FDA ANNOUNCEMENT

NOVIS PR LLC Issues Voluntary Nationwide Recall of PECGEN DMX Due to a Labeling Error

Summary

Company Announcement Date:
May 29, 2019

FDA Publish Date:
May 30, 2019

Reason for Announcement:
Incorrect dosage on label

Company Name:
NOVIS PR LLC

Brand Name:
Pecgen DMX,

Product Description:
PECGEN DMX, 16 oz, liquid cough syrup

FDA Announcement

Novis PR LLC is voluntarily recalling 5 lots of PECGEN DMX, 16 oz, a liquid cough syrup to the consumer level. The product has been found to provide incorrect dosage information on its label due to a typographical error. The drug facts label (example below) incorrectly states children 6 to under 2 years of age, 1 teaspoonful every 4 hours, not to exceed 4 teaspoonfuls in 24 hours or directed by physician. The label should state children 6 to under 12, 1 teaspoonful every 4 hours, not to exceed 4 teaspoonfuls in 24 hours or as directed by physician. Additionally, the label does not advise consumers to consult a doctor for children under 2 years of age.

| Children 6 to under 2 years of age | 1 teaspoonful (tsp) every 4 hours not to exceed 4 teaspoonfuls in 24 hours, or as directed by a doctor |

**Risk Statement:** There is no evidence that cough and cold medicines are safe or effective for young children. However, there is evidence that children have been harmed by overdoses of these products. Problems include seizures, coma, and death. Dextromethorphan can also interact with Tylenol or other cough/cold medications to be highly toxic—more than if given alone. To date, NOVIS PR LLC has not received any reports of adverse events related to this recall.

The product is used as a Cough suppressant and expectorant and is packaged in Amber plastic 16 oz bottles in cases of 12 units with NDC 52083-630-16. The affected PECGEN DMX lots include the following lot numbers and expiration dates: D80202 Exp date 02/20, D80210 Exp 02/20, D80818 Exp 09/20, D80819 Exp 09/20, D80820 Exp 09/20.

Error was discovered by an email notification of an unidentified individual alerting of incorrect information in label.

PECGEN DMX was distributed in Puerto Rico to Wholesalers and retail pharmacies. Product is only sold in Puerto Rico.

Novis PR LLC is notifying its distributors and customers by letters and phone calls the collection of the units and is arranging the return of all recalled products.

Consumers who have PECGEN DMX which is being recalled should stop using/return to place of purchase/discard/contact their doctor, etc.

Distributors/retailers that have PECGEN DMX which is being recalled should stop distributing the product and must return it to place of purchase.

Consumers with questions regarding this recall can contact Novis PR LLC at (787) 767-2072 or info@kramernovis.com (mailto:info@kramernovis.com%20)from Monday thru Friday, 7:30am – 4:30pm (AST).

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online:** [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)

- **Regular Mail or Fax:** Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) 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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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**FDA Contact Information**

**Consumers:**
Novis PR LLC

📞 (787) 767-2072

📧 info@kramernovis.com (mailto:info@kramernovis.com)

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**Product Photos**

![Product Photos]

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