Mylan – Recall of insulin glargine

- On July 6, 2022, the FDA announced a voluntary consumer-level recall of one lot of Mylan's (a Viatris company) interchangeable biosimilar insulin glargine (insulin glargine-yfgn) prefilled pens because of the potential for the label to be missing on some pens.
- This recall pertains only to the unbranded interchangeable biosimilar, insulin glargine-yfgn pens and does not impact the branded interchangeable biosimilar Semglee® (insulin glargine-yfgn) pens.
- The recalled batch was distributed between April 4, 2022 and May 5, 2022.

Product Description	NDC#	Lot# (Expiration Date)
Insulin glargine (Insulin glargine-yfgn) injection, 100 units/mL (U-100)	49502-394-75	BF21002895 (8/2023)

- Insulin glargine is indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.
- A missing label on insulin glargine prefilled pens, for patients receiving treatment with more than one type of insulin (e.g., both short and long-acting insulin), could lead to a mix-up of products/strengths, resulting in administration of the wrong insulin. Administration of the wrong insulin could result in less optimal glycemic control (either high or low blood sugar) which could result in serious complications.
- To date, Mylan has not received any reports of adverse events related to this recall.
- Patients who have the recalled insulin glargine should contact their physician or health care provider if they have experienced any problems that may be related to using the recalled insulin glargine.
- Anyone with an existing inventory of the recalled product should stop distribution and quarantine the product immediately.
- Contact Viatris Customer Relations by phone at **1-800-796-9526** or by email at **customer.service@viatris.com** for more information about the recall. Contact Sedgwick at **1-877-643-8438** for return information.