Clifton Health Department
Food Recall Notification

Food/Drug/Pet Recall: Viona Pharmaceuticals

TOPIC: Metformin HCl Extended-Release Tablets - USP 750 mg by Viona Pharmaceuticals: Recall - Due to the Detection of N-Nitrosodimethylamine (NDMA) Impurity

ISSUE: Viona Pharmaceuticals is recalling 2 (two) lots of Metformin Hydrochloride Extended-Release Tablets - USP 750 mg because it has been found to contain levels of Nitrosodimethylamine (NDMA) impurities above acceptable daily limits. This product was manufactured by Cadila Healthcare Limited, Ahmedabad, India in November 2019, for U.S. distribution by Viona Pharmaceuticals Inc.
NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables.
To date, neither Viona Pharmaceuticals, nor Cadila Healthcare Limited have received any reports of adverse events related to this recall.

BACKGROUND: Metformin is used as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus.

RECOMMENDATIONS:
. Patients who have received impacted lots of Metformin Hydrochloride Extended-Release Tablets - USP 750 mg are advised to continue taking their medication and contact their physician for advice regarding an alternative treatment.
. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Health professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:
. Complete and submit the report online.
. Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on form, or submit by fax to 1-800-FDA-0178.