Exela Pharma Sciences – Recall of Ibuprofen Injection

- On February 8, 2017, Exela Pharma Sciences, in association with marketer X-Gen Pharmaceuticals, announced a voluntary user-level recall of one lot of ibuprofen lysine injection because particulate matter was found in some of the vials.

Product Description	NDC #	Lot # (expiration date)
Ibuprofen lysine injection 20 mg/2 mL (10 mg/mL) vial	39822-1030-2	PLND1613 (2/2018)

- The product can be identified by the X-Gen logo, and by the NDC number on the individual vial.
- Ibuprofen lysine injection is indicated to close a clinically significant patent ductus arteriosus in premature infants weighing between 500 and 1500 g, who are no more than 32 weeks gestational age when usual medical management (eg, fluid restriction, diuretics, respiratory support, etc.) is ineffective.
- Particulate matter injected into the bloodstream has the potential to block blood vessels, provoke an immune reaction, and/or lead to microinfarcts which could be life threatening.
- To date, neither Exela nor X-Gen has received any reports of adverse events related to this recall.
- Consumers, distributors, and retailers that have the recalled ibuprofen lysine injection should discontinue use and return the recalled product to their wholesaler, distributor, X-Gen, or Exela.
- Patients should contact their healthcare provider if they have experienced any issues related to using the recalled product.
- For any questions regarding this recall, contact Exela at **1-888-451-4231** or X-Gen at **1-866-390-4411**.