Fresenius Kabi USA – Recall of fluorouracil

- On June 28, 2019, Fresenius Kabi USA announced a voluntary, consumer-level recall of two lots of fluorouracil injection due to the potential for glass particulate.
    - Additional information may be found in the press release.
- The recalled fluorouracil injection lots were distributed between December 6 2018 and February 20, 2019:

Product Description	NDC#	Lot# (Expiration Date)
Fluorouracil injection 5g/100mL (50mg/mL), 100mL fill in a 100mL vial	63323-117-69	6120341 (4/2020)
	63323-117-61	6120420 (4/2020)

- Fluorouracil is a chemotherapy drug that is administered intravenously and indicated for the treatment of a variety of cancers.
- Fresenius Kabi has decided to take this action due to glass particulates found in 5 vials of the remaining inventory of lot 6120341 during an inspection for a quality investigation. Lot 6120420 is included in this recall as a precautionary measure because it was filled immediately post lot 6120341 as part of the same filling campaign.
- The administration of glass particulate, if present in a parenteral drug, poses a moderate safety risk to patients. Reports in the literature suggest that sequelae of thromboembolism, such as pulmonary emboli, phlebitis, granulomas, or fibrosis may occur.
- To date, Fresenius Kabi has not received adverse event reports related to the recalled product.
- Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled fluorouracil injection.
- Pharmacies and healthcare facilities that have the recalled drug product should immediately quarantine and stop dispensing the recalled drug product.
- For more information regarding this recall, contact Fresenius Kabi by phone at **1-800-551-7176** or by email at **productcomplaint.USA@fresenius-kabi.com**.