June 5, 2019

COM-2019-023

Recall: Voluntary Nationwide Recall of PECGEN DMX

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. It is for this reason that we inform you that on June 5, 2019 the US Food and Drug Administration (FDA) issued a statement notifying that Novis PR LLC is voluntarily recalling five lots of PECGEN DMX, 16 oz an OTC cough syrup. The recall was made due to a labeling error providing incorrect dosing information for children 2-6 years of age. This product was only sold in Puerto Rico. The affected lots by the recall is detailed on Table 1.

Table 1: Affected Product of PECGEN DMX

NDC	Product	Count	Affected Lot	Expiration date
52083-0630-16	PECGEN DMX	16oz	D80202	02/20
	PECGEN DMX	16oz	D80210	02/20
	PECGEN DMX	16oz	D80818	09/20
	PECGEN DMX	16oz	D80819	09/20
	PECGEN DMX	16oz	D80820	09/20

The Pharmacy must:

1. Identify if they have the product in inventory and immediately stop using and dispensing the product.
2. Contact all members that in the previous 90 days received the recalled medication and advised them to discontinue use and talk to their doctor. As per manufacturer instructions, patients that have product subject to this recall should immediately cease the use, return or discard it and talk to their doctor if necessary.
3. Any question regarding this recall should be directed to NOVIS PR LLC at (787)767-2072 or info@kramernovis.com from Monday to Friday. 7:30 am-4:30pm (AST).

For additional information visit:
https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/novis-pr-llc-emite-recogido-voluntario-nivel-nacional-de-pecgen-dmx-debido-error-en-etiqueta

Clinical Department

2 Street 1, Suite 500 Guaynabo, PR 00968 | Tel. 787.522.5252 | Fax 1.866.912.2830 | www.pharmpix.com