

Pharmacy_Subscriberlist@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Monday, September 21, 2015 2:28 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Recall notice - EMD Serono

EMD Serono has notified Teva Pharmaceuticals USA, Inc. of their intent to recall the below mentioned lot of Clomiphene Citrate Tablets, USP 50 mg distributed under the Teva label. This sub-recall is being carried out to the pharmacy level. This recall has been initiated due to an unidentified impurity that exceeded the limits for qualification according to ICH Q3A and given the nature of the impurity, also exceeds the maximum daily exposure noted in the FDA Guidance for Industry entitled "M7 Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk" (dated May 2015). EMD Serono reports that based on the currently available information the benefit-risk profile of Clomiphene Citrate 50mg (Lot# 233169) continues to remain positive. This supports the initial medical safety assessment which concluded the impurity presence is not considered to be a major public health concern.

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

Lot#	Exp.Date	Size	NDC
233169	212016	1carton of 10 Tablets each. Each carton contains 2 blister packs of 5 tablets each.	0093-0041-03