



Clifton Health Department Food Recall Notification



Food/Drug/Pet Recall: AuroMedics Pharma, LLC

[AuroMedics Pharma LLC Issues Voluntary Nationwide Recall of Polymyxin B for Injection USP, 500,000 Unit per Vial, Due to the Presence of Particulate Matter](#)

FOR IMMEDIATE RELEASE – January 26, 2022 – East Windsor, New Jersey, AuroMedics Pharma LLC has initiated a voluntary recall of lot number CPB200013 of Polymyxin B for Injection USP, 500,000 Units/Vial, to the consumer level from the USA market due to a product complaint for the presence of particulate matter, identified as hair being discovered in a vial within this lot.

Risk Statement: The administration of an intravenous product containing hair, even with the use of a filter, could cause a patient to experience serious hypersensitivity reactions that may be life-threatening. To date, AuroMedics Pharma LLC has not received reports of any adverse events or identifiable safety concerns attributed to the product consumed from this lot.

Polymyxin B for Injection USP is a sterile, white lyophilized cake or powder, suitable for preparation of sterile solutions for intramuscular, intravenous, intrathecal, or ophthalmic use indicated in the treatment of infections or the urinary tract, meninges (membranes that protect the brain and spinal cord), and bloodstream caused by susceptible strains of bacteria. It is packaged in a carton containing vials for Parenteral or Ophthalmic Administration, NDC 55150-234-10. The affected Polymyxin B for Injection lot being recalled is CPB200013 with an expiration date of 09/2022. AuroMedics shipped the entire lot to wholesalers nationwide from March 19, 2021, through June 14, 2021.