Valsartan and Valsartan-HCTZ Products – Recall Update

- On August 2, 2018, the FDA announced an update to the list of products included in the valsartan recall and to the list of products not included in the valsartan recall.
    - On July 13th, the FDA initiated a series of announcements regarding the recall of certain batches of valsartan and valsartan-hydrochlorothiazide (HCTZ) tablets because of unacceptable levels of N-nitrosodimethylamine (NDMA).
    - Valsartan is a medication commonly used to treat high blood pressure and heart failure.

- In addition to updating the lists, the FDA revised information related to A-S Medication on the list of products included in the recall. The agency will continue to provide information when it becomes available.

- The FDA is working with drug manufacturers to ensure future valsartan active pharmaceutical ingredients (APIs) are not at risk of NDMA formation. The agency reminds manufacturers to thoroughly evaluate their API manufacturing processes, and changes to those processes, to detect any unsafe impurities. If a manufacturer detects new or higher levels of impurity, they should take action to prevent changes to the product's safety profile.

- NDMA is classified as a probable human carcinogen by the U.S. Environmental Protection Agency. The presence of NDMA was unexpected in the recalled valsartan products and is thought to be related to changes in the way the active substance was manufactured.
    - NDMA has been found to increase the occurrence of cancer in animal studies. These animal studies were done using amounts of NDMA much higher than the impurity levels in the recalled valsartan batches.
    - NDMA is found in some water supplies and in some foods. Consuming up to 96 nanograms NDMA/day is considered reasonably safe for human ingestion.
    - It is estimated that over the course of a person's lifetime, consuming this amount of NDMA would result in less than one additional case of cancer for every 100,000 people. To put this in context, currently one out of every three people in the U.S. will experience cancer in their lifetime.

- The amounts of NDMA found in the recalled batches of valsartan exceeded these acceptable levels. The FDA wanted to put some context around the actual potential risk posed to patients who used versions of valsartan or valsartan-HCTZ that may have contained high levels of NDMA.