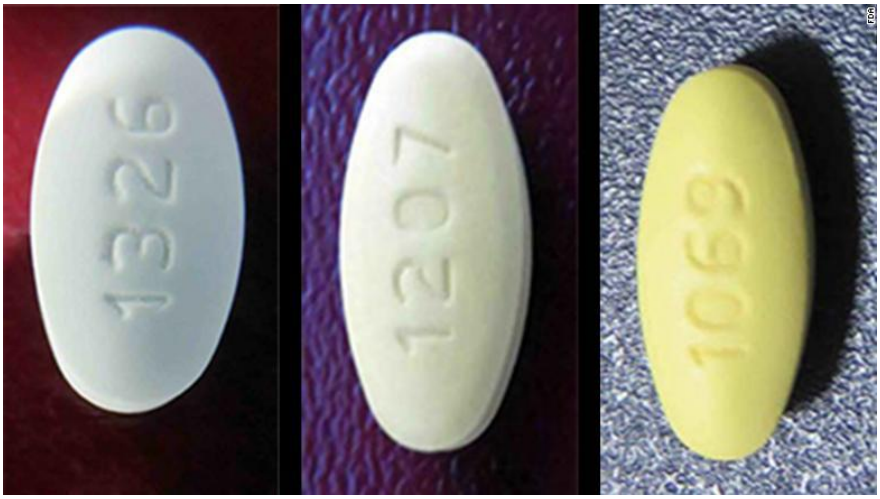
The FDA again adds more drugs to its valsartan recall list

By Jen Christensen, CNN



The FDA added more products to its Valsartan recall list

Story highlights

- The FDA added an additional lot of RemedyRepack to its recall list for drugs containing valsartan
- Imports to the US from the Chinese company that manufactured the valsartan ingredient have been stopped

*(CNN)*The US Food and Drug Administration again added to its list of products that are included in the recall of drugs containing valsartan, a generic ingredient that helps people with high blood pressure and heart failure. That ingredient in the recalled drugs was tainted with a possible carcinogen.

The FDA testing of these products determined that an additional lot of brands sold under the name RemedyRepack needed to be added to the recall list.
Several pills that contain valsartan have been under a voluntary recall since July. The drugs were tainted with N-nitrosodimethylamine, or NDMA, an impurity that is considered a possible carcinogen by the US Environmental Protection Agency. It's an organic chemical used to make liquid rocket fuel and a byproduct from manufacturing some pesticides and processing fish. NDMA can be unintentionally introduced into manufacturing through certain chemical reactions.
Not all versions of the drugs have been recalled, but the FDA keeps a regularly updated list of the drugs that have been impacted.

After valsartan recall, study offers 'modest reassurance' on short-term cancer risk

The agency began testing valsartan products for the substance NDMA after it learned that Zhejiang Huahai Pharmaceuticals found it in several batches of its medications. The FDA also began testing for another impurity, N-Nitrosodiethylamine, or NDEA, after it was identified in three lots of the drugs made by Torrent Pharmaceuticals. NDEA is also a suspected human carcinogen. Not all batches of these medications have been found to be contaminated.

The FDA placed Zhejiang Huahai Pharmaceuticals on an import alert at the end of September, meaning all active pharmaceutical products and finished products made by the company will not be permitted to enter the US. The FDA made that decision after its recent inspection of the facility.

It's unclear exactly what the cancer risk is if you take the contaminated pills; the FDA believed the risk was low. It estimated that if 8,000 people took the highest dose of valsartan (320 mg) containing NDMA from these recalled batches daily for four years, there may be one additional case of cancer over the lifetimes of 8,000 people. Many patients take a much lower dose and therefore their risks are theoretically much lower.

The agency said it is continuing to run tests to evaluate the cancer risk from the contaminated pills.

What to do if you take a drug with valsartan

If you are worried your drug could be on the recall list, talk with your doctor or pharmacist before changing any routine with your medicine. Because not all valsartan drugs are involved in the recall, they might be able to switch you to a version of the drug made by another company. The FDA keeps a second list of valsartan products not currently recalled.

If you know your drug is on the recall list, the FDA suggests you continue taking it until your doctor or pharmacist provides a replacement.