Accord Healthcare – Recall of Hydrochlorothiazide

- On August 27, 2018, Accord Healthcare announced a voluntary, consumer-level recall of one lot of hydrochlorothiazide (HCTZ) 12.5 mg tablets because a 100-count bottle of HCTZ tablets has been found to contain 100 spironolactone 25 mg tablets.

- Accord is recalling the following lot involved in a potential mix-up of labeling:

Product Description	NDC #	Lot #
HCTZ 12.5 mg tablets	16729-182-01	PW05264

- HCTZ tablets are indicated in the management of hypertension (HTN) either as the sole therapeutic agent or to enhance the effectiveness of other antihypertensive drugs in the more severe forms of HTN. HCTZ is also indicated as adjunctive therapy in edema associated with congestive heart failure, hepatic cirrhosis, and corticosteroid and estrogen therapy. HCTZ has also been found useful in edema due to various forms of renal dysfunction such as nephrotic syndrome, acute glomerulonephritis, and chronic renal failure.

- Spironolactone tablets are indicated in the management of primary hyperaldosteronism, edematous conditions for patients with congestive heart failure, cirrhosis of the liver accompanied by edema and/or ascites, nephrotic syndrome, essential HTN, hypokalemia, severe heart failure.

- Use of spironolactone tablets instead of HCTZ tablets, poses the risk of contracting hyperkalemia in certain individuals resulting in adverse events that range from limited health consequences to life-threatening situations in certain individuals.

    — To date, Accord has not received any reports of adverse events related to this recall.

- Accord's HCTZ 12.5 mg tablets are light orange to peach colored, round, biconvex tablets debossed with H on one side and 1 on another side.

    — If a patient is in possession of an Accord HCTZ tablet that does not match the description or image, or if a patient is unsure, the patient should return to their pharmacy or healthcare provider for confirmation.

- Accord is notifying its wholesalers, distributors and retailers by letter and is arranging for return of all recalled products. Wholesalers, distributors, and retailers that have product which is being recalled should discontinue distribution of the product and notify consumers.

- Patients that have the recalled product should return the product to the pharmacy.

- Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using the recalled product.

- For more information regarding this recall contact Accord Healthcare by phone at 1-855-869-1081, fax at 1-817-868-5362, or e-mail at rxrecalls@inmar.com.