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Valsartan Recall – Update

- On September 13, 2018, the FDA announced an update to the ongoing investigation surrounding the recent voluntary recall of several drug products containing the active pharmaceutical ingredient (API) valsartan.

- The FDA's latest testing of products shows an additional unexpected impurity in three lots of Torrent's recalled valsartan drug products. This second impurity, N-Nitrosodiethylamine (NDEA) is a known animal and suspected human carcinogen. These Torrent products were included in the company's recall on August 23, 2018.

- The FDA and the European Medicines Agency have learned that Zhejiang Huahai Pharmaceuticals (ZHP) found NDEA in several batches of its valsartan API. The FDA immediately began retesting all valsartan API and products, including both recalled products and those currently marketed in the U.S., for NDEA.

- Based on FDA testing to date, the agency discovered NDEA in some of ZHP's valsartan API. This impurity was also found in Torrent's valsartan 160 mg (lot BV47D001) and 320 mg (lots BV48D001 and BV48D002) tablets, which were made using API from ZHP and were part of the earlier recall. The FDA's testing shows that not all products made using ZHP valsartan API contain the NDEA impurity.

- The FDA is continuing to test all products that contain valsartan for NDEA and related impurities. If the agency finds NDEA in products that have not been recalled, the FDA will work with companies to ensure all affected products are removed from the market.

- The FDA is also evaluating the risks NDEA in these products poses to patients. The FDA expects to complete this risk analysis in the coming days and will continue to provide updates to the public as new information becomes available.

- Like N-Nitrosodimethylamine (NDMA), which was previously found in the recalled valsartan products, NDEA is also formed from a specific sequence of manufacturing steps and chemical reactions.

    — The FDA will post a preliminary method for detecting NDEA, which manufacturers and global regulators can use to screen other products for the potential presence of this impurity.

- The FDA will also update the list of drugs included in the recall and the list of drugs not included in the recall as products are tested for NDEA and as more information becomes available.

    — Patient and healthcare providers should continue to check these lists, as they may change.

- The FDA reminds patients taking valsartan from a recalled lot to continue taking their current medicine until their doctor or pharmacist provides a replacement or a different treatment option. Any patient taking valsartan from a recalled lot who has not yet spoken to their pharmacist or doctor should do so promptly.

- Patients should contact their healthcare provider if they have experienced any problems that might be related to taking or using their valsartan prescription.

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- At this time, the FDA's testing supports the conclusion that not all valsartan products contain NDMA or NDEA, so pharmacists may be able to provide a valsartan medication not affected by the recall, or doctors may prescribe a different medication that treats the same condition.