



2019 Drug recalls

November 19 - <u>Precision Dose Inc. Issues Voluntary Nationwide Recall of Ranitidine Oral</u> Solution, USP 150 mg/10 mL Due to Possible Presence of N-nitrosodimethylamine (NDMA) Impurity | FDA

November 15 - <u>Golden State Medical Supply, Inc. Issues a Voluntary Nationwide Recall of</u> Ranitidine Hydrochloride 150mg and 300mg Capsules (Manufactured by Novitium Pharma LLC) Due to an Elevated Amount of Unexpected Impurity, N-Nitrosodimethylamine (NDMA) | FDA

October 25 - Lannett Issues Voluntary Nationwide Recall of Ranitidine Syrup (Ranitidine Oral Solution, USP), 15mg/ml due to an Elevated Level of the Unexpected Impurity, N-Nitrosodimethylamine (NDMA) | FDA

September 12 - <u>Darmerica LLC Issues Voluntary Nationwide Recall of Quinacrine</u> <u>Dihydrochloride Due to A Labeling Error | FDA</u>

September 12 - KRS Global Biotechnology, Inc. Issues Voluntary Nationwide Recall of All Human and Animal Sterile Drug Products Due to Lack of Assurance of Sterility | FDA

September 9 - <u>Plastikon Healthcare Issues Voluntary Nationwide Recall of Milk of Magnesia</u> <u>Oral Suspension 2400 mg/30 mL due to Microbial Contamination | FDA</u>

August 30 - Pacifico National, Inc. dba AmEx Pharmacy Issues Voluntary Nationwide Recall for all Lots of Bevacizumab | FDA

July 23 - Jubilant Cadista Pharmaceuticals Inc. Issues Voluntary Nationwide Recall of Drospirenone and Ethinyl Estradiol Tablets, USP, Due to Out-of-Specification Dissolution Test Results.

July 2 - <u>Fresenius Kabi Issues Voluntary Nationwide Recall of Two Lots of Fluorouracil Injection</u> <u>Due to the Potential for Glass Particulate</u>.

June 25 - Macleods Pharmaceutical Limited Issues Voluntary Nationwide Consumer Level Recall of Losartan Potassium 50mg and Losartan Potassium/Hydrochlorothiazide combination Tablets 50mg/12.5mg, 100mg/12.5mg and 100mg/25mg due to detection of NMBA (N-Nitroso-N Methyl-4-aminobutyric acid) Impurity.

June 11 - <u>Teva Pharmaceuticals USA, Inc. Expands Voluntary Nationwide Recall of Losartan</u> <u>Potassium to 50 mg and 100 mg Tablets USP, Sold Exclusively to Golden State Medical</u> <u>Supply, Inc.</u>

May 29 - <u>NOVIS PR LLC Issues Voluntary Nationwide Recall of PECGEN DMX Due to a</u> <u>Labeling Error</u>.





May 28 - <u>Heritage Pharmaceuticals Inc. Issues Voluntary Nationwide Recall of Amikacin Sulfate</u> Injection, USP 1gm/4 mL (250mg/mL) and Prochlorperazine Edisylate Injection, USP 10mg/2mL (5mg/mL) as a Result of a Sterility Test Failure.

May 11 - <u>Novartis Issues Voluntary Nationwide Recall of Promacta® 12.5mg for Oral</u> <u>Suspension Due to Potential Peanut Contamination</u>.

April 30 - <u>Sagent Pharmaceuticals Issues Voluntary Nationwide Recall of Ketorolac</u> <u>Tromethamine Injection, USP, 60mg/2mL (30mg per mL) Due to Lack of Sterility Assurance</u>.

April 29 - <u>AmEx Pharmacy Issues Voluntary Nationwide Recall for one Lot of Bevacizumab</u> <u>1.25mg/0.05mL 31 G Syringe Due to Reported Defective Delivery System</u>.

April 26 - <u>Teva Pharmaceuticals USA, Inc. Issues Voluntary Nationwide Recall of Losartan</u> Potassium 25mg and 100mg Tablets USP, Sold Exclusively to Golden State Medical Supply.

April 24 - Legacy Pharmaceutical Packaging, LLC Expands Voluntary Nationwide Recall of Losartan Potassium Tablets, USP, 50mg Due to the Detection of Trace Amounts of N-Nitroso N-Methyl 4-amino butyric acid (NMBA) Impurity Found in the Active Pharmaceutical Ingredient (API).

April 21 - <u>Alvogen Inc. Issues Voluntary Nationwide Recall of Fentanyl Transdermal System</u> <u>Due to Product Mislabeling</u>.

April 18 - <u>Updated: Torrent Pharmaceuticals Limited Expands Voluntary Nationwide Recall of</u> Losartan Potassium Tablets, USP and Losartan Potassium/Hydrochlorothiazide Tablets, USP.

April 5 - Brian Richardson DBA "In Tha Pink" Issues Voluntary Nationwide Recall of Kopi Jantan Tradisional Natural Herbs Coffee Due to Presence of Undeclared Sildenafil and Tadalafil.

March 18 - <u>Mylan Institutional LLC Initiates Voluntary Nationwide Recall of Levoleucovorin</u> <u>Injection Due to the Presence of Particulate Matter</u>.

March 15 - Legacy Pharmaceutical Packaging, LLC Issues Voluntary Nationwide Recall of Losartan Potassium Tablets, USP, 25mg, 50mg, And 100mg Due to The Detection of Trace Amounts Of N-Nitroso N-Methyl 4-Amino Butyric Acid (NMBA) Impurity Found in The Active Pharmaceutical Ingredient (API).

March 15 - <u>Hospira, Inc. Issues a Voluntary Nationwide Recall of 8.4% Sodium Bicarbonate</u> Injection, USP Due to the Presence of Particulate Matter.

March 4 - <u>Apotex Corp. Issues Voluntary Nationwide Recall of Drospirenone and Ethinyl</u> Estradiol Tablets, USP, 28x3 Blister Pack/Carton Due to Possibility of Missing/Incorrect Tablet <u>Arrangement</u>.

March 1 - <u>Updated: Torrent Pharmaceuticals Limited Issues Voluntary Nationwide Recall of</u> Losartan Potassium Tablets, USP and Losartan Potassium /Hydrochlorothiazide Tablets, USP.





March 1 - <u>AurobindoPharma USA, Inc. Initiates a Voluntary Nationwide Consumer Level Recall</u> Expansion of 38 Lots of Amlodipine Valsartan Tablets USP and Valsartan Tablets, USP due to the detection of NDEA (N-Nitrosodiethylamine) Impurity.

February 28 - <u>Camber Pharmaceuticals, Inc. Issues Voluntary Nationwide Recall of Losartan</u> Potassium Tablets, USP, 25 mg, 50 mg and 100 mg Due to the Detection of Trace Amounts of N-Nitroso N-Methyl 4-amino butyric acid (NMBA) Impurity found in the Active Pharmaceutical Ingredient (API).

February 22 - <u>Macleods Pharmaceuticals Limited issues voluntary nationwide consumer level</u> recall of one lot (BLM 715A) of Losartan Potassium/Hydrochlorothiazide combination tablets 100mg/25mg due to detection of NDEA (N-Nitrosodiethylamine) impurity.

January 22 - <u>UPDATED: Torrent Pharmaceuticals Limited issues voluntary nationwide recall of</u> Losartan Potassium tablets, USP and Losartan Potassium and Hydrochlorothiazide tablets, USP.

January 3 - <u>Torrent Pharmaceuticals Limited expands voluntary nationwide recall of Losartan</u> Potassium tablets, USP.



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U.S. Department of Health and Human Services

200 Independence Avenue, SW Room 509F, HHH Building Washington, D.C. 20201

1-800-368-1019 (TDD/TTY: 1-800-537-7697)

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Albanian: VINI RE: Nëse flisni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në **1-800-228-8554 (TTY: 1-888-987-5832)**.

BCC.DISC002.20171127 COM-11REV101116 Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1-800-228-8554 (TTY: 1-888-987-5832) 번으로 전화해 주십시오.

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