Valsartan-Containing Products – Recall Update

- On August 22, 2018, the FDA announced an update to the voluntary, consumer-level recall of valsartan-containing products due to the presence of an impurity, N-nitrosodimethylamine (NDMA).

- The FDA continues to maintain a list of drugs included in the recall and a list of drugs not included in the recall. The list of drugs included in the recall was updated to include an additional amlodipine/valsartan/hydrochlorothiazide product from RemedyRepack, a repackager of Torrent Pharmaceuticals.

- In addition, the FDA is releasing a gas chromatography-mass spectrometry (GC/MS) headspace method for manufacturers and regulators to detect and quantify NDMA in valsartan active pharmaceutical ingredient (API) and finished drug products. The FDA is using this method to test potential NDMA-containing APIs and drug products.

- On July 13th, the FDA initiated a series of announcements regarding the recall of certain batches of valsartan-containing tablets because of unacceptable levels of NDMA.

- Prior Clinical News Summaries summarizing the valsartan recalls were released July 17th, July 19th, July 27th, July 30th, August 3rd, August 9th, August 14th, August 20th, and August 22nd.

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