
From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Thursday, January 04, 2018 12:41 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Product Recall - AuroMedics Pharma Inc.

AuroMedics Pharma LLC is recalling one lot of Ampicillin and Sulbactam for Injection USP, 1.5 g (equivalent to 1 g ampicillin as the sodium salt plus 0.5 g sulbactam as the sodium salt) in a Single-Dose vial NDC 55150-116-20, Lot AF0117001-A, expiry date Dec 2018. This recall is being carried out to the pharmacy/hospital level. This recall is due to a confirmed customer report for the presence of visible particulate matter, confirmed as glass, within a single vial. To date, AuroMedics has not received reports of any adverse events or identifiable safety concerns attributed to the product consumed. The entire lot was shipped to customers nationwide on February 9, 2017.

In the event particulate is administered to a patient, it may result in local site reaction, phlebitis, pulmonary granuloma, occlusion of blood vessels, thromboembolic events and systemic immune response. The risk is reduced by the possibility of detection.

Please immediately check your inventory, quarantine, discontinue distribution of the affected product, and contact your wholesaler for directions.