From:	General Board of Pharmacy Subscriber List on behalf of Board of Pharmacy
To:	PHARM-GENERAL@DCALISTS.CA.GOV
Subject:	Recall notice - QuVa Pharma
Date:	Friday, April 01, 2016 3:09:35 PM

AUDIENCE: Consumer, Pharmacy

ISSUE: QuVa Pharma located at 1075 West Park One Drive Suite 100 Sugar Land, TX (Unlicensed) is recalling ot 143212-0 of Phenylephrine 100mcg/ml in 0.9%NS 10ml syringes. QuVa Pharma labeled these product to appear as if they were compounded and dispensed by Healix Infusion Therapy Inc (NRP 834 and NSC 99415) located at 1075 West Park One Drive Suite 200 Sugar Land, TX.

QuVa Pharma has become aware that Phenylephrine 100 mcg/ml in 0.9% sodium chloride 10 ml syringe (Product Code 75901-1205-35) lot 14312-0 has correct labels on the syringe and the case but has some units that are incorrectly labeled on the light protective overwrap. The incorrect overwrap labels are printed as Phenylephrine 40 mcg/ml in NS 10 ml syringe lot 14312-0. Copies of the labels have been attached.

RECOMMENDATION: QuVa Pharma suggests quarantining the lot. Do not discard or destroy any of the material and to ship back all of the product to QuVa.

Customers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product. Providers who have dispensed any sterile product distributed by QuVa Pharma to a patient(s) for use outside of the provider's office should contact the patient(s) to whom product was dispensed and advise the patient(s) of this recall.

QuVa Pharma may be reached at 1-866-654-2451 with questions.
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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