Mylan – Recall of levoleucovorin

- On February 1, 2019, Mylan announced a voluntary recall of two lots of levoleucovorin injection due to the presence of sub-visible particulate matter exceeding the specification.
- The recalled lots were distributed between August 2017 and July 2018.

Product Description	NDC#	Lot# (Expiration Date)
Levoleucovorin injection 250 mg/25 mL, 10 mL vial	67457-601-30	APB032 (4/2019); APB033 (4/2019)

- Levoleucovorin is indicated for rescue after high-dose methotrexate therapy in osteosarcoma; to diminish the toxicity and counteract the effects of impaired methotrexate elimination and of inadvertent overdosage of folic acid antagonists; and for use in combination chemotherapy with 5-fluorouracil in the palliative treatment of patients with advanced metastatic colorectal cancer.
- Per Mylan, intravenous administration of a solution containing particulates could lead to local irritation, vasculitis/phlebitis, antigenic or allergic reactions, and microvascular obstruction, including pulmonary embolism.
- To date, Mylan has not received any reports of adverse events related to this recall.
- Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled levoleucovorin.
- Anyone with an existing inventory of the recalled product should stop use and distribution, and quarantine the product immediately.
- For more information regarding this recall, contact Stericycle (appointed company for Mylan) at **1-866-551-2706**.