From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Monday, October 23, 2017 11:46 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Octagam [Immune Globulin Intravenous (human)] 10 Percent Liquid Preparation]: Voluntary Market Withdrawal

ISSUE: Octapharma USA Inc. is initiating a voluntary market withdrawal of octagam 10% [Immune Globulin Intravenous (human)] 10% Liquid Preparation] that is labeled with lot numbers K724B8541 & K725A8541. Although there have been no reports of serious injury at this time, Octapharma has determined, through consultation with the public health authorities at FDA, the most prudent course of action is to suspend further administration of octagam 10% from these particular production lots.

BACKGROUND: Lot numbers K724B8541 & K725A8541 are affected by this recall.

RECOMMENDATION: Distributors that received these lots of octagam 10% from Octapharma are asked to immediately quarantine these lots and contact Octapharma for return instructions.

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

Read the MedWatch Safety Alert, including a link to the FDA Market Withdrawal notice, at:
https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm581586.htm