Valsartan and Valsartan-HCTZ Products – Recall and Safety Update

- On July 27, 2018, the FDA announced a safety update regarding the chemical known as N-nitrosodimethylamine (NDMA), which was found in certain batches of recalled valsartan and valsartan-HCTZ tablets.
    - On July 13th, the FDA initiated a series of announcements regarding the recall of certain batches of valsartan and valsartan-HCTZ tablets because of unacceptable levels of NDMA.
    - Valsartan is a medication commonly used to treat high blood pressure and heart failure.

- 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.

- Based on records from the manufacturer of the recalled valsartan, some levels of the impurity may have been in the valsartan-containing products for as long as four years. FDA scientists estimate that if 8,000 people took the highest valsartan dose (320 mg) from the recalled batches daily for the full four years, there may be one additional case of cancer over the lifetimes of these 8,000 people. This assessment led to FDA's decision to have these batches recalled.

- Patients taking valsartan from a recalled batch should continue taking their current medicine until their doctor or pharmacist provides a replacement or a different treatment option.

- It is important to know that not all valsartan products contained NDMA, so pharmacists may be able to provide a refill of valsartan medication from batches that that are not affected by the recall, or doctors may prescribe a different medication that treats the same indications.

- The FDA has provided a list of valsartan products included in the recall and a list of products *not* included in the recall.
    - The FDA will continue to update these lists as more information becomes available.