FDA testing levels of carcinogen in diabetes drug metformin

December 9 2019

(HealthDay)—Levels of possible cancer-causing chemicals in metformin

diabetes medications are under investigation by the U.S. Food and Drug Administration.

During the past year and a half, several types of drugs—including angiotensin II receptor blockers and ranitidine (Zantac)—have been found to contain small amounts of genotoxic substances called nitrosamines, such as N-nitrosodimethylamine (NDMA). Exposure to genotoxic substances above acceptable levels over long periods may increase the risk for cancer, the FDA said.

The FDA has been investigating the presence of nitrosamines in other drug products, and some metformin diabetes medicines in other countries were reported to have low levels of NDMA, according to Janet Woodcock, M.D., director of the FDA Center for Drug Evaluation and Research. But NDMA levels in metformin drugs abroad are within the range that naturally occurs in some foods and in water, she noted. Nonetheless, regulators in some other countries are recalling certain metformin drugs, Woodcock said. No metformin recalls affect the U.S. market at the moment.

Woodcock said the FDA is investigating whether metformin in the United States contains NDMA, and whether it exceeds the acceptable daily limit of 96 ng. "The agency will also work with companies to test samples of metformin sold in the U.S. and will recommend recalls as appropriate if high levels of NDMA are found," Woodcock said in an agency statement. "If as part of our investigation, metformin drugs are recalled, the FDA will provide timely updates to patients and health care professionals."

More information: More Information