Camber – Recall of Montelukast

- On August 31, 2018, the FDA announced a voluntary, patient-level recall of one lot of Camber's montelukast 10 mg tablets because sealed bottles were found to contain losartan 50 mg tablets.
    - This recall is not related to the recent valsartan recalls that were due to an impurity, N-nitrosodimethylamine (NDMA).
- Camber is recalling the following lot:

Product Description	NDC #	Lot # (Expiration Date)
Montelukast 10 mg tablets, 30-count bottle	31722-726-30	MON17384 (12/31/2019)

- Montelukast is indicated for the following in patients ≥ 15 years of age: prophylaxis and chronic treatment of asthma, prevention of exercise-induced bronchoconstriction, and for the relief of symptoms of seasonal allergic rhinitis and perennial allergic rhinitis.
- Losartan is indicated for the treatment of hypertension (HTN), to reduce the risk of stroke in patients with HTN and left ventricular hypertrophy, and for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria in patients with type 2 diabetes and a history of HTN.
- The tablet mix-up may pose a safety risk as taking losartan tablets when not prescribed has the potential to cause renal dysfunction, elevated potassium levels and low blood pressure.
    - This safety risk is especially high for pregnant women taking montelukast, because losartan could harm or kill the fetus.
- Patients should contact their healthcare provider or pharmacist to determine if their medicine has been recalled. Patients should also look at the drug name and company name on the label of their prescription bottle. If the information is not on the bottle, patients should contact the pharmacy that dispensed the medicine.
- Camber's montelukast 10 mg tablets are beige, rounded square-shaped, film coated tablets that are imprinted with "I" on one side and "114" on the reverse. Losartan tablets are white and oval-shaped with the letter "l" imprinted on one side and the number "5" imprinted on the reverse.
- The FDA recommends that patients who have the recalled product should contact their healthcare provider or pharmacist immediately.
- 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 Camber at 1-866-495-1995.