Company Announcement

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Premier Pharmacy Labs Issues Voluntary Nationwide Recall of Specific Sterile Injectable Products Lots Due to a Potential Lack of Sterility Assurance

For Immediate Release

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Contact

Consumers

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Media

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Announcement

Premier Pharmacy Labs is voluntarily recalling the following products due to a potential lack of sterility assurance:

Product Name/Description	Product NDC Number	Type of Packaging	Indication	Premier Pharmacy Labs Lot Number	Beyond Use Dates	Quantity Shipped	Date(s) Distributed

Product Name/Description	Product NDC Number	Type of Packaging	Indication	Premier Pharmacy Labs Lot Number	Beyond Use Dates	Quantity Shipped	Date(s) Distributed
Morphine Sulfate (Single Dose Syringe) 2mg/mL Preservative Free Injection	69623-129-10	Rigid plastic syringe, 3mL	pain reliever/ reducer	MOR030518IJDSA MOR030518IJDSB MOR030518IJDSC MOR030518IJDSD MOR030518IJDSE	06/03/2018 06/03/2018 06/03/2018 06/03/2018 06/03/2018	925 904 928 930 868	03/23/2018 03/23/2018 03/23/2018 03/23/2018 03/28/2018
Morphine Sulfate (Single Dose Syringe) 4mg/mL Preservative Free Injection	69623-127-10	Rigid plastic syringe, 3mL	pain reliever/ reducer	MOR022318NWDSA MOR022318NWDSB MOR022318NWDSC MOR022318NWDSD MOR022318NWDSE	05/24/2018 05/24/2018 05/24/2018 05/24/2018 05/24/2018	540 925 920 902 905	03/06/2018 03/06/2018 03/06/2018 03/16/2018 03/16/2018
Hydromorphone HCL (Single Dose Syringe) 1mg/mL Preservative Free Injection	69623-249-10	Rigid plastic syringe, 3mL	pain reliever/ reducer	HYD030118IJDSA HYD030118IJDSB HYD030118IJDSD HYD030118IJDSE	05/30/2018 05/30/2018 05/30/2018 05/30/2018	921 870 928 851	03/22/2018 03/22/2018 03/22/2018 03/22/2018
Neostigmine Methylsulfate (Single Dose Syringe) 1mg/mL Injection	69623-234-14	Rigid plastic syringe, 3mL	to reverse some of the nerve and muscle blocking agents used in surgery.	NEO022218SVDS	08/21/2018	600	03/19/2018

Microbial contamination was detected during routine testing of subsequent unreleased product lots due to interaction between the product syringe and tamper evident container closure, which may result in the potential introduction of microorganisms into the products.

Administration of non-sterile injection products that are intended to be sterile may result in a site-specific or systemic infection, which in turn may cause hospitalization, significant morbidity (permanent organ damage), or a fatal outcome. To date, Premier Pharmacy Labs has not received any reports of adverse events related to this issue, but understanding the potential risk, is voluntarily initiating this product recall.

The product can be identified by the product description in the above table and beyond use date (BUD) on the individual product or shipping bag. The listed product lots were distributed Nationwide to hospital pharmacy, clinic, and healthcare facilities.

Premier Pharmacy Labs is notifying its distributors and customers by certified letter and is arranging for return/replacement of all recalled products. Hospital pharmacy, clinic, and healthcare facilities that have product which is being recalled should stop using and return to Premier Pharmacy Labs per the official recall notification/customer reply form included in the certified letter sent to all affected clients.

Consumers with questions regarding this recall can contact Premier Pharmacy Labs by calling 1-800-752-7139 between the hours of 8:30 am and 5:00 pm Eastern Time, Monday through Friday or sending an email to **recalls@premierpharmacylabs.com (mailto:recalls@premierpharmacylabs.com)**. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: **www.fda.gov/medwatch/report.htm (http://www.fda.gov/MedWatch/report.htm)**
- Regular Mail or Fax: Download form **www.fda.gov/MedWatch/getforms.htm (http://www.fda.gov/MedWatch/getforms.htm)** or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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

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