

FDA Recall – Sunny Pharmtech, Inc. Cyclophosphamide Injection

Purpose of this communication:

We are writing to inform you that Sunny Pharmtech, Inc. is voluntarily recalling three lots of Long Grove Pharmaceuticals Cyclophosphamide for Injection, USP, 1 g/vial and 2 g/vial, to the user level due to the presence of particulate matter identified as steel. The affected product was distributed to wholesalers, distributors, hospitals, and pharmacies from May 2024 through October 2024. There is a reasonable probability of serious adverse events, including death, if a patient receives an intravenous infusion containing particulate matter. Potential complications may include phlebitis, granuloma, occlusion, or life-threatening thromboembolic events, particularly for cancer patients who may have comorbidities or be immunosuppressed. To date, no adverse events or injuries associated with this issue have been reported.

What do I need to do?

- Please review the following recall notice [here](#).
- Immediately review inventory for the affected lots, discontinue use, quarantine any impacted product, and follow the manufacturer's instructions for return or disposition.
- Confirm whether any CareCentrix patients may have been affected by this recall and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

Thank you in advance for your cooperation and continued partnership.