Drug Recall

DATE OF RECALL: July 08, 2020

DRUG NAME: Metformin Hydrochloride Extended-Release Tablets

RECALLING FIRM: Lupin Pharmaceuticals, Inc.

REASON FOR RECALL: This recall is being issued, because analysis revealed that certain tested batches were above the Acceptable Daily Intake Limit for the impurity N-Nitrosodimethylamine (NDMA).

FDA LINK: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lupin-pharmaceuticals-inc-issues-voluntarily-nationwide-recall-metformin-hydrochloride-extended

OTHER DETAILS: See FDA Link

RECALLED PRODUCT:

Product Description	NDC Number	Affected Lots	Expiration Date
Metformin Hydrochloride Extended-Release 500 mg Gastric Tablets	68180-0338-01	All Lots Within Expiry	All Lots Within Expiry
Metformin Hydrochloride Extended-Release 1000 mg Gastric Tablets	68180-0339-09	All Lots Within Expiry	All Lots Within Expiry
Metformin Hydrochloride Extended-Release 500 mg Osmotic Tablets	68180-0336-07	All Lots Within Expiry	All Lots Within Expiry
Metformin Hydrochloride Extended-Release 1000 mg Osmotic Tablets	68180-0337-07	All Lots Within Expiry	All Lots Within Expiry