FDA Requests Removal of All Ranitidine Products (Zantac) from the Market

FDA advises consumers, patients and health care professionals after new FDA studies show risk to public health.

April 6, 2020 By Food and Drug Administration (FDA)

The U.S. Food and Drug Administration today announced it is requesting manufacturers withdraw all prescription and over-the-counter (OTC) ranitidine drugs from the market immediately. This is the latest step in an ongoing investigation of a contaminant known as N-Nitrosodimethylamine (NDMA) in ranitidine medications (commonly known by the brand name Zantac). The agency has determined that the impurity in some ranitidine products increases over time and when stored at higher than room temperatures and may result in consumer exposure to unacceptable levels of this impurity. As a result of this immediate market withdrawal request, ranitidine products will not be available for new or existing prescriptions or OTC use in the U.S.

“The FDA is committed to ensuring that the medicines Americans take are safe and effective. We make every effort to investigate potential health risks and provide our recommendations to the public based on the best available science. We didn’t observe unacceptable levels of NDMA in many of the samples that we tested. However, since we don’t know how or for how long the product might have been stored, we decided that it should not be available to consumers and patients unless its quality can be assured,” said Janet Woodcock, MD, director of the FDA’s Center for Drug Evaluation and Research. “The FDA will continue our efforts to ensure impurities in other drugs do not exceed acceptable limits so that patients can continue taking medicines without concern.”

NDMA is a probable human carcinogen (a substance that could cause cancer). In the summer of 2019, the FDA became aware of independent laboratory testing that found NDMA in ranitidine. Low levels of NDMA are commonly ingested in the diet, for example NDMA is present in foods and in water. These low levels would not be expected to lead to an increase in the risk of cancer. However, sustained higher levels of exposure may increase the risk of cancer in humans. The FDA conducted thorough laboratory tests and found NDMA in ranitidine at low levels. At the time, the agency did not have enough scientific evidence to recommend whether individuals should continue or stop taking ranitidine medicines, and continued its investigation and warned the public in September 2019 of the potential risks and to consider alternative OTC and prescription treatments.

New FDA testing and evaluation prompted by information from third-party laboratories confirmed that NDMA levels increase in ranitidine even under normal storage conditions, and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during distribution and handling by consumers. The testing also showed that the older a ranitidine product is, or the longer the length of time since it was manufactured, the greater the level of NDMA. These conditions may raise the level of NDMA in the ranitidine product above the acceptable daily intake limit.

With today's announcement, the FDA is sending letters to all manufacturers of ranitidine requesting they withdraw their products from the market. The FDA is also advising consumers taking OTC ranitidine to stop taking any tablets or liquid they currently have, dispose of them properly and not buy more; for those who wish to continue treating their condition, they should consider using other approved OTC products. Patients taking prescription ranitidine should speak with their health care professional about other treatment options before stopping the medicine, as there are multiple drugs approved for the same or similar uses as ranitidine that do not carry the same risks from NDMA. To date, the FDA's testing has not found NDMA in famotidine (Pepcid), cimetidine (Tagamet), esomeprazole (Nexium), lansoprazole (Prevacid) or omeprazole (Prilosec).

In light of the current COVID-19 pandemic, the FDA recommends patients and consumers not take their medicines to a drug take-back location but follow the specific disposal instructions in the medication guide or package insert or follow the agency's recommended steps, which include ways to safely dispose of these medications at home.

The FDA continues its ongoing review, surveillance, compliance and pharmaceutical quality efforts across every product area, and will continue to work with drug manufacturers to ensure safe, effective and high-quality drugs for the American public.

The FDA encourages health care professionals and patients to report adverse reactions or quality problems with any human drugs to the agency's MedWatch Adverse Event Reporting program:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm; or
- Download and complete the form, then submit it via fax at 1-800-FDA-0178.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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