From:	Board of Pharmacy
To:	PHARM-GENERAL@DCALISTS.CA.GOV
Cc:	Pharmacy_Subscriberlist@DCA
Subject:	PRODUCT RECALL - Teva
Date:	Thursday, September 15, 2016 7:06:22 PM

Teva Pharmaceuticals, USA Inc.
URGENT DRUG RECALL - RETAIL LEVEL - INITIATED 09/13/16

mitoXANTRONE Injection USP (concentrate) 20 mg/10 mL (2 mg/mL)

RECALLED BY:
Teva Pharmaceuticals USA, Inc. (Teva)
Horsham, PA 19044

Strength: 20 mg/10mL (2 mg/mL)
Vial Size: 10 mL
NDC: 0703-4685-01

Lot #31318574B - Exp. Date 9/2016
Lot #31319610B - Exp. Date 7/2017
Lot #31320058B - Exp. Date 11/2017
Lot #31320497B - Exp. Date 12/2017
Lot #31320744B - Exp. Date 2/2018

Teva is voluntarily recalling the above lots of mitoXANTRONE Injection USP (concentrate) 20 mg/10 mL (2 mg/mL) distributed under the TEVA PARENTERAL MEDICINES, INC. label. This recall is being carried out at the RETAIL LEVEL due to potential failure to meet the specifications for Impurity D throughout shelf-life. The increased Impurity D may or may not contribute to adverse effects, and the probability to cause significant adverse health consequence is not high.

Inquiries regarding this recall are to be directed to the following:
Recall Stock Response forms - Inmar at 800-967-5952, Option 1 then Option 3
Customer service related questions - Teva Customer Service at 800-545-8800
Medical-related questions - Medical Information 888-838-2872, option 3, then option 4
Product quality complaint-related questions - Quality Assurance Services 888-838-2872, option 3, then option 3
Email - rxrecalls@inmar.com