM, Louik C, Rasmussen SA, the National Birth Defects Prevention Study. Maternal exposure to statins and risk for birth defects: A case-series approach. Am J Med Genet Part A 2008;146A:2701-5.
12. Ofori B, Rey E, Bérard A. Risk of congenital anomalies in pregnant users of statin drugs. Br J Clin Pharmacol 2007 Oct;64:496-509.
13. Pollack PS, Shields KE, Burnett DM, Osborne MJ, Cunningham ML, Stepanavage ME. Pregnancy outcomes after maternal exposure to simvastatin and lovastatin. Birth Defects Res A Clin Mol Teratol 2005;73:888-96.
14. Edison RJ, Muenke M. Mechanistic and epidemiologic considerations in the evaluation of adverse birth outcomes following gestational exposure to statins. Am J Med Genet A 2004;131:287-98.
15. Manson JM, Freyssinges C, Ducrocq MB, Stephenson WP. Postmarketing surveillance of lovastatin and simvastatin exposure during pregnancy. Reprod Toxicol 1996;10:439-46.

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 Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate Tablets
Asparaginase Erwinia Chrysanthemi (Erwinaze)
Atropine Sulfate Injection
Atropine Sulfate Ophthalmic Ointment
Azacitidine for Injection
Belatacept (Nulojix) Lyophilized Powder for Injection
Bumetanide Injection
Bupivacaine Hydrochloride and Epinephrine Injection
Bupivacaine Hydrochloride Injection
Calcitriol Injection 1MCG/ML
Calcium Disodium Versenate Injection
Calcium Gluconate Injection
Cefazolin Injection
Cefotaxime Sodium Injection
Cefotetan Disodium Injection
Cefoxitin for Injection
Ceftazidime and Avibactam (AVYCAZ®) for Injection, 2 grams/0.5 grams
Ceftolozane and Tazobactam (Zerbaxa) Injection
Chlordiazepoxide Hydrochloride Capsules
Chloroprocaine Hydrochloride Injection
Continuous Renal Replacement Therapy (CRRT) Solutions
Cortisone Acetate Tablets
Cyclopentolate Ophthalmic Solution
Cysteamine Hydrochloride Ophthalmic Solution
Desmopressin Acetate Nasal Spray
Dexamethasone Sodium Phosphate Injection
Dexmedetomidine Injection
Digoxin Injection
Diltiazem Hydrochloride 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
Famotidine Injection
Famotidine Tablets
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
Histreline Acetate Implant
Hydrocortisone Tablets
Hydromorphone Hydrochloride Injection
Hydroxocobalamin Injection
Hydroxypropyl (Lacrisert) Cellulose Ophthalmic Insert
Imipenem and Cilastatin for Injection
Isoniazid Injection
Ketamine Injection
Ketoprofen Capsules
Ketorolac Tromethamine Injection
Letermovir (Prevymis) 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
Lithium Oral Solution
Lorazepam Injection
Loxapine Capsules
Mepivacaine Hydrochloride Injection
Methohexital Sodium (Brevital) Injection
Methyldopa Tablets
Midazolam Injection
Misoprostol Tablets
Morphine Sulfate Injection
Multi-Vitamin Infusion (Adult and Pediatric)
Nefazodone Hydrochloride Tablets
Nizatidine Capsules

Ondansetron Hydrochloride Injection
Pantoprazole Sodium for Injection
Parathyroid Hormone (Natpara) Injection
Physostigmine Salicylate Injection
Pindolol Tablets
Potassium Acetate 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 23.4% Injection
Sodium Chloride Injection USP, 0.9% Vials and Syringes
Succimer (Chemet) Capsules
Sulfasalazine Tablets
Tacrolimus Capsules
Technetium Tc99m Succimer Injection (DMSA)
Teprotumumab-trbw
Thiothixene Capsules
Timolol Maleate Ophthalmic Gel Forming Solution
Triamcinolone Hexacetonide Injectable suspension
Trimethobenzamide Hydrochloride Capsules
Valproate Sodium Injection
Varenicline Tartrate (Chantix) Tablets
Vecuronium Bromide for Injection