Pharma and Marksans Pharma Ltd. are to recall certain lots of extended-release metformin.
Valisure had submitted a request to the FDA seeking broad recalls of the drug. Apotex said in a statement that NDMA was found in one lot of its 500 milligram extended-release metformin and that it is recalling all lots of that version as a precaution. The company recalled metformin in Canada earlier this year because of NDMA concerns and had previously stopped making metformin for the U.S. market, though some is still in circulation.

About 21 million prescriptions for extended-release metformin were written in the U.S. last year, according to data compiled by Bloomberg Intelligence, accounting for roughly a quarter of metformin prescriptions overall.

“We have been looking closely at this problem over many months in order to provide patients and health care professionals with clear and accurate answers,” Patrizia Cavazzoni, acting director of the FDA’s Center for Drug Evaluation and Research, said in a statement. “Now that we have identified some metformin products that do not meet our standards, we’re taking action.”

Patients should continue to take their metformin until they talk to a doctor, the FDA said.

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The FDA began investigating metformin in December after some versions of the medication sold in other countries were found to be contaminated with NDMA. In February, the agency said it hadn’t found NDMA in excess of acceptable limits.

The FDA said Thursday it had found NDMA in finished tablets of metformin, not in the active ingredient. Active ingredients are the key building blocks in drugs that make them effective against a disease or condition. They are mixed with inactive ingredients to produce finished pills.

Millions of blood-pressure pills known as angiotensin II receptor blockers were recalled beginning in July 2018 after it was found their active ingredients were contaminated with NDMA as a byproduct of the manufacturing process.

In addition to metformin and the blood-pressure drugs, the FDA last month asked for a recall of all versions of Zantac, which is also sold under the name ranitidine, after the agency determined that the chemical makeup of the stomach drug can cause NDMA to form and increase when stored at high temperatures.

(Updates with company names in third paragraph)

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