FDA – Withdrawal of ranitidine

- On April 1, 2020, the FDA announced the request to withdraw all prescription and over-the-counter (OTC) ranitidine drugs from the market immediately due to the presence of N-Nitrosodimethylamine (NDMA). Ranitidine products will not be available for new or existing prescriptions or OTC use in the U.S.

- The FDA has determined that NDMA 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.

- 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.

- Consumers taking OTC ranitidine should 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 Pepcid® (famotidine), Tagamet® (cimetidine), Nexium® (esomeprazole), Prevacid® (lansoprazole) and Prilosec® (omeprazole).

- 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.

    — Mix the medicine with an unappealing substance such as dirt, cat litter, or used coffee grounds; do not crush tablets or capsules.
    — Place the mixture in a container such as a sealed plastic bag.
    — Throw away the container in the trash at home.
    — Remove or delete all personal information on the prescription label of empty medicine bottles or packaging, then throw away or recycle them.