STERILE COMPOUNDED PRODUCT RECALL

AUDIENCE: Consumer, Pharmacy

ISSUE: Leiter's Enterprises, Inc. ("Leiter's") is voluntarily recalling the following lots of sterile products compounded that remain within expiry due to concerns over sterility assurance.

Product Description	Lot Numbers	Expiration Dates
Atropine Sulfate 0.01% in 0.9% Sodium Chloride (Ophthalmic Solution) 10ml total Volume in a 15ml dropper Bottle	All unexpired lots	11/13/2016 – 01/02/2017
Brilliant Blue G 0.025% in 0.9% Sodium Chloride (Injection) 1ml Total Volume in a 2 ml vial (Preservative Free)	All unexpired lots	09/20/2016 – 10/10/2016
Cefuroxime Sodium 10 mg/ml 0.9% Sodium Chloride (Injection 1ml total Volume in a 2ml vial (Preservative Free)	All unexpired lots	09/24/2016 –
Cyclopentolate HCl 1% - Tropicamide 1% - Phenylephrine HCl 2.5% in Sterile Water for Injection (Ophthalmic Solution) 1ml Total Volume in a 15ml dropper Bottle	All unexpired lots	10/03/2016 – 11/06/2016
Cyclopentolate HCl 1% - Tropicamide 1% Phenylephrine HCl 2.5% in Sterile Water for Injection (Ophthalmic Solution) 10 ml Total Volume in a 5ml dropper Bottle	All unexpired lots	09/25/2016 – 10/01/2016
Lidocaine HCl 1% - Phenylephrine HCl 1.5% in Sterile Water for Injection (Injection) 1 ml total Volume in a 2 ml vial (Preservative Free)	All unexpired lots	10/03/2016 –
Mitomycin 0.02% (0.2 mg/ml)in Sterile Water for Injection (Injection) 1 ml total Volume in a 2ml vial(Preservative Free)	All unexpired lots	11/05/2016 –
Moxifloxacin 1 mg/min Sterile Balanced Salt Solution (BSS) Intravitreal Injection 1ml total Volume in a 2ml vial	All unexpired lots	09/21/2016-2/2/2017
Placebo for Prednisolone Acetate 1% Oph Suspension	All unexpired lots	10/11/2016 – 01/16/2017
Vancomycin 10 mg/ml 0.9% Sodium Chloride (Injection) 1 ml total Volume in a 2ml vial (Preservative Free)	All unexpired lots	10/05/2016 – 01/10/2017

RECOMMENDATION: Leiter's recommends the following actions:

- Further distribution or use of any remaining product should cease immediately. If you have further distributed this product, you should notify your patients to the consumer level. Immediately examine your inventory for the products mentioned above subject to this recall. Please call us to arrange for return and credit.
- Discontinue use of the products;
- If you would like to receive additional information regarding this product recall, please contact us at (800) 292-6772 ext. 4101 and request the Recall Coordinator.

To date, Leiter's has not received any reports of adverse events associated with this issue. Adverse reactions or quality problems experienced with the use of these products may be reported using the following options:

- Calling Leiter's at (800) 292-6772 between the hours of 8:00am and 5:30pm Pacific Standard Time, Monday through Friday.
- Customers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.
- Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:
  - Complete and submit the report Online: www.fda.gov/MedWatch/report
  - Download form 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

Product Description	Lot Numbers	Expiration Dates