

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

BD has become aware that the FDA has placed Bupivacaine manufactured by Huons Co., Ltd. on import alert #66-40 - Detention Without Physical Examination of Drugs From Firms Which Have Not Met Drug GMPs. This enforcement action is a regulatory mechanism to automatically block a non-compliant company's drug products from U.S. importation. Import Alert 66-40 is reserved for serious CGMP compliance failures – typically documented through FDA or equivalent inspections. Huons Co., Ltd. issued a product recall for its Bupivacaine ampules requesting quarantine of all ampules.

Huons Co., Ltd. manufactured bupivacaine ampules were recalled due to quality issues identified during a recent FDA inspection and limited reports of drug ineffectiveness. These ampules are included in BD anesthesia trays. While theoretical risk exists if a compromised injectable were used (e.g., localized infection, inflammatory response or reduced anesthetic effectiveness), no patient harm or product sterility failures have been identified.

BD has not received any reported complaints or adverse events associated with this issue.

The following BD Anesthesia Trays containing Huons Co., Ltd Bupivacaine:

Catalog Number	Product Name
400866	BD® Spinal Tray with BD® Whitacre Needle 25 G x 3.5 in.; lidocaine HCL (1%), 5 mL, bupivacaine HCL (0.75%) with dextrose (8.25%), 2 mL (marcaine)
400868	BD® Spinal Tray with BD® Whitacre Needle 24 G x 3.5 in.; lidocaine HCL (1%), 5 mL, bupivacaine HCL (0.75%) with dextrose (8.25%), 2 mL (marcaine)
405609	BD® Spinal Tray with BD® Quincke Needle 22 G x 3.5 in.; lidocaine HCL (1%), 5 mL, bupivacaine HCL (0.75%) with dextrose (8.25%), 2 mL (marcaine)
405621	BD® Spinal Tray with BD® Quincke Needle 25 G x 3.5 in.; lidocaine HCL (1%), 5 mL, bupivacaine HCL (0.75%) with dextrose (8.25%), 2 mL (marcaine)
405632	BD® Spinal Tray with BD® Quincke Needle 26 G x 3.5 in.; lidocaine HCL (1%), 5 mL, bupivacaine HCL (0.75%) with dextrose (8.25%), 2 mL (marcaine)
405637	BD® Spinal Tray with Sprotte® Needle 24 G x 3.5 in.; lidocaine HCL (1%), 5 mL, bupivacaine HCL (0.75%) with dextrose (8.25%), 2 mL (marcaine)
405645	BD® Spinal Tray with BD® Whitacre Needle 22 G x 3.5 in.; lidocaine HCL (1%), 5 mL, bupivacaine HCL (0.75%) with dextrose (8.25%), 2 mL (marcaine)

- 405652 BD® Spinal Tray with BD® Whitacre Needle 24 G x 3.5 in.; lidocaine HCL (1%), 5 mL, bupivacaine HCL (0.75%) with dextrose (8.25%), 2 mL (marcaine)
- 405658 BD® Spinal Tray with BD® Whitacre Needle 25 G x 3.5 in.; lidocaine HCL (1%), 2 mL, bupivacaine HCL (0.75%) with dextrose (8.25%), 2 mL (marcaine)
- 405671 BD® Spinal Tray with BD® Whitacre Needle 25 G x 3.5 in.; lidocaine HCL (1%), 5 mL, bupivacaine HCL (0.75%) with dextrose (8.25%), 2 mL (marcaine), clear drape
- 405672 BD® Spinal Tray with BD® Whitacre Needle 25 G x 3.5 in.; lidocaine HCL (1%), 5 mL, bupivacaine HCL (0.75%) with dextrose (8.25%), 2 mL (marcaine)
- 405673 BD® Spinal Tray with BD® Whitacre Needle 25 G x 3.5 in.; lidocaine HCL (1%), 5 mL, bupivacaine HCL (0.75%) with dextrose (8.25%), 2 mL (marcaine)
- 405674 BD® Spinal Tray with BD® Whitacre Needle 25 G x 3.5 in.; lidocaine HCL (1%), 5 mL, bupivacaine HCL (0.75%) with dextrose (8.25%), 2 mL (marcaine)
- 405675 BD® Spinal Tray with BD® Whitacre Needle 25 G x 3.5 in.; lidocaine HCL (1%), 5 mL, bupivacaine HCL (0.75%) with dextrose (8.25%), 2 mL (marcaine)
- 405707 BD® Spinal Tray with Sprotte® Needle 24 G x 3.5 in.; lidocaine HCL (1%), 5 mL, bupivacaine HCL (0.75%) with dextrose (8.25%), 2 mL (marcaine)
- 405709 BD® Spinal Tray with BD® Whitacre Needle 25 G x 3.5 in.; lidocaine HCL (1%), 5 mL, bupivacaine HCL (0.75%) with dextrose (8.25%), 2 mL (marcaine)
- 405721 BD® Spinal Tray with BD® Whitacre Needle 25 G x 3.5 in.; lidocaine HCL (1%), 5 mL, bupivacaine HCL (0.75%) with dextrose (8.25%), 2 mL (marcaine)
- 405723 BD® Spinal Tray with BD® Whitacre Needle 25 G x 3.5 in.; lidocaine HCL (1%), 5 mL, bupivacaine HCL (0.75%) with dextrose (8.25%), 2 mL (marcaine)
- 405735 BD® Spinal Tray with BD® Quincke Needle 25 G x 3.5 in.; lidocaine HCL (1%), 5 mL, bupivacaine HCL (0.75%) with dextrose (8.25%), 2 mL (marcaine)
- 405741 BD® Spinal Tray with BD® Whitacre Needle 25 G x 3.5 in., BD® Quincke Needle 22 G x 3.5 in.; lidocaine HCL (1%), 5 mL, bupivacaine HCL (0.75%) with dextrose (8.25%), 2 mL (marcaine)
- 406704 BD® Spinal Tray with BD® Whitacre Needle 25 G x 3.5 in.; lidocaine HCL (1%), 5 mL, bupivacaine HCL (0.75%) with dextrose (8.25%), 2 mL (marcaine)