Recall -- Firm Press Release

Ben Venue Laboratories, Inc. Issues A Voluntary Nationwide Patient Level Recall Of Acetylcysteine Solution 10%, Usp, Lot 2005479

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FOR IMMEDIATE RELEASE - February 14, 2014 - Ben Venue Laboratories, Inc. today issued a nationwide voluntary product recall:

Acetylcysteine Solution 10%, USP, (Manufactured for Roxane Laboratories, Inc.) 10%, 30 mL per vial – NDC #0054-3025-02 – Lot 2005479 – Exp. Date March 2014

This voluntary recall was initiated on February 14, 2014 after the discovery of a single visible glass particle in a vial within the lot listed above. There have been no complaints or adverse events related to a piece of glass in vials of this lot. All other product parameters were within specifications.

Acetylcysteine for inhalation is usually delivered via a Nebulizer, but can also be delivered via direct instillation into a tracheostomy, or into the bronchial-pulmonary tree during bronchoscopy. Glass particles can cause airway obstruction resulting in symptoms of choking, wheezing, difficulty breathing, coughing and potentially hemoptysis. Use of an inhaled product with glass particles has the potential to cause choking which could be life-threatening. Aerosolization of small glass particles in the airways could result in recurrent infections (due to obstruction of airways, and decreased clearance of airway secretions).

Acetylcysteine is indicated as adjuvant therapy for patients with abnormal, viscid, or inspissated mucous secretion. Acetylcysteine, administered orally, is indicated as an antidote to prevent or lessen hepatic injury which may occur following the ingestion of a potentially hepatotoxic quantity of acetaminophen.

The nationwide voluntary recall is to the patient level. This recall is limited to the one lot number listed above.

Hospitals, emergency rooms, clinics, physician offices and other healthcare facilities and providers should not use the product lot listed above for patient care and should immediately quarantine any product for return.

Patients who may have received product dispensed from this one lot should return the product to their pharmacist. Distributors/retailers that have not received a recall packet should contact GENCO Pharmaceutical Services, 6101 North 64th Street, Milwaukee, WI 53218.

For information regarding the recall process, call GENCO at 800-633-1422. For technical product information or to report a technical product complaint, call 800-962-8364 and select menu option 5. Adverse reactions or quality problems experienced with the use of this product may be reported to the U.S. Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

1. Complete and submit the report Online: www.fda.gov/medwatch/report.htm
2. Regular Mail or Fax: Download form 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

Ben Venue Laboratories has informed the FDA of its actions and is maintaining ongoing discussion with the agency. This nationwide voluntary recall is being conducted with the knowledge of the FDA.

Ben Venue is located in Bedford, Ohio. For more information, visit www.benvenue.com.

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