PERFORMRx℠

Drug Information Update

September 2021

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NEWLY AVAILABLE GENERICS

Generic Name/ Dosage Form	Brand Name	Manufacturer	Indication
ursodiol 200 mg, 400 mg capsule	Reltone	FH2 Pharma LLC	• For the treatment of radiolucent, noncalcified gallbladder stones < 20 mm in greatest diameter in patients whom elective cholecystectomy would be undertaken except for the presence of increased surgical risk due to systemic disease, advanced age, idiosyncratic reaction to general anesthesia, or for those patients who refuse surgery; and for the prevention of gallstone formation in obese patients experiencing rapid weight loss.
baclofen 50 mcg/mL (1 mL) syringe	Gablofen	Sagent Pharmaceuticals	• For the management of severe spasticity in adult and pediatric patients age 4 years and above.
nebivolol hcl 2.5 mg, 5 mg, 10 mg, 20 mg	Bystolic	Forest/Allergan	• For the treatment of hypertension, to lower blood pressure, used alone or in combination with other antihypertensive agents.
difluprednate 0.05% ophthalmic drops	Durezol	Alcon/Novartis	• Indicated for the treatment of inflammation and pain associated with ocular surgery. • Indicated for the treatment of endogenous anterior uveitis

NEW DRUG ENTITIES/STRENGTHS/COMBINATIONS

Drug Name	Generic Name	Description	Comments
Vaxneuvance 0.5 mL intramuscular syringe	Pneumococcal 15-valent conjugate vaccine	Vaccine indicated for active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in adults 18 years of age and older.	New Formulation
Multrys 1,000mcg-60mcg-3mcg-6mcg/mL intravenous solution	zinc/copper/manganese/selenium	Parenteral nutrition product providing trace elements.	New Strength
Welireg 40 mg tablet	belzutifan	A hypoxia-inducible factor inhibitor indicated for treatment of adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery.	New Entity
Loreev XR 1, 2, 3 mg capsule,extended release	lorazepam	Extended release lorazepam product, 505(b)(2) approval pathway.	New Dosage Form (3 mg is also new strength)
Opdivo 120 mg/12 mL intravenous solution	nivolumab	New indication for urothelial carcinoma, adjuvant treatment for high risk patients after radical resection of UC.	New Strength

Drug Name	Generic Name	Description	Comments
hydroxychloroquine 100, 300, 400 mg tablet	hydroxychloroquine	Alternative strength hydroxychloroquine tablets	New Strength
Invega Hafyera 1,092 mg/3.5 mL intramuscular syringe	paliperidone palmitate	New 6-month regimen for treatment of schizophrenia	New Dosing Regimen and Strength
Trudhesa 0.725 mg/pump act. (4 mg/mL) nasal spray	dihydroergotamine mesylate	Nasal DHE for migraine treatment, like Migranal.	New Strength

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†
Opdivo	nivolumab injection, 40 mg/4 mL, 100 mg/10 mL, 240 mg/24 mL solution in single-dose vials	Bristol Myers Squibb	Opdivo is a programmed death receptor-1 blocking antibody indicated for the adjuvant treatment of patients with urothelial carcinoma (UC) who are at high risk of recurrence after undergoing radical resection of UC. *Note: Opdivo has many other indications not presented here because there were no changes*
Xarelto	rivaroxaban tablets, 2.5 mg, 10 mg, 15 mg, 20 mg	Janssen Pharmaceuticals	Xarelto is a factor Xa inhibitor indicated to reduce the risk of major thrombotic vascular events in patients with peripheral artery disease (PAD), including patients after recent lower extremity revascularization due to symptomatic PAD.
Tibsovo	ivosidenib tablets, 250 mg	Agios Pharmaceuticals	Tibsovo is an isocitrate dehydrogenase-1 (IDH1) inhibitor indicated for the treatment of adult patients with a susceptible IDH1 mutation as detected by an FDA-approved test with locally advanced or metastatic cholangiocarcinoma who have been previously treated.
Briviact	brivaracetam tablets, 10 mg, 25 mg, 50 mg, 75 mg, 100 mg; oral solution, 10 mg/mL; injection 50 mg/5 mL vial	UCB Pharma	Treatment of partial-onset seizures in patients ~~four years~~ **1 month** of age and older.
Brukinsa	zanubrutinib capsules, 80 mg	Beigene USA	A kinase inhibitor indicated for the treatment of adult patients with: • Mantle cell lymphoma (MCL) who have received at least one prior therapy.* • **Waldenström's macroglobulinemia (WM).**

Brand Name	Generic Name/ Dosage Form	Manufacturer	Newly Approved Indication†
			• **Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen.*** **This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.*

RECALLS

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Atovaquone Oral Suspension, USP, 750 mg/5 mL, 210 mL bottle, Rx Only, Mfd. By: KVK-Tech, Inc., Newtown, PA 18940, NDC 10702-223-21.	Class I	Drugs	Batch # 16653A, 16654A, Exp 12/2022	Temperature abuse: the firm received customer complaints of unusual grittiness in the product.	KVK-Tech, Inc.
Sodium Bicarbonate in 5% Dextrose Injection, 150 mEq per 1,000 mL (12.6 mg per mL), 1,000 mL bags, Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903 NDC 70324-326-01	Class I	Drugs	Lot Number: BUP, exp. date 03/23/22	Non-Sterility: firm's third party lab confirmed microbial contamination.	SterRx, LLC
MEDICALLY MINDED Hand Sanitizer Gel, ANTIMICROBIAL FORMULA, (Ethyl Alcohol 70% v/v), 8 FL OZ (236 mL) bottle, Manufactured by Asiaticon, S.A. de C.V.	Class I	Drugs	Lot No: E082020, "Best Buy": 5/21/2022	Chemical Contamination: FDA analysis found 1 lot of MEDICALLY MINDED Hand Sanitizer Gel, ANTIMICROBIAL FORMULA (ethyl alcohol 70%) to be below the label claim for	Global Sanitizers LLC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Conkal 62, Jardines del Ajusco, Tlalpan, Ciudad de Mexico, C.P. 14200, Distributed by SBL Brands, LLC. Las Vegas, NV 89119. Made in Mexico UPC: 6 76753 00420 8,				ethanol content and to contain methanol.	
MEDICALLY MINDED Hand Sanitizer Gel, ANTIMICROBIAL FORMULA, (Ethyl Alcohol 70% v/v), 8.5 FL OZ / 250 mL bottle, Made in Mexico, Distributed by SBL Brands, LLC Las Vegas, NV 89119. UPC: 6 76753 00359 1	Class I	Drugs	Lot No: E082020, "Best Buy": 5/21/2022	Chemical Contamination: FDA analysis found 1 lot of MEDICALLY MINDED Hand Sanitizer Gel, ANTIMICROBIAL FORMULA (ethyl alcohol 70%) to be below the label claim for ethanol content and to contain methanol.	Global Sanitizers LLC
Florance Morris ANTISEPTIC Hand Sanitizer (ethyl alcohol 70%), packaged in a) 8.45 fl oz (250 mL) bottles and b) 33.81 fl oz (1L) bottles, Distributed by: Asimex	Class I	Drugs	All lots including but not limited to: 200520673 and 200601685	Chemical Contamination: FDA analysis found the product contains methanol, additionally it is sub-potent for ethanol content.	Grupo Asimex de Mexico SA de CV

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
International LLC, 9100 S Dadeland Blvd, Ste 912, Miami, FL 33156, COUNTRY OF ORIGIN: MEXICO.					
Lidocaine Hydrochloride Topical Solution, USP, 4% , 50 mL glass bottles, Rx Only, Teligent Pharma Inc. Buena, New Jersey 08310, NDC 52565-009-50.	Class I	Drugs	Lot #:14218, Exp. Date 08/2022	Superpotent Drug	Teligent Pharma, Inc.
Hydro Pinapple Burn Max Health Thach Dua, packaged in a box containing 20g x 10 goi/sachets, MATXI CORP, UPC 8 936188 880108	Class I	Drugs	All lots within expiry.	Marketed without an approved NDA/ ANDA - presence of undeclared sibutramine	Ebay Seller - John Nguyen
AMINOSYN II 15% An Amino Acid Injection, Sulfite-Free, 2000 mL in flexible containers, Rx ONLY, Hospira, Inc., Lake	Class I	Drugs	Lot: 4989094 Exp. 01-APR-2022	Presence of Particulate Matter: Particulate matter identified as fibers, hair, and proteinaceous material along with other particles, found in retain smples.	ICU Medical Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Forest, IL 60045. NDC 0409-7171-17					
Miss Slim, capsules, packaged in 10-count and 30-count box, Distributed by : His Enterprise Made in USA UPC 742137605030	Class II	Drugs	all lots	Marketed without ANDA/NDA approval	HIS ENTERPRISE INC
PDI Povidone-Iodine Prep Pad MEDIUM, 1 Prep Pad [2.0x2.5 in (5.1x6.4 cm)], Professional Disposables International Inc., Orangeburg, NY 10962-1376 Reorder No. B40600; UPC (01)00310819000147, NDC 10819-3883-1,	Class II	Drugs	Lot #'s EXP date 11800977, 2021-07-31; 11800978 2021-08-02; 11800979 2021-08-04; 11801123 2021-08-06; 11801124 2021-08-09; 11801125 2021-08-15; 11801126 2021-08-16; 11801228 2021-08-28; 11801230 2021-09-11; 11801231 2021-09-13; 11801232 2021-09-18; 11801234 2021-10-25; 11801417 2021-10-28; 11801418 2021-11-01; 11801419 2021-11-07; 11801420 2021-11-15; 11801421 2021-11-20; 11801709 2021-11-29; 11801710 2021-12-04; 11900195 2022-02-19; 11900196 2022-02-21; 11900197 2022-02-	SubPotent: Out of Specification	Professional Disposables International, Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			25; 11900370 2022-04-01; 11900372 2022-04-03; 11900371 2022-04-05; 11900647 2022-05-04; 11900623 2022-05-21; 11900624 2022-05-24; 11900646 2022-05-29; 11900967 2022-08-13; 11900968 2022-08-26; 11900969 2022-08-28; 11901043 2022-09-11; 11901044 2022-09-18; 11901318 2022-10-03; 11901330 2022-10-08; 11901331 2022-10-16; 11901446 2022-10-28; 11901447 2022-11-19; 11901448 2022-12-19; 11901739 2023-01-02; 11901752 2023-01-09; 12000045 2023-01-14; 12000048 2023-01-18; 12000046 2023-01-21; 12000047 2023-01-24; 12000333 2023-01-25; 12000675 2023-02-16; 12000334 2023-02-27; 12000335 2023-02-27; 12000336 2023-02-28; 12000676 2023-03-16; 12000815 2023-03-29; 12000816 2023-05-05; 12000914 2023-05-13;		

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			12000915 2023-05-18; 12000951 2023-05-22; 12000950 2023-06-01; 12001366 2023-08-12; 12001367 2023-08-14; 12001368 2023-08-17; 12001370 2023-08-21; 12001369 2023-08-21; 12001371 2023-08-25; 12001372 2023-09-30; 12001818 2023-09-30; 12001820 2023-09-30; 12001819 2023-11-30; 12001821 2023-11-30; 12001822 2023-11-30; 12001972 2023-12-31; 12001973 2023-12-31; 12001974 2023-12-31; 12001975 2023-12-31; 12001976 2023-12-31; 12001977 2023-12-31; 12001978 2023-12-31; 12100080 2023-12-31; 12100081 2023-12-31; 12100082 2024-02-29; 12100084 2024-02-29; 12100447 2024-03-31; 11800978, 11800979, 11801123, 11801124, 11801125, 11801126, 11801228, 11801230, 11801231, 11801232, 11801234, 11801417,11801418,		

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			11801419, 11801420, 11801421, 11801709, 11801710, 11900195, 11900196, 11900197, 11900370, 11900371, 11900372, 11900623, 11900624, 11900646, 11900647, 11900967, 11900968, 11900969, 11901043, 11901044, 11901318, 11901330, 11901331, 11901446, 11901447, 11901448, 11901739, 11901752, 12000045, 12000046, 12000047, 12000048, 12000333, 12000334, 12000335, 12000336, 12000675, 12000676, 12000815, 12000816, 12000914, 12000915, 12000950, 12000951, 12001366, 12001367, 12001368, 12001369, 12001370, 12001371, 12001372, 12001818, 12001819, 12001820, 12001821, 12001822, 12001972, 12001973, 12001974, 12001975, 12001976, 12001977, 12001978, 12100080, 12100081, 12100082, 12100084 and 12100447		

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
PDI Povidone-Iodine Prep Pad Large, 1 Prep Pad, Professional Disposable International, Inc., Orangeburg, NY 10962 - 1376 USA Reorder No C12400 NDC 10819-3883-3, UPC (01)00310819000154	Class II	Drugs	Lot #'s 11801215, EXP 2021-08-22; 11801504, EXP 2021-11-06; 11801717,EXP 2021-12-07; 11900421, EXP 2022-04-04; 11901076, EXP 2022-08-29; 11901571, EXP 2022-11-19; 12000388, EXP 2023-03-13; 12001533 EXP 2023-07-28; 12100459 EXP 2024-03-31;	SubPotent: Out of Specification	Professional Disposables International, Inc
PDI Povidine Iodine Swabstick (1's), 1 swabstick, Professional Disposable International, Inc. Orangeburg, NY 10962 -1376 Reorder No S41350 NDC 10819-3885-1, UPC (01)00310819000178.	Class II	Drugs	Lot #'s 11900790, EXP 2021-07-25; 11900919, EXP 2021-07-28; 11900920, EXP 2021-08-12; 11900921, EXP 2021-08-15; 11901106, EXP 2021-08-27; 11901107, EXP 2021-08-30; 11901128, EXP 2021-09-05; 11901129, EXP 2021-09-12;11901249, EXP 2021-09-25; 11901250, EXP 2021-10-17; 11901391, EXP 2021-10-19; 11901392, EXP 2021-10-22; 11901438, EXP 2021-10-24; 11901439, EXP 2021-10-08; 11901457, EXP 2021-11-07; 11901541, EXP 2021-11-18;	SubPotent: Out of Specification	Professional Disposables International, Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			11901603, EXP 2021-11-19; 11901604, EXP 2021-12-19; 11901669, EXP 2021-12-19; 11901670, EXP 2021-11-16; 11901702, EXP 2021-12-02; 11901703, EXP 2021-12-14; 12000082, EXP 2021-12-19; 12000083, EXP 2022-01-24; 12000118, EXP 2022-01-03; 12000119, EXP 2022-01-30; 12000249, EXP 2022-01-10; 12000250, EXP 2022-01-10; 12000348, EXP 2022-02-13; 12000349, EXP 2022-02-28; 12000398, EXP 2022-02-05; 12000456, EXP 2022-03-12; 12000457, EXP 2022-03-12; 12000683, EXP 2022-03-23; 12000684, EXP 2022-03-30; 12000685, EXP 2022-04-04; 12000922, EXP 2022-05-15; 12000923, EXP 2022-05-19; 12000927, EXP 2022-05-21; 12000989, EXP 2022-06-15; 12000990, EXP 2022-06-05;		

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			12000991, EXP 2022-06-10; 12001154, EXP 2022-06-26; 12001155, EXP 2022-06-24; 12001231, EXP 2022-07-26; 12001232, EXP 2022-07-21; 12001243, EXP 2022-07-03; 12001244, EXP 2022-07-04; 12001537, EXP 2022-08-31; 12001538, EXP 2022-08-31; 12001539, EXP 2022-08-31; 12001540, EXP 2022-09-30; 12001666, EXP 2022-09-30; 12001667, EXP 2022-09-30; 12001668, EXP 2022-09-30; 12001669, EXP 2022-09-30; 12001841, EXP 2022-10-31; 12001842, EXP 2022-10-31; 12001959, EXP 2022-10-31; 12002072, EXP 2022-11-30; 12100123, EXP 2023-02-28; 12100124, EXP 2023-02-28; 12100454, EXP 2023-03-31; 12100455, EXP 2023-03-31; 12100590, EXP 2023-04-30; 12100591, EXP 2023-04-30;		

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
PDI Povidone-Iodine Swabstick (3's), 3 Swabsticks, Professional Disposable International, Inc., Orangeburg, NY 10962 -1376 Reorder No S41125 NDC 10819-3885-2, UPC (01)00310819000185	Class II	Drugs	Lot #'s 11900761, EXP 2022-11-03; 11900917, EXP 2022-11-04; 11900918, EXP 2022-11-05; 11901008, EXP 2022-11-06; 11901009, EXP 2022-11-07; 11901124, EXP 2022-11-08; 11901125, EXP 2022-11-09; 11901126, EXP 2022-11-10;11901127, EXP 2022-11-11; 11901179, EXP 2022-11-12; 11901180, EXP 2022-11-13; 11901247, EXP 2022-11-14; 11901248, EXP 2022-11-15; 11901388, EXP 2022-11-16;11901389, EXP 2022-11-17; 11901390, EXP 2022-11-18; 11901419, EXP 2022-11-19; 11901420, EXP 2022-11-20; 11901480, EXP 2022-11-21; 11901558, EXP 2022-11-22;11901590, EXP 2022-11-23; 11901591, EXP 2022-11-24; 11901592, EXP 2022-11-25; 11901691, EXP 2022-11-26; 11901692, EXP 2022-11-27;	SubPotent: Out of Specification	Professional Disposables International, Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			12000054, EXP 2022-11-28; 12000055, EXP 2022-11-29; 12000116, EXP 2022-11-30; 12000117, EXP 2022-12-01; 12000172, EXP 2022-12-02; 12000173, EXP 2022-12-03; 12000189, EXP 2022-12-04; 12000190, EXP 2022-12-05; 12000287, EXP 2022-12-06; 12000288, EXP 2022-12-07; 12000346, EXP 2022-12-08; 12000347, EXP 2022-12-09; 12000452, EXP 2022-12-10; 12000453, EXP 2022-12-11; 12000454, EXP 2022-12-12; 12000455, EXP 2022-12-13; 12000679, EXP 2022-12-14; 12000680, EXP 2022-12-15; 12000681, EXP 2022-12-16; 12000682, EXP 2022-12-17; 12000881, EXP 2022-12-18; 12000882, EXP 2022-12-19; 12000883, EXP 2022-12-20; 12000884, EXP 2022-12-21; 12001003, EXP 2022-12-22;		

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			12001004, EXP 2022-12-23; 12001005, EXP 2022-12-24; 12001006, EXP 2022-12-25; 12001150, EXP 2022-12-26; 12001151, EXP 2022-12-27; 12001184, EXP 2022-12-28; 12001283, EXP 2022-12-29; 12001284, EXP 2022-12-30; 12001285, EXP 2022-12-31; 12001510, EXP 2023-01-01; 12001513, EXP 2023-01-02; 12001514, EXP 2023-01-03; 12001515, EXP 2023-01-04; 12001598, EXP 2023-01-05; 12001599, EXP 2023-01-06; 12001600, EXP 2023-01-07; 12001786, EXP 2023-01-08; 12001789, EXP 2023-01-09; 12001790, EXP 2023-01-10; 12001843, EXP 2023-01-11; 12001844, EXP 2023-01-12; 12001981, EXP 2023-01-13; 12001982, EXP 2023-01-14; 12002006, EXP 2023-01-15; 12002007, EXP 2023-01-16;		

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			12002148, EXP 2023-01-17; 12002149, EXP 2023-01-18; 12100119, EXP 2023-01-19; 12100120, EXP 2023-01-20; 12100237, EXP 2023-01-21; 12100238, EXP 2023-01-22; 12100239, EXP 2023-01-23; 12100240, EXP 2023-01-24; 12100456, EXP 2023-01-25; 12100457, EXP 2023-01-26; 12100537, EXP 2023-01-27;		
PDI Povidone-Iodine Cleansing Scrub Swabstick (1's), 1 Swabstick, Professional Disposable International, Inc., Orangeburg, NY 10962 -1376 Reorder No S48050, NDC 10819-3891-2, UPC (01)00310819000192.	Class II	Drugs	Lot #'s 11901081, EXP 2023-04-04; 11901340, EXP 2023-04-05; 11901593, EXP 2023-04-06; 11901594, EXP 2023-04-07; 12000784, EXP 2023-04-08; 12000992, EXP 2023-04-09; 12001492, EXP 2023-04-10; 12001699, EXP 2023-04-11; 12100121, EXP 2023-04-12; 12100453, EXP 2023-04-13;	SubPotent: Out of Specification	Professional Disposables International, Inc
PDI Povidone-Iodide Cleansing Scrub Swabstick (3's), 3 Swabsticks, Professional	Class II	Drugs	Lot #'s 11901080, EXP 2023-04-14; 11901339, EXP 2023-04-15; 11901755, EXP 2023-04-16; 12000016, EXP 2023-04-17;	SubPotent: Out of Specification	Professional Disposables International, Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Disposable International, Inc., Orangeburg, NY 10962 -1376, Reorder No S82125, NDC 10819-3891-3, UPC (01)00310819000208.			12000397, EXP 2023-04-18; 12000987, EXP 2023-04-19; 12001578, EXP 2023-04-20; 12001814, EXP 2023-04-21;		
PDI Duo-Swab Povidone-Iodine Cleansing Scrub Swabstick, (1's), Step 1, packaged as a) Step 1 Scrub, 1 Swabstick, NDC 10819-3891-1, b) Step 2 Prep, 1 Swabstick, NDC 10819-3890-1, Professional Disposable International, Inc., Orangeburg, NY 10962 -1376 Reorder No S23125, UPC (01)00318019000161	Class II	Drugs	SKU S23125 Lot #'s 11900971, 11901517, 11901756, 12000199, 12000286, 12000459, 12000686, 12000751, 12001009, 12001316, 12001795, 12001809, 12001862, 12001863, 12002140, 12002141, 12100392 and 12100393	SubPotent: Out of Specification	Professional Disposables International, Inc
Pi yen chin Ophthalmic Redness Reliever Drops Made in China, Net Wt.: 10 ml (0.34 fl/oz) Exclusive U.S. Distributor:	Class II	Drugs	Lot 180901 Exp: 8/2021 Lot 190601 Exp: 5/2022 Lot 191201 Exp: 11/2022 Lot 200701 Exp:6/2023 Lot 201101 Exp: 10/2023 Lot 210501 Exp: 4/2024	Labeling: Not Elsewhere Classified; The packaging states these are ophthalmic drops. However, they are manufactured as nasal drops	ANHUI WELCOME FOREIGN TRADE CO.,LTD.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
(Chinese writing)International Nature Nutraceuticals, Inc. New York, NY 10002 www.INNHERB.com. Konzon NDC 51367-008-10				and sterility cannot be assured.	
Erythromycin Topical Solution USP, 2%, 60mL bottle, Rx only, Teligent Pharma, Inc. Buena, NJ 08310, NDC 52565-027-59	Class II	Drugs	Lot #: 14892, Exp 1/2022	Defective container: possibility for lack of seal integrity.	Teligent Pharma, Inc.
Sodium Bicarbonate in 5% Dextrose Injection, 150 mEq per 1,000 mL (12.6 mg per mL), 1,000 mL bags, Rx only, SterRx, 141 Idaho Ave., Plattsburgh, NY 12903	Class II	Drugs	Lot Numbers: BTW, exp. date 03/08/22 BUI, exp. date 03/16/22	Lack of Assurance of Sterility	SterRx, LLC
Micafungin for Injection, 50 mg/vial, Single-Dose Vial, Sterile, Rx Only, For Intravenous Infusion Only, Manufactured for:	Class II	Drugs	Lot 467111, exp 1/2023	Labeling; Incorrect or Missing Package Insert: The package insert provided with the product does not include all required sections approved	XELLIA PHARMACEUTICALS USA, LLC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089. NDC 70594-036-01				for this product. This includes aspects of Adverse Reactions, Drug Interactions and Use in Specific Populations.	
Micafungin for Injection, 100 mg/vial, Single-Dose Vial, Sterile, Rx Only, For Intravenous Infusion Only, Manufactured for: Xellia Pharmaceuticals USA, LLC, Buffalo Grove, IL 60089. NDC 70594-037-01	Class II	Drugs	Lot 467111, exp 1/2023	Labeling; Incorrect or Missing Package Insert: The package insert provided with the product does not include all required sections approved for this product. This includes aspects of Adverse Reactions, Drug Interactions and Use in Specific Populations.	XELLIA PHARMACEUTICALS USA, LLC
Sodium Phenylbutyrate POWDER, 250 grams bottle, Rx Only, Sigmapharm Laboratories, LLC Bensalem, PA 19020 NDC 42794-086-14 UPC Code# 3 42794 086 14 4	Class II	Drugs	Lot Numbers: 1813001, 1813101, 1813201, EXP. May 2023; 1822601, 1822701, EXP Nov 2023; 1905701, 1905801, 1906501, 1906601, 1906701, EXP May 2024	Failed Impurities Specifications: Out of Specification impurity results obtained during routine testing.	SigmaPharm Laboratories LLC
FLUDARABINE PHOSPHATE FOR	Class II	Drugs	Lot# 31327913C, Exp. Date 10/2022	Lack of Assurance of Sterility: the manufacturing firm had	Custopharm, Inc.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
INJECTION, USP, 50 mg per vial, Single dose vial, Rx Only, Mfd for: Leucadia Pharmaceuticals Carlsbad, CA 92011 U.S.A, NDC 24201-237-01				microbial recoveries during environmental monitoring in aseptic areas of manufacturing.	
Trulicity (dulaglutide), 0.75 mg/0.5 mL, 4 Single-Dose Pens per box, Rx only, Eli Lilly and Company, Indianapolis, IN 46285, NDC 0002-1433-80	Class II	Drugs	Lot number: D396436C	Labeling: Label error on declared strength - autoinjector devices labeled as 0.75 mg / 0.5 mL actually contain 1.5 mg / 0.5 mL of product.	Eli Lilly & Company
Carvedilol 25 mg, 180-count bottle, Rx only, Manufactured by Zydus Pharm, Pennington, NJ 08534, NDC 68382-0095-05, Repackaged by RemedyRepack Inc., Indiana, PA 15701, NDC 70518-1826-01	Class II	Drugs	Lot # B1273286-071521, Exp 07/31/2022	A 500 count bottle of Carvedilol 25 mg tablets contained two Paroxetine Tablets, 40 mg. Product was repackaged into 180 count bottles.	RemedyRepack Inc.
CHINA_GEL (Camphor 3.00%, Menthol 5.00%) A	Class II	Drugs	Lot #: a)B122DY, exp 2021-05; B183GN, exp 2021-07; B262BF,	CGMP deviations: Product being recalled as it was made	China Gel Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
TOPICAL PAIN RELIEVER, packaged as a) 2 OZ (56.8g) tube, NDC 76305-300-13; b) 4 OZ (113.5g) jar, UPC 6 87806 10004 2, NDC 76305-300-02; c) 6 OZ (170 g) tube, UPC 6 87806 10006 2, NDC 76305-300-03; d) 8 OZ (226.8g) jar, UPC 6 87806 10008 2, NDC 76305-300-04; e) 16 OZ (453.6g), Bottle w/ Pump, UPC 6 87806 10016 7, NDC 76305-300-03; f) 128 OZ (3.78L) Gallon, UPC 6 87806 10128 7, NDC 76305-300-06; Distributed by: CHINA-GEL LLC, Arlington Heights, IL 60005,			exp 2021-09; C002KF, exp 2022-01; C030HT, exp 2022-02; C094LT, exp 2022-04; C275CW, exp 2022-10; C338CH, exp 2022-12; b) B122DX, exp 2021-05; B183GP, exp 2021-07; B262BE, exp 2021-09; C002KF, exp 2022-01; C030HT, exp 2022-02; C094LT, exp 2022-04; C275CW, exp 2022-10; C330BG, exp 2022-12 c) B122DY, exp 2021-05; B183GN, exp 2021-07; B262BF, exp 2021-09; C002KF, exp 2022-01; C030HT, exp 2022-02; C094LT, exp 2022-04;C156FF, exp 2022-06; C247JB, exp 2022-09; C338CH, exp 2022-12. d)B122DX, Exp 05/2021; B122DY , EXP 05-2021; B183GP, EXP 07-2021; B262BE, EXP 09-2021; B262BF, EXP 09-2021; C002KF, EXP 01-2022; C030HT, EXP 02-2022; C094LT, EXP 04-2022; C156FF, EXP 06-2022; C247JB, EXP 09-2022; C275CW, EXP 10-	in the same facility where contamination with B. cepacia was found in other products.	

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
			2022; C330BG, EXP 12-2022; e) B100JS, Exp 04/2021; B183GQ, EXP 07-2021; B255KZ, EXP 09-2021; C030HS, EXP 02-2022; C100AH, EXP 04-2022; C247JF, EXP 09-2022; f) B122DY , EXP 05-2021; B183GN, EXP 07-2021; B183GP, EXP 07-2021; B262BF, EXP 01-2022; C002KF, EXP 02-2022; C030HT, EXP 02-2022; C094LT, EXP 04-2022; C156FF, EXP 09-2022; C275CW, EXP 12-2022; C338CH, EXP 05-2022;		
CHINA-GEL WHITE (Camphor 3.00%, Menthol 5.00%), A TOPICAL PAIN RELIEVER, packaged in a) 2 oz(56.8g) Tube, 76305-301-13 ; b) 4 oz (113.5 g) jar, UPC 6 87806 20004 1, NDC 76305-301-02 ; c) 6 OZ (170 g) tube, UPC 6 87806 20006 5, NDC 76305-301-03; d) 8 oz	Class II	Drugs	Lot #: a)B100JS, Exp 04/2021; B183GQ, EXP 07-2021; B255KZ, EXP 09-2021; C030HS, EXP 02-2022; C100AH, EXP 04-2022; C247JF, EXP 09-2022; b)B100JS, Exp 04/2021; B183GQ, EXP 07-2021; B255KZ, EXP 09-2021; C030HS, EXP 02-2022; C100AH, EXP 04-2022; C247JF, EXP 09-2022; c)B100JS, Exp 04/2021; B183GQ, EXP 07-2021; B255KZ, EXP 09-2021; C030HS, EXP 02-	CGMP deviations: Product being recalled as it was made in the same facility where contamination with B. cepacia was found in other products.	China Gel Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
(226.8 g) Jar, UPC 6 87806 20008 9, NDC 76305-301-04; e) 16 oz (453.6 g) Bottle w/ Pump, UPC 6 87806 20016 4, NDC 76305-301-05; f) 120 oz (3.78L) gallon, UPC 6 87806 20128 4, NDC 76305-301-06: Distributed by: CHINA-GEL LLC, Arlington Heights, IL 60005,			2022; C100AH, EXP 04-2022; C247JF, EXP 09-2022; d)B100JS, Exp 04/2021; B183GQ, EXP 07-2021; B255KZ, EXP 09-2021; C030HS, EXP 02-2022; C100AH, EXP 04-2022; C247JF, EXP 09-2022; e)B100JS, Exp 04/2021; B183GQ, EXP 07-2021; B255KZ, EXP 09-2021; C030HS, EXP 02-2022; C100AH, EXP 04-2022; C247JF, EXP 09-2022; f)B100JS, Exp 04/2021; B183GQ, EXP 09-2021; B255KZ, EXP 09-2021; C030HS, EXP 04-2022; C100AH, EXP 06-2022; C247JF, EXP 10-2022;		
aulief (Organic Camphor 3.00% Organic Menthol 5.00%), topical pain relief, packaged as a) 3.2 oz (90.7g) tube UPC 6 87806 30003 1 NDC 76305-302-01 ; b) 7.0 oz (198.5g) tube, UPC 6 87806 30007 9, NDC	Class II	Drugs	Lot #: a) B136HN, Exp 05/2021; b) B136HN, Exp 05/2021; c) B136HN, Exp 05/2021	CGMP deviations: Product being recalled as it was made in the same facility where contamination with B. cepacia was found in other products.	China Gel Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
76305-302-02; c) 16 oz (453.6g)Bottle w/ Pump, UPC 6 87806 30016 1, NDC 76305-302-03; Distributed by: CHINA-GEL LLC, Arlington Heights, IL 60005,					
MEDICALLY MINDED ANTIMICROBIAL Hand Sanitizer Gel with Aloe Vera, (Ethyl Alcohol 70% v/v), 10 FL OZ / 300 mL, Manufactured by Grupo V-Klean S.A. de C.V, Calle Alborada 124, Parques del Pedregal, Tlalpan, 14250 Ciudad de Mexico, CDMX, Distributed by SBL Brands, LLC. Las Vegas, NV 89119. Made in Mexico UPC: 6 76753 00417 8	Class II	Drugs	Lot No: GV4420205 Best By, 5/21/2022	CGMP Deviations: lots and products of hand sanitizer are being recalled because they were manufactured under the same conditions as the product lot found to contain methanol.	Global Sanitizers LLC
MEDICALLY MINDED Hand Sanitizer Gel, ANTIMICROBIAL	Class II	Drugs	Lot No: E372020, "Best Buy": 5/21/2022;	CGMP Deviations: lots and products of hand sanitizer are being recalled because	Global Sanitizers LLC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
FORMULA, (Ethyl Alcohol 70% v/v), 8.5 FL OZ (250 mL) bottle, Manufactured by Asiaticon, S.A. de C.V. Conkal 62, Jardines del Ajusco, Tlalpan, Ciudad de Mexico, C.P. 14200, Distributed by SBL Brands, LLC. Las Vegas, NV 89119. Made in Mexico UPC 6 76753 00414 7				they were manufactured under the same conditions as the product lot found to contain methanol.	
MEDICALLY MINDED Hand Sanitizer Gel, ANTIMICROBIAL FORMULA, (Ethyl Alcohol 70% v/v), 8.5 FL OZ / 250 mL bottle, Made in Mexico, Distributed by SBL Brands, LLC Las Vegas, NV 89119. UPC: 6 76753 00359 1 ,	Class II	Drugs	Lot No: E212020, "Best Buy": 5/21/2022	CGMP Deviations: lots and products of hand sanitizer are being recalled because they were manufactured under the same conditions as the product lot found to contain methanol.	Global Sanitizers LLC
MEDICALLY MINDED Hand Sanitizer Gel,	Class II	Drugs	Lot No: E332020, E212020 "Best Buy": 5/21/2022	CGMP Deviations: lots and products of hand sanitizer	Global Sanitizers LLC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
ANTIMICROBIAL FORMULA, (Ethyl Alcohol 70% v/v), 8 Fl OZ (236 mL) bottle, Manufactured by Asiaticon, S.A. de C.V. Conkal 62, Jardines del Ajusco, Tlalpan, Ciudad de Mexico, C.P. 14200. Distributed by SBL Brands, LLC Las Vegas, NV 89119 UPC: 6 76753 00420 8 ,				are being recalled because they were manufactured under the same conditions as the product lot found to contain methanol.	
Cyclobenzaprine Hydrochloride Tablets, 7.5mg, 100 count tablets per bottle, Rx Only, Manufactured by: Actavis Laboratories FL, Inc. Fort Lauderdale, FL 33314, Distributed by: Actavis Pharma, Inc., Parsippany, NJ 07054, NDC 0591-3330-01	Class II	Drugs	1408821A, exp. date 08/2023 (labeler - Teva)	CGMP Deviations: Out of specification (OOS) test result for Total Aerobic Microbial Count (TAMC) and Total Yeast and Mold Count (TYMC) for an excipient batch of Dibasic Calcium Phosphate.	Teva Pharmaceuticals USA

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Cyclobenzaprine Hydrochloride Tablets, 7.5mg, 100 count tablets per bottle, Rx Only, Manufactured by: Actavis Laboratories FL, Inc. Fort Lauderdale, FL 33314, NDC 70199-014-01	Class II	Drugs	1408822A, exp. date 08/2023 (labeler - Casper)	CGMP Deviations: Out of specification (OOS) test result for Total Aerobic Microbial Count (TAMC) and Total Yeast and Mold Count (TYMC) for an excipient batch of Dibasic Calcium Phosphate.	Teva Pharmaceuticals USA
Cyclobenzaprine Hydrochloride Tablets, 7.5mg, 100 count tablets per bottle, Rx Only, Manufactured by: Actavis Laboratories FL, Inc. Fort Lauderdale, FL 33314, NDC 57237-266-01	Class II	Drugs	1408824A, exp. date 08/2023 (labeler - Rising)	CGMP Deviations: Out of specification (OOS) test result for Total Aerobic Microbial Count (TAMC) and Total Yeast and Mold Count (TYMC) for an excipient batch of Dibasic Calcium Phosphate.	Teva Pharmaceuticals USA
Clopidogrel Tablets, USP, 75 mg, 500-count bottle, Rx only, Manufactured for: Macleods Pharma USA, Inc., Plainsboro, NJ 08536, Manufactured by: Macleods Pharmaceutical Ltd., Baddi, Himachal,	Class II	Drugs	Lot # BCA82021A, Exp 06/2023	Presence of foreign matter	Macleods Pharma Usa Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Pradesh, INDIA NDC 33342-060-15					
Naproxen Sodum Tablets USP 220 mg, (Caplet), Manufactured by: Granules India Limited, Sy.No. 160/A, 161/E, 162, &174/A, Gagillapur Village, Dundigal-Gandimalsamma Monday, Medchai-Maikhajgir District - 500043, Telangana, INDIA. NDC 62207-762-36	Class II	Drugs	7620060a	CGMP Deviations	Granules USA, Inc.
Artificial Tears Ointment, Lubricant Eye Ointment, Net Wt. 3.5 g (1/8 oz.) per tube, Sterile, Manufactured by: Akorn, Inc., Lake Forest, IL 60045, NDC 17478-062-35	Class II	Drugs	Lot #: 9G01A, Exp 06/2022; 9H32A, Exp 07/2022; 9K82A, 9K82B, Exp 09/2022	Non-Sterility - OOS sterility testing observed during 12-month controlled room temperature stability testing. The microbiological investigation identified the organism as a member of the Bacillus cereus group.	Akorn, Inc.
QiYu Hand Sanitizer (ethyl alcohol 75% (v/v)),	Class II	Drugs	Production Batch No.: Q20200510	Subpotent	NATIVE PROMOTIONS, INC

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
16.9 FL OZ (500 ML) bottles, Manufactured by: Guangzhou Minghui Cosmetics Co., Ltd, Baiyun District, Guanzhou, China Distributed by Native Promotional Products, Tulsa, OK NDC 74447-010					
HAND SANITIZER (alcohol 80%), Alchol Antiseptic 80% topical solution, Hand Sanitizer non-sterile solution, Net weight (6 lbs 14.2 oz) 1 gallon; Net Quantity (3785 mL), Manufactured by Soapdaddy LLC, 2401 E. 85th Street, Kansas City, MO 64131	Class II	Drugs	Lot# 20-151 to 20-159 and 20-161 to20-163, Exp 06/11/2022	CGMP Deviations: Product manufactured in same facility where product was found to contain acetaldehyde and acetal above the allowable limits.	Charles Paint Research Inc
HAND SANITIZER (alcohol 80%), Alchol Antiseptic 80% topical solution, Hand Sanitizer non-sterile solution, Net	Class II	Drugs	Lot# 20-160, Exp 06/11/2022	CGMP Deviations: Product contains acetaldehyde and acetal above the allowable limits.	Charles Paint Research Inc

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
weight (6 lbs 14.2 oz) 1 gallon; Net Quantity (3785 mL), Manufactured by Soapdaddy LLC, 2401 E. 85th Street, Kansas City, MO 64131					
Florance Morris ANTISEPTIC Hand Sanitizer (ethyl alcohol 70%), packaged in a) 8.45 fl oz (250 mL) bottles and b) 33.81 fl oz (1L) bottles, Distributed by: Asimex International LLC, 9100 S Dadeland Blvd, Ste 912, Miami, FL 33156, COUNTRY OF ORIGIN: MEXICO.	Class II	Drugs	All lots including but not limited to a) 200520674 and b) 200525677	CGMP Deviations: All other lots are being recalled because they were manufactured under the same conditions as the product lots found to contain methanol.	Grupo Asimex de Mexico SA de CV
Betamethasone Dipropionate Lotion USP (Augmented), 0.05%, packaged in a) 30 mL bottle (NDC 61748-480-30), b) 60 mL bottle (NDC 61748-480-60), Rx only,	Class II	Drugs	Lot #: a) 372286, 372289, Exp 1/31/2022, b) 372286, 372289, Exp 1/31/2022	Failed impurities/degradation specification: Out of Specification for an unknown impurity observed in topical product.	Akorn, Inc.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Manufactured by: Hi-Tech Pharmacal Co. Inc., Amityville,NY 11701					
Oxycodone Hydrochloride Tablets, USP, 10 mg, 100 count bottle, Rx only, Marketed by: Rhodes Pharmaceuticals L.P., Coventry RI 02816, Manufactured by: Purdue Pharma L.P., Stanford, CT 06901 NDC 42858-002-01	Class II	Drugs	Lot # WP5K0Y, exp. date 02/28/2023	Presence of Foreign Tablets/Capsules; A single foreign tablet Hydrochlorothiazide/Lisinopril 25/20 was found in one bottle	Rhodes Pharmaceuticals, L.P.
Spironolactone Ophthalmic Solution 0.005 mg/mL, 15 mL bottles, Rx only, Greenpark Compounding Pharmacy	Class II	Drugs	Lots: 03012021@35; 04132021@10; 05102021@12; 06012021@28; 07012021@25; 03012021@36; 04132021@12; 05102021@11; 06012021@29; 07132021@14; 03152021@9; 06162021@21; 07132021@16; 03152021@10; 06162021@22	Lack of Assurance of Sterility	Prescription Labs Inc dba Greenpark
Kroger 70% Isopropyl Alcohol First Aid Antiseptic 32 FL OZ (1	Class II	Drugs	Lot: 0542077 Exp. 07/2023	Labeling: Label Mix-Up.The recall has been initiated after receiving one complaint	Vi-Jon, Inc.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
QT) 946 mL 5 Dist. By The Kroger Co., Cincinnati, Ohio 45202 NDC 30142-810-45, UPC 0 11110 37049				about incorrect labeling.The primary label on the front and back label on some of the bottles have 70% Isopropyl 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	
MIC+Methyl B12 injection Methionine Inositol Choline+Methylcobalamin 25 mg/50 mg/50 mg/1 mg/mL, 10 mL vial sterile, Rx only, Promise Pharmacy 31818 US Hwy 19N Palm Harbor FL 34684 1-888-3PROMIS	Class II	Drugs	Lot# 06152021@2, Exp 09/13/2021	Lack of processing controls	Promise Pharmacy, LLC
Bleomycin for Injection, USP, packaged in 15 units per single dose vial, Rx	Class III	Drugs	BL0018	Labeling: Not elsewhere classified: Mislabeling	Hikma Pharmaceuticals USA Inc.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
only, Manufactured by Thymoorgan Pharmazie GmbH Schiffgraben 23, 38690 Gosfar, Germany Distributed by Hikma USA Inc. Berkeley Heights, NJ 07922, NDC 0143-9240-01					
Lidocaine Ointment USP, 5% Rx Only, Net Wt 35.44 g(1 1/4 oz)packaged in a laminat tube, Teligent Pharma, Inc. Buena, New Jersey 08310, NDC 52565-008-14.	Class III	Drugs	Lot #: 15378, Exp 3/2023; 14418 EXP 10/2021	Failed Viscosity Specifications: lot does not meet specification for Viscosity, which was determined through routine testing.	Teligent Pharma, Inc.
Donepezil HCL Tablets, USP, 5 mg, 90-count bottle, Rx only, Manufactured by: Jubilant Generics Ltd. India, Marketed by: Jubilant Cadista Pharmaceuticals Inc. Salisbury, MD 21801 NDC 59746-329-90	Class III	Drugs	Lot # DN120006A, exp. date 12/2021	Subpotent	Jubilant Cadista Pharmaceuticals, Inc.

Product Description	Classification	Product Type	Code Info	Reason for Recall	Recalling Firm
Candesartan Cilexetil Tablets, USP 16 mg, 30 count bottles, Manufactured for: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 NDC 0378-3231-93	Class III	Drugs	Lot # 3107334, exp. date October 2021	Failed Impurities/Degradation Specifications; out of specification for Related Compound	Viatris
Glycopyrrolate Injection, USP 4mg per 20mL, 20 mL Multi-Dose Vials, Rx only, Mfd for Meitheal Pharmaceuticals, Chicago, IL 60631. NDC 71288-408-21	Class III	Drugs	Lot #: G0010120, Exp. Date December 2021; G0080520, Exp. Date April 2022; G0090221, G0100221, Exp. Date January 2023	Failed Impurities/Degradation Specifications	Meitheal Pharmaceuticals Inc

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

FDA DRUG SAFETY COMMUNICATIONS

[9/01/2021] FDA requires warnings about increased risk of serious heart-related events, cancer, blood clots, and death for JAK inhibitors that treat certain chronic inflammatory conditions

What safety concern is FDA announcing?

Based on a completed U.S. Food and Drug Administration (FDA) review of a large randomized safety clinical trial, we have concluded there is an increased risk of serious heart-related events such as heart attack or stroke, cancer, blood clots, and death with the arthritis and ulcerative colitis medicines Xeljanz and Xeljanz XR (tofacitinib). This trial compared Xeljanz with another type of medicine used to treat arthritis called tumor necrosis factor (TNF) blockers in patients with rheumatoid arthritis. The trial's final results also showed an increased risk of blood clots and death with the lower dose of Xeljanz. A prior DSC based upon earlier results from this trial, reported an increased risk of blood clots and death only seen at the higher dose.

We are requiring new and updated warnings for two other arthritis medicines in the same drug class as Xeljanz, called Janus kinase (JAK) inhibitors, Olumiant (baricitinib) and Rinvoq (upadacitinib). Olumiant and Rinvoq have not been studied in trials similar to the large safety clinical trial with Xeljanz, so the risks have not been adequately evaluated. However, since they share mechanisms of action with Xeljanz, FDA considers that these medicines may have similar risks as seen in the Xeljanz safety trial.

Two other JAK inhibitors, Jakafi (ruxolitinib) and Inrebic (fedratinib), are not indicated for the treatment of arthritis and other inflammatory conditions and so are not a part of the updates being required to the prescribing information for Xeljanz, Xeljanz XR, Olumiant, and Rinvoq. Jakafi and Inrebic are used to treat blood disorders and require different updates to their prescribing information. If FDA becomes aware of any additional safety information or data that warrants updates to the prescribing information for these medicines, we may take further action and will alert the public.

What is FDA doing?

We are requiring revisions to the Boxed Warning, FDA's most prominent warning, for Xeljanz/Xeljanz XR, Olumiant, and Rinvoq to include information about the risks of serious heart-related events, cancer, blood clots, and death. Recommendations for health care professionals will include consideration of the benefits and risks for the individual patient prior to initiating or continuing therapy. In addition, to ensure the benefits of these three medicines outweigh the risks in patients who receive them, we are limiting all approved uses to certain patients who have not responded or cannot tolerate one or more TNF blockers. Changes will also be made to several sections of the prescribing information and to the patient Medication Guide.

What are Xeljanz/Xeljanz XR, Olumiant, and Rinvoq and how can they help me?

Xeljanz/Xeljanz XR, Olumiant, and Rinvoq are used to treat certain serious, chronic, and progressive inflammatory conditions. Xeljanz was the first to be approved in 2012. All three medicines are approved to be used alone or with other drugs to treat rheumatoid arthritis (RA), a condition in which the body

attacks its own joints, causing pain, swelling, joint damage, and loss of function. Xeljanz is also approved to treat psoriatic arthritis, a condition that causes joint pain and swelling; ulcerative colitis, which is a chronic, inflammatory disease affecting the colon; and polyarticular course juvenile idiopathic arthritis, a type of childhood arthritis. Xeljanz/Xeljanz XR, Olumiant, and Rinvoq work by decreasing the activity of the immune system; an overactive immune system contributes to RA, psoriatic arthritis, ulcerative colitis, and polyarticular course juvenile idiopathic arthritis.

What should patients do?

Those taking Xeljanz/Xeljanz XR, Olumiant, or Rinvoq should tell your health care professional if you are a current or past smoker, or have had a heart attack, other heart problems, stroke, or blood clots in the past as these may put you at higher risk for serious problems with the medicines. Patients starting these medicines should also tell your health care professional about these risk factors. Seek emergency help right away if you have any symptoms that may signal a heart attack, stroke, or blood clot, including:

- Discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back
- Severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
- Unusual pain or discomfort in your arms, back, neck, jaw, or stomach
- Shortness of breath with or without chest discomfort
- Breaking out in a cold sweat
- Nausea or vomiting
- Feeling lightheaded
- Weakness in one part or on one side of your body
- Slurred speech
- Drooping on one side of your mouth
- Swelling of a leg or arm
- Leg pain or tenderness, or red or discolored skin in the painful or swollen leg or arm

Treatment with these medicines is associated with an increased risk of certain cancers including lymphoma and lung cancer, so inform your health care professional if you experience signs and symptoms such as swelling of lymph nodes in your neck, armpits, or groin; constantly feeling tired; fever; night sweats; persistent or worsening cough; difficulty breathing; hoarseness or wheezing; or unexplained weight loss. Talk to your health care professional if you have any questions or concerns.

What should health care professionals do?

Health care professionals should consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Xeljanz/Xeljanz XR, Olumiant, or Rinvoq. This is particularly the case in patients who are current or past smokers, those with other cardiovascular risk factors, those who develop a malignancy, and those with a known malignancy other than a successfully treated nonmelanoma skin cancer. Reserve these medicines for patients who have had an inadequate response or intolerance to one or more TNF blockers. Counsel patients about the benefits and risks of these medicines and advise them to seek emergency medical attention if they experience signs and symptoms of a heart attack, stroke, or blood clot.

What did FDA find?

When FDA first approved Xeljanz, we required the manufacturer, Pfizer, to conduct a safety clinical trial in patients with RA who were taking methotrexate to evaluate the risk of serious heart-related events, cancer, and infections. The trial studied two doses of Xeljanz (5 mg twice daily, which is the approved dosage for RA, and a higher 10 mg twice daily dosage) in comparison to a TNF blocker also used to treat the condition. Patients in the trial were required to be at least 50 years old and have at least one risk factor for heart disease.

Our review of the final trial results showed a higher rate of serious heart-related events such as heart attack and stroke, cancer, blood clots, and death in patients treated with both doses of Xeljanz compared to those treated with TNF blockers. Importantly, a higher rate of blood clots and death was seen with both doses of Xeljanz compared to TNF blockers, whereas previous interim results showed the risk only with the higher dose. For cancers, a higher rate of lymphomas was observed in patients treated with Xeljanz compared to those treated with TNF blockers. A higher rate of lung cancers was observed in current or past smokers treated with Xeljanz compared to those treated with TNF blockers. Current or past smokers had an additional increased risk of overall cancers (See Data Summary).

Other JAK inhibitors have not been studied in similar large safety clinical trials, so the risk with these medicines has not been evaluated. However, since they share mechanisms of action with Xeljanz, FDA considers that these medicines may have similar risks as seen in the safety trial with Xeljanz.

What is my risk?

All medicines have side effects even when used correctly as prescribed, but in general the benefits of taking a medicine outweigh these risks. It is important to know that people respond differently to all medicines depending on their health, other medicines they are taking, the diseases they have, genetic factors, and many other factors. As a result, we cannot determine how likely it is that someone will experience these side effects when taking Xeljanz/Xeljanz XR, Olumiant, or Rinvoq.

However, if you are a current or past smoker, or have had a heart attack, other heart problems, stroke, or blood clots in the past, you should tell your health care professional as these may put you at higher risk for serious problems with these medicines.

How do I report side effects from Xeljanz, Olumiant, or Rinvoq?

To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving Xeljanz/Xeljanz XR, Olumiant, Rinvoq, 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 alerts about Drug Safety Communications on medicines or medical specialties of interest to you.

Facts about Xeljanz/Xeljanz XR (tofacitinib), Olumiant (baricitinib), and Rinvoq (upadacitinib)

- These medicines are part of a class called Janus kinase (JAK) inhibitors and are used to treat certain serious, chronic, and progressive inflammatory conditions.
- All three medicines are approved to be used alone or with other medicines to treat rheumatoid arthritis. Xeljanz is also approved to treat psoriatic arthritis, ulcerative colitis, and polyarticular course juvenile idiopathic arthritis.
- These medicines work by decreasing the activity of the immune system.
- These medicines are available to be given orally as immediate-release tablets, extended release tablets that release the medicine into the body over time, and solution.
- Common side effects of these medicines include upper respiratory tract infections such as the common cold and sinus infections, bronchitis, headache, cough, increased cholesterol levels, high blood pressure, increased muscle enzyme levels, rash, nausea, diarrhea, acne, cold sores, and shingles.

Additional Information for Patients

- FDA is requiring new and updated warnings about an increased risk of serious heart-related events such as heart attack or stroke, cancer, blood clots, and death with the medicines Xeljanz/Xeljanz XR (tofacitinib), Olumiant (baricitinib), and Rinvoq (upadacitinib) used to treat certain serious inflammatory conditions including rheumatoid arthritis (RA) and ulcerative colitis.
- We are also limiting the use of these medicines to certain patients who are not treated effectively or who experience severe side effects with another type of medicine used to treat serious inflammatory conditions called tumor necrosis factor (TNF) blockers.
- If you are taking Xeljanz/Xeljanz XR, Olumiant, or Rinvoq, tell your health care professional if you are a current or past smoker, or have had a heart attack, other heart problems, stroke, or blood clots in the past as these may put you at higher risk for serious problems with the medicines. Before starting these medicines, also tell your health care professional about these risk factors.
- Seek emergency help right away if you have any symptoms that may signal a heart attack, stroke, or blood clot, including:
    - Discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back
    - Severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
    - Pain or discomfort in your arms, back, neck, jaw, or stomach
    - Shortness of breath with or without chest discomfort
    - Breaking out in a cold sweat
    - Nausea or vomiting
    - Feeling lightheaded
    - Weakness in one part or on one side of your body
    - Slurred speech
    - Drooping on one side of your mouth
    - Swelling of a leg or arm
    - Leg pain or tenderness, or red or discolored skin in the painful or swollen leg or arm
- Also inform your health care professionals if you experience signs and symptoms such as:
    - Swelling of lymph nodes in your neck, armpits or groin
    - Constantly feeling tired
    - Fever

  - Night sweats
  - Persistent or worsening cough
  - Difficulty breathing
  - Hoarseness or wheezing
  - Unexplained weight loss.
- Read the patient Medication Guide every time you receive a prescription for Xeljanz/Xeljanz XR, Olumiant, or Rinvoq. The Medication Guide will be updated with this new or other important information about your medicine. It explains the important things that you need to know. These include the side effects, what the medicine is used for, how to take and store it properly, and other things to watch out for when you are taking the medicine.
- Talk to your health care professional if you have any questions or concerns.
- To help FDA track safety issues with medicines, report side effects from Xeljanz, Olumiant,
  - Rinvoq, 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 alerts about Drug Safety Communications on medicines or medical specialties of interest to you.

Additional Information for Health Care Professionals

• FDA is requiring new and updated warnings about an increased risk of major adverse cardiovascular events, malignancy, thrombosis, and mortality with the Janus kinase (JAK) inhibitors Xeljanz, Xeljanz XR (tofacitinib), Olumiant (baricitinib), and Rinvoq (upadacitinib).
• Reserve these medicines for patients who have had an inadequate response or intolerance to one or more TNF blockers.
• Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Xeljanz/Xeljanz XR, Olumiant, or Rinvoq, particularly in patients who are current or past smokers, those with other cardiovascular risk factors, those who develop a malignancy, and those with a known malignancy other than a successfully treated nonmelanoma skin cancer.
• Inform patients about the symptoms of serious cardiovascular events and to seek emergency medical attention if they occur.
• Encourage patients to read the Medication Guide they receive with each prescription, which explains the safety risks and provides other important information.
• To help FDA track safety issues with medicines, report adverse events involving Xeljanz/Xeljanz XR, Olumiant, Rinvoq, 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 alerts about Drug Safety Communications on medicines or medical specialties of interest to you.

Data Summary

When FDA first approved Xeljanz (tofacitinib), we required the manufacturer, Pfizer, to conduct a randomized safety clinical trial in patients with rheumatoid arthritis (RA) who were taking methotrexate to evaluate the risk of cardiovascular events, malignancy, and infections. It was a multicenter, randomized, open-label trial to evaluate two doses of Xeljanz (5 mg twice daily (N=1455), which is the approved dosage for RA, and a higher 10 mg twice daily dosage (N=1456)) in comparison to treatment with a tumor necrosis factor (TNF) blocker (N=1451).

Patients in the trial were required to be 50 years of age or older and have at least one cardiovascular risk factor. The co-primary endpoints were major adverse cardiovascular events (MACE), defined as cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke; and malignancy, excluding nonmelanoma skin cancer (NMSC). The trial was designed to exclude a prespecified risk margin of 1.8 for the hazard ratio of combined Xeljanz regimens when compared to the TNF blocker control for each co-primary endpoint. The median on-study follow-up time was 4 years.

The mean age of the population was 61 years and the median age was 60 (range 50-88 years). Most patients were female (78 percent) and Caucasian (77 percent). The noninferiority criterion was not met for the comparison of the combined Xeljanz regimens to TNF blockers for the endpoints of MACE and malignancies since the upper limit of the 95% confidence intervals (CI) for these hazard ratios exceeded the prespecified noninferiority criterion of 1.8. For MACE, the estimated hazard ratio and 95% CI associated with the combined Xeljanz regimens relative to TNF blockers were 1.33 (0.91, 1.94). For malignancies excluding NMSC, the estimated hazard ratio and 95% CI associated with the combined Xeljanz regimens relative to TNF blockers were 1.48 (1.04, 2.09).

There was an increased risk of death, MACE, malignancies, and thrombosis associated with both regimens of Xeljanz. The data showed evidence of a dose-dependent increased risk for MACE, all-cause mortality, and thrombosis at both doses of Xeljanz when compared to treatment with TNF blockers. Additionally, the data showed evidence of a non-dose-dependent increased risk for malignancy excluding NMSC at both doses of Xeljanz when compared to TNF blockers. Lymphomas and lung cancers were observed at a higher rate in patients treated at both doses of Xeljanz compared to those treated with TNF blockers. In particular, a higher rate of lung cancers was observed in current or past smokers treated with Xeljanz. Current or past smokers had an additional increased risk of overall cancers.

Other JAK inhibitors have not been studied in similar large safety clinical trials, so the risk with these medicines has not been evaluated. However, since they share mechanisms of action with Xeljanz, FDA considers that these medicines may have similar risks as seen in the safety clinical trial with Xeljanz.

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
Atropine Sulfate Injection
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 (AVYCAZÂ®) 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
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
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
Mannitol Injection
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
Sodium Phosphates Injection
Sulfasalazine Tablets
Tacrolimus Capsules
Technetium Tc99m Succimer Injection (DMSA)
Teprotumumab-trbw
Thiothixene Capsules
Timolol Maleate Ophthalmic Gel Forming Solution
Tocilizumab Injection
Triamcinolone Hexacetonide Injectable suspension
Trimethobenzamide Hydrochloride Capsules
Valproate Sodium Injection
Varenicline Tartrate (Chantix) Tablets
Vecuronium Bromide for Injection