From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Monday, February 27, 2017 1:43 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Edex (alprostadil for injection) 10 mcg 2 Pack by Endo Pharmaceuticals: Recall - Potential Lack of Sterility Assurance

AUDIENCE: Urology, Pharmacy, Patient

ISSUE: Endo Pharmaceuticals Inc. is recalling one lot of Edex (alprostadil for injection) 10 mcg to the consumer level. This product recall is due to the detection by Endo of a defect in the crimp caps used in the manufacture of the subject product lot. This defect has the potential to lead to a loss of container closure integrity, which could impact the product's sterility assurance and may lead to serious adverse events such as infections, both localized at the site of injection and systemically.

The recall applies to the 10 mcg strength, packaged in a 2 pack carton, (NDC 52244-010-02), product lot number 207386, Expiration Date: May 2019. The affected lot was distributed from December 13, 2016 through February 13, 2017 to wholesale distributors and retail pharmacies throughout the United States. See the press release for product photos.

BACKGROUND: Edex (alprostadil for injection) is a prescription only intracavernous injection indicated for the treatment of male erectile dysfunction.

RECOMMENDATION: Consumers in possession of any unused prescribed Edex 10 mcg product bearing lot number 207386 should immediately discontinue use of the product and return the unused product. Please contact Inmar at 1-844-529-1586, Monday through Friday (9am to 5pm EST) or email Edex@inmar.com (refer to press release for further information).

Pharmacists and wholesalers are asked to check their inventories for lot number 207386, segregate any impacted inventory and contact Inmar at extension #1 at 1-800-967-5952, Monday through Friday (9 a.m. to 5 p.m. EST) or via e-mail at rxrecalls@inmar.com for instructions on product return. Pharmacists who have dispensed impacted product are asked to notify their patients of this recall. Pharmacies and wholesalers that received lot number 207386 will receive a letter as well as a copy of this press release with their recall notification information.

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

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