American Health Packaging – Recall of valsartan

- On March 7, 2019, the American Health Packaging announced a voluntary, consumer-level recall of one lot of valsartan tablets due to the detection of trace amounts of an unexpected impurity, N-Nitrosodiethylamine (NDEA).

- NDEA is a potential human carcinogen. To date, American Health Packaging has not received any reports of injury or adverse events related to this recall.

  — This recall is being initiated in response to the recall by the manufacturer (Aurobindo Pharma), which included the affected lot that was repackaged by American Health Packaging.
  — Refer to the FDA site for updates regarding angiotensin II receptor blocker recalls.

- The recalled product is listed below:

Product Description	NDC#	Lot# (Expiration Date)
Valsartan 160 mg tablets (unit dose blisters)	60687-139-01 (carton), 60687-139-11 (individual dose)	179791 (3/31/2020)

- Valsartan is used to control high blood pressure and for the treatment of heart failure.

- Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication. Patients who are on valsartan should continue taking their medication, as the risk of harm to a patient's health may be higher if the treatment is stopped immediately without any alternative treatment.

- Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled valsartan.

- Anyone with an existing inventory of the recalled product should stop use and distribution, and quarantine the product immediately.

- Contact Aurobindo Pharma by phone at **1-866-850-2876** or email at **pvg@aurobindousa.com** for questions regarding the recall. Contact GENCO at **1-877-475-5864** for product return information.