FDA Updates and Press Announcements on NDMA in Zantac (ranitidine)

10/2/19: UPDATE - FDA provides update on testing of ranitidine for NDMA impurities

Update [10/2/19] FDA is continuing to test ranitidine products from multiple manufacturers and is assessing the potential impact on patients who have been taking ranitidine. In addition, the agency has asked manufacturers of ranitidine to conduct their own laboratory testing to assess levels of NDMA in their ranitidine products and to send samples of ranitidine products to FDA to be tested by our scientists.

FDA observed the testing method used by a third-party laboratory uses higher temperatures. The higher temperatures generated very high levels of NDMA from ranitidine products because of the test procedure. FDA published the method for testing angiotensin II receptor blockers (ARBs) for nitrosamine impurities. That method is not suitable for testing ranitidine because heating the sample generates NDMA.

FDA recommends using an LC-HRMS testing protocol to test samples of ranitidine. FDA's LC-HRMS testing method does not use elevated temperatures and has shown the presence of much lower levels of NDMA in ranitidine medicines than reported by the third-party laboratory. International regulators using similar LC-MS testing methods have also shown the presence of low levels of NDMA in ranitidine samples.

FDA will test ranitidine oral solution products and has begun testing samples of other H2 blockers and proton-pump inhibitors to help inform this ongoing investigation. To date, the agency's early, limited testing has found unacceptable levels of NDMA in samples of ranitidine. The agency will provide more information as it becomes available.

9/26/19: STATEMENT - FDA alerts health care professionals and patients to voluntary recall of ranitidine medicines

9/24/2019: PRESS RELEASE - FDA announces voluntary recall of Sandoz ranitidine capsules following detection of an impurity

9/13/2019 : STATEMENT - Statement alerting patients and health care professionals of NDMA found in samples of ranitidine

FDA-published testing method to provide an option for regulators and industry to detect NDMA impurities

The link below is to an FDA-published testing method to provide an option for regulators and industry to detect nitrosamine impurities in ranitidine drug substances and drug products. This method should be validated by the user if the resulting data are used to support a required quality assessment of the API or drug product, or if the results are used in a regulatory submission.

- LC-HRMS method: an LC-MS method for the detection of NDMA in ranitidine drug substance and drug products

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