

Product Recall: IntegraDose Compounding Services, LLC Issues Voluntary Nationwide Recall of Cefazolin Injection Products Due to a Lack of Sterility Assurance

The Board of Pharmacy has received notice of the following product market withdrawal:

Summary

Company Announcement Date: September 20, 2021 FDA Publish Date: September 21, 2021

Product Type: Drugs; Pharmaceutical Quality Reason for Announcement:

Lack of sterility assurance.

Company Name: IntegraDose Compounding Services, LLC Brand Name: IntegraDose

Compounding Services, LLC Product Description: Cefazolin

Company Announcement

Minneapolis, Minnesota, IntegraDose Compounding Services is voluntarily recalling nine lots, listed in the table below, of cefazolin 2 gram in 20 mL syringe for injection and two lots of cefazolin 3 gram in 100 mL 0.9% sodium chloride bag for injection due to a lack of sterility assurance resulting from compounding in a newly installed biologic safety cabinet without completing dynamic smoke study testing.

Description – Cefazolin 2 gram in 20 mL syringe for injection NDC – 71139-7087-1 Lot Number – 20210803CEF-1 Exp Date – 09/17/2021

Description – Cefazolin 2 gram in 20 mL syringe for injection NDC – 71139-7087-1 Lot Number – 20210805CEF-3 Exp Date – 09/19/2021

Description – Cefazolin 2 gram in 20 mL syringe for injection NDC – 71139-7087-1 Lot Number – 20210806CEF-1 Exp Date – 09/20/2021

Description – Cefazolin 2 gram in 20 mL syringe for injection NDC – 71139-7087-1 Lot Number – 20210806CEF-2 Exp Date – 09/20/2021

Description – Cefazolin 2 gram in 20 mL syringe for injection NDC – 71139-7087-1 Lot Number – 20210809CEF-1 Exp Date – 09/23/2021

Description – Cefazolin 2 gram in 20 mL syringe for injection NDC – 71139-7087-1 Lot Number – 20210809CEF-2 Exp Date – 09/23/2021

Description – Cefazolin 2 gram in 20 mL syringe for injection NDC – 71139-7087-1 Lot Number – 20210810CEF-1 Exp Date – 09/24/2021

Description – Cefazolin 2 gram in 20 mL syringe for injection NDC – 71139-7087-1 Lot Number – 20210811CEF-1 Exp Date – 09/25/2021

Description – Cefazolin 2 gram in 20 mL syringe for injection NDC – 71139-7087-1 Lot Number – 20210812CEF-1 Exp Date – 09/26/2021

Description – Cefazolin 3 gram in 100 mL 0.9% sodium chloride bag for injection NDC – 71139-7053-1 Lot Number – 20210722CEF-2 Exp Date – 09/20/2021

Description – Cefazolin 3 gram in 100 mL 0.9% sodium chloride bag for injection NDC – 71139-7053-1 Lot Number – 20210728CEF-1 Exp Date – 09/26/2021

Intravenous administration of a non-sterile drug could result in serious infections ranging from fever, chills, and malaise, to severe adverse events such as septicemia, bacterial meningitides and wound infection which may be life-threatening. The possibility of a breach in sterility assurance in distributed product, while not confirmed, cannot be eliminated. No batches of product have been identified as containing microorganisms. To date, IntegraDose Compounding Services has not received reports of any adverse events associated with this issue for these lots.

Cefazolin is an antibiotic and the products are packaged in zip-locking bags containing ten units. The lots were distributed nationwide in the USA to hospitals from 8/12/21 to 9/15/21. IntegraDose Compounding Services has initiated an investigation to determine the root cause and corrective and preventative actions.

IntegraDose Compounding Services has notified its direct customers via a recall letter and is arranging for impacted product to be returned. Anyone with an existing inventory of the recalled lots should stop use and distribution and quarantine immediately.

Consumers with questions regarding this recall can contact IntegraDose Compounding Services by phone at (612-672-5216) or e-mail (celse1@fairview.org) on Monday - Friday, 8:00 AM – 4:00 PM CDT.

The Board of Pharmacy strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures