令和4年9月27日
令和4年度医薬品等安全対策部会安全対策調査会
参考資料2

FDA works to avoid shortage of sitagliptin following detection of nitrosamine impurity

[8/9/2022] FDA recently became aware of a nitrosamine impurity, Nitroso-STG-19 (known as NTTP), in certain samples of sitagliptin, a medicine used to treat type 2 diabetes mellitus. To avoid a shortage and help ensure patients have access to an adequate supply of the medicine, FDA will not object to the temporary distribution of sitagliptin containing NTTP above the acceptable intake limit of 37 ng per day, and up to 246.7 ng per day.

The manufacturer of a marketed product that contains sitagliptin should contact the Center for Drug Evaluation and Research's Drug Shortages Staff (mailto:drugshortages@fda.hhs.gov) when its testing shows levels of NTTP that exceed 37 ng per day. FDA will determine on a case-by-case basis whether those drugs should be released for distribution.

Sitagliptin is a prescription drug used to control high blood sugar in patients with type 2 diabetes mellitus. It could be dangerous for patients with this condition to stop taking their sitagliptin without first talking to their health care professional. FDA recommends prescribers continue to use sitagliptin when clinically appropriate to prevent a gap in patient treatment.

NTTP belongs to the nitrosamine class of compounds, some of which are classified as probable or possible human carcinogens (substances that could cause cancer), based on laboratory tests. Although there are no data available to directly evaluate the carcinogenic potential of NTTP, FDA used information available on closely related nitrosamine compounds to calculate lifetime exposure limits for NTTP.

Agency scientists evaluated the risk of exposure to NTTP at interim acceptable intake levels up to 246.7 ng per day and determined that it presents minimal additional cancer risk when compared to a lifetime of exposure to NTTP at the 37 ng per day level.

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.