

Information Sharing: FDA and Minnesota State Board of Pharmacy

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Deputy Director



2005 Sterile Compounding Issue

- FDA Notification
 - Two patients blinded after receiving contaminated compounded trypan blue ophthalmic solution
 - Pharmacy compounded and sold trypan blue for office use

2005 Sterile Compounding Issue

- FDA and Board of Pharmacy Investigation
 - Numerous USP 797 deficiencies
 - Lack of patient specific prescriptions
 - Compounding a commercially available product

2005 Sterile Compounding Issue

- MN Board of Pharmacy
 - Embargo of all sterile compounded drug products
 - Pharmacy agreed to cease sterile compounding
- Source of infection
 - Purified water used to rinse compounding equipment

2014 Compounding Issue

- Pharmacy sold in 2010
 - New Pharmacist-in-Charge, Owner
 - Ceased sterile compounding, November 2012
- FDA Inspection Notice - August 2014
 - MN Board surveyor observation
 - Pharmacy only doing human/veterinary nonsterile compounding

2014 Compounding Issue

- Form FDA 483 issued, nine observations
 - Compounding nasal sprays and capsules for inhalation, irrigations
 - Methylene blue syringes labeled as sterile
 - Lack of testing
- MN Board of Pharmacy Findings
 - Significant number of additional violations



Questions

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