Laboratory analysis of ranitidine and nizatidine products – Safety update

- On December 4, 2019, the FDA announced that they are asking manufacturers of ranitidine and nizatidine products to expand their testing for the N-nitrosodimethylamine (NDMA) impurity, to include all lots of the medication before making them available to consumers.

- If testing shows NDMA above the acceptable daily intake limit (96 nanograms per day or 0.32 parts per million for ranitidine), the manufacturer must inform the FDA and should not release the lot for consumer use.

- Over the past several weeks, the FDA has communicated about the detection of NDMA in common heartburn medications (ranitidine, commonly known as Zantac®, and nizatidine) available over-the-counter or by prescription.

- The FDA has launched an investigation to understand the cause of this impurity in these drugs and to provide information for patients and consumers who take them. As part of this investigation, the FDA has asked manufacturers to conduct their own laboratory testing to examine levels of NDMA in ranitidine and nizatidine and to send samples to the FDA for testing.

- The FDA continues to work with industry and regulatory agencies around the world to determine the reasons for NDMA in these drugs and have developed and posted multiple testing methods to identify NDMA in ranitidine.

- FDA scientists have determined ranitidine does not form NDMA in typical stomach conditions. However, the FDA needs to further test how ranitidine and nizatidine behave in the human body and they have plans to study this.

- There is also some evidence that there may be a link between the presence of nitrites and the formation of NDMA in the body if ranitidine or nizatidine are also present. Because of this, consumers who wish to continue taking these drugs should consider limiting their intake of nitrite-containing foods, e.g. processed meats and preservatives like sodium nitrite.

- The FDA's recommendations for consumers and patients have not changed. Consumers taking OTC ranitidine or nizatidine can consider using other OTC products approved for their condition.

- So far, the FDA and industry testing of medicines in the histamine-2 (H2) blocker and proton pump inhibitor (PPI) classes has identified NDMA only in ranitidine and nizatidine. The FDA's tests of samples of alternatives such Pepcid® (famotidine), Tagamet® (cimetidine), Nexium® (esomeprazole), Prevacid® (lansoprazole) and Prilosec® (omeprazole) show no NDMA impurities at this time.

- Patients taking prescription ranitidine or nizatidine should speak with their healthcare provider about other treatment options. There are multiple drugs approved for the same or similar uses as ranitidine and nizatidine.