From:	General Board of Pharmacy Subscriber List on behalf of Board of Pharmacy
To:	PHARM-GENERAL@DCALISTS.CA.GOV
Subject:	Amikacin Sulfate Injection USP, 1 gram/4mL (250 mg/mL) Vials by Teva: Recall - Glass Particulate Matter
Date:	Thursday, March 10, 2016 1:53:30 PM

AUDIENCE: Pharmacy, Infectious Disease

ISSUE: Teva Pharmaceuticals announced a voluntary recall of one lot of amikacin sulfate injection USP, 1 gram/4mL (250 mg/mL) vials due to the potential presence of particulate matter identified as glass in one vial. The recalled lot # is 4750915, Expiration Date 9/2017.

The administration of a glass particulate, if present in an intravenous drug, may result in local irritation or swelling in response to the foreign material. More serious potential outcomes would include blockage and clotting in blood vessels, which may be life-threatening if a critical organ is affected.

BACKGROUND: Amikacin sulfate injection USP is used in the short-term treatment of serious infections due to susceptible strains of Gram-negative bacteria, and has also been shown to be effective in staphylococcal infections and may be considered as initial therapy under certain conditions in the treatment of known or suspected staphylococcal disease.

Amikacin sulfate injection is packaged in pharmacy bulk packages, containing ten 1 gram/4 mL (250 mg/mL) vials per shelf pack. Amikacin sulfate injection 250 mg/mL, 4 mL vials were distributed nationwide through wholesalers, retailers and pharmacies.

RECOMMENDATION: Teva is arranging for impacted product to be returned to Inmar. Anyone with an existing inventory of the recalled lot should stop use and distribution, and quarantine the product immediately. Customers should notify all retail and medical facility accounts. Customers who have further distributed the recalled product should notify any accounts or additional locations which may have received the recalled product and instruct them if they have redistributed the product to notify their accounts, locations or facilities.

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

[03/09/2016 - Press Release - Teva Pharmaceuticals]

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