Metformin Extended-Release Products – Safety update

- On May 28, 2020, the FDA announced that laboratory testing has revealed levels of N-Nitrosodimethylamine (NDMA) above the agency's acceptable intake limit in several lots of the extended-release (ER) formulation of metformin.
    - FDA testing has not shown NDMA in immediate release metformin products.
- The FDA is in contact with five firms to recommend they voluntarily recall their products. Company recall notices will be posted on FDA's website. There are additional manufacturers of the metformin ER formulation that supply a significant portion of the U.S. market, and their products are not being recalled.
- The FDA is continuing to work closely with manufacturers to ensure appropriate testing. Assessments are underway to determine whether metformin ER recalls will result in shortages and the agency will work closely with manufacturers to prevent or reduce any impact of shortages.
- Patients should continue taking metformin even after recalls occur, until they consult with their health care professional who can prescribe a replacement.
- Patients with type 2 diabetes could face dangerous health risks if they stop taking their prescribed metformin. The FDA recommends that health care professionals continue to prescribe metformin when clinically appropriate.
- The agency is working with manufacturers of the recalled tablets to identify the source of the NDMA impurity. At this time, the elevated levels of NDMA have been found in some finished-dose tablets of the ER formulation but have not detected NDMA in samples of the metformin active pharmaceutical ingredient.
- The agency is also asking all manufacturers of metformin containing ER products to evaluate the risk of excessive NDMA in their product and to test each batch before it is released into the U.S. market. If testing shows NDMA above the acceptable intake limit, the manufacturer should inform the agency and should not release the batch to the U.S. market.
- In late 2019, the FDA announced it had become aware of NDMA in some metformin products in other countries. The agency immediately began testing to determine whether the metformin in the U.S. supply was at risk, as part of the ongoing investigation into nitrosamine impurities across medication types.
- By February 2020, the agency had identified very low levels of NDMA in some samples, but at that time, no FDA-tested sample of metformin exceeded the acceptable intake limit for NDMA.
- The FDA will continue to monitor NDMA in metformin, along with other drug products, and will provide timely updates of new developments, including product recalls. For more information about NDMA, visit the FDA's nitrosamines webpage.