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Mylan NV has announced that its US-based Mylan Institutional business is expanding its voluntary nationwide recall to the hospital/user level, of select lots of the following injectable products, due to the presence of visible foreign particulate matter observed during testing of retention samples.

Gemcitabine for Injection, USP is an intravenously administered product indicated for the treatment of ovarian cancer, breast cancer, non-small cell lung cancer and pancreatic cancer. These lots were distributed in the US between January 8, 2014, and February 10, 2015, and were manufactured and packaged by Agila Onco Therapies Limited, a Mylan company. Lot 7801084 and 7801110 are packaged with a Pfizer Injectable label.

Methotrexate Injection, USP 25 mg/mL can be administered intramuscularly, intravenously, intra-arterially, or intrathecally and is indicated for certain neoplastic diseases, severe psoriasis and adult rheumatoid arthritis. The lot was distributed in the US between December 8, 2014, and December 19, 2014, and was packaged by Agila Onco Therapies Limited, a Mylan company.

Administration of a sterile injectable that has foreign particulates has the potential of severe health consequences. To date, Mylan has not received any reports of adverse events related to this recall.

The company is notifying its distributors and customers by letter and is arranging for return of all recalled products. Distributors, retailers, hospitals, clinics, and physicians that have these products which are being recalled should stop use and return to the place of purchase.

This recall is being conducted with the knowledge of the US Food and Drug Administration.